CMS-4068-P-1201

Submitter : Mr. Glenn Kamen **Date & Time:** 10/04/2004 08:10:42

Organization : Lancaster General Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

"See Attached"

CMS-4068-P-1201-Attach-1.doc

Horizon Healthcare Services is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Horizon Healthcare services the home infusion needs of thousands of patients in south central Pennsylvania every year including many Medicare recipients. Founded in 1984, our highly trained healthcare professionals have the experience and skills necessary to create positive clinical outcomes for the patients we serve while at the same time conserving scarce healthcare dollars by treating patients at home and avoiding costly hospitalizations.

Horizon Healthcare Services appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

* Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm <http://www.nhianet.org/perdiemfinal.htm> .

* CMS should establish specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require specific standards for home infusion pharmacies under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the X12N 837 P billing format for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should mandate that prescription drug plans maintain open formularies for infusion drugs to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Glenn S. Kamen

Director of Sales

Horizon Healthcare Services
2106 Harrisburg Pike, Suite 101
Lancaster, PA 17601

CMS-4068-P-1202

Submitter : Ms. Mary Dewane **Date & Time:** 10/04/2004 08:10:20

Organization : Schaller Anderson

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached document

CMS-4068-P-1202-Attach-1.doc

Comments on 42 CFR (CMS-4068-P)

Subpart B-Eligibility. Election and Enrollment

This section invites comment on the auto-enrollment process for full benefit dual eligible individuals who do not select a MA-PD or PDP plan. We recommend that CMS consider auto-enrollment of full benefit dually eligible individuals who do not select an MA-PD or PDP plan into an MA Special Needs plan, if that plan currently provides prescription drug coverage under Medicaid to such individuals. This would help CMS maintain continuity of care and to minimize potential beneficiary disruption.

Subpart C-Benefits and Beneficiary Protections

Many dually eligible individuals have multiple chronic medical and behavioral health conditions. Adverse selection is a potential issue among MA Special Needs plans, as well as MA-PD or PDP plans that enroll large numbers of dual eligibles. MA Special Needs plans may have an incentive to structure their formularies to minimize enrollment of specific types of high needs dually eligible individuals. The proposed rule does not appear to establish any additional formulary requirements for MA Special Needs plans that provide prescription drug coverage. We recommend that CMS consider requiring MA Special Needs plans to provide more extensive coverage of certain types of prescription drugs than required for other MA-PD or PDP plans. In particular, CMS should consider mandating more extensive coverage of anti-retrovirals and mental health drugs. This may help to prevent some of the potential adverse selection that could occur through formulary design.

Subpart J-Coordination Under Part D with Other Prescription Drug Coverage and Coordination of Benefits

This section delineates the drug coverage under Part D with respect to coordination of benefits for drugs covered by other plans, including Medicaid. It states there are relatively limited applicability of coordination of benefits between Part D plans and State Medicaid programs because drugs that must be excluded from Medicare coverage are drugs that also may be excluded from Medicaid. Drugs such as benzodiazepines are frequently utilized in the Medicaid population; this coordination issue will result in a large number of medically necessary drugs that must be covered by State Medicaid plans. Additionally, coverage of Drugs under Part B must meet very strict approval criteria. According to Medicare guidelines, certain medical services, which are deemed reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, are, covered services. FDA approval is often one of the main criteria of Medicare's coverage guidelines for drugs and biologicals. However, in the case of chemotherapeutic agents, for example, FDA approval does not always keep pace with clinically indicated efficacy. Therefore, the need exists to address off-label drug uses, which have been validated by clinical trials.

Otherwise a large number of drugs potentially covered under Part B will fall on Part D plans. There is also the potential for "double-dipping" for drugs potentially covered under Part B and Part D. Ideally, Part B drug coverage should be eliminated altogether (with all drugs covered through Part D).

CMS-4068-P-1203

Submitter : Mr. Charles Thompson **Date & Time:** 10/04/2004 08:10:52

Organization : Med Four LLC

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Please see comments in attached word document

CMS-4068-P-1203-Attach-1.doc

Specialized Pharmaceutical Services for Chronic Disease Management

3555 Rutherford Road
Taylors, SC 29687

Phone: 864.370.3529
Fax: 864.235.4514

Med Four LLC is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Med Four is an independently owned home infusion company located in Taylors, SC just outside of Greenville, SC which has been servicing the home infusion needs of the Upstate South Carolina region since 1989.

Med Four appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

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Thank you in advance for your consideration of these important issues.

Sincerely,

Charles Thompson
President
Med Four LLC

CMS-4068-P-1204

Submitter : Mrs. Jody Horak **Date & Time:** 10/04/2004 08:10:52

Organization : Toledo IV Care

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Please see comment in attached word document.

CMS-4068-P-1205

Submitter : **Date & Time:** **10/04/2004 08:10:07**

Organization : **Illinois Campaign for Better Health Care**

Category : **Consumer Group**

Issue Areas/Comments

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

423.120 (b) P&T Committee Decisions should be binding

We strongly recommend that the final rule ensures that decisions made by a PDP?s P&T committee are considered binding. We feel that congress?s intentions in requiring P&T committees will be undermined if they are not empowered to make binding decisions and recommendations regarding proposed formularies. We also feel that decisions regarding cost-containment strategies, as they related to access to covered Part D Medications and formulary structures, should be subject to binding recommendations of the P&T committee. We fell that only with these provisions will beneficiaries be ensured access to the covered Part D medications as intended by congress.

423.120(b)(1) Regarding the independence of P&T committees

Although we support the intentions in the proposed rule to ensure the independence of P&T committees from PDP-sponsor influences, we feel that the provisions in the proposed rule are wholly inadequate. We strongly encourage the final rule to include the following provisions:

1. P&T committee members must not only be ?free and independent? of the PDP sponsor, but also of pharmaceutical manufacturers. This should be explicitly stated in the final rule.
2. Committee appointments should be public record, and CMS must be required to create a process whereby the ?independence? of a committee member can be challenged and reviewed.
3. All PDP sponsors should be explicitly required in the final rule to operate a P&T committee, regardless of whether they initially plan to have a formulary.
4. All P&T committee meetings should be public to encourage accountability. In addition, the minutes and decisions of P&T committees should be available upon request to beneficiaries and their advocates.
5. Because the proposed rules only required a numerical value for independent members but not for the size of the committee, a statistical majority of free and independent members needs to be required.
6. Regardless of the final requirements regarding independent membership, the final rules should stipulate that the free and independent members must be present at any given meeting in order to make a binding decision.
7. The final rule must not only encourage but require P&T committees to seek input from plan enrollees, or in initial decisions before January of 2006, from Part-D eligible beneficiaries within that plan?s service area, and specifically from within the most vulnerable populations: disabled individuals, those with rare or pharmacologically complex conditions, and beneficiaries over the age of 75.

This is not an exhaustive list of ways to strength the power and independence of P&T committees. We strongly urge CMS to consider additional and alternative provisions

BENEFITS AND BENEFICIARY PROTECTIONS

423.104 Definition of "person"

We recommend that the definition of "person" explicitly include family members, charities, and caretakers. Also, we encourage individuals who receive prescription medications through pharmaceutical manufacturer patient assistance programs be allowed to count these medications as ?incurred costs? consistent with the average cost of these medications through an individual?s PDP. Pharmaceutical manufacturer patient assistance programs provided medications only to individuals whom they certify, in conjunction with the treating physician, as not able to afford medications without assistance. Due to the nature of the vulnerable populations receiving this type of assistance, we feel that it is unfair to restrict their access to catastrophic coverage.

423.104 (e)(2)(ii) Limiting cost-sharing tiers

The proposed rules do not include a limit on tiered cost-sharing. We strongly encourage such a limit to be placed on the use of cost-sharing tiers. Also, applying different cost-sharing tiers to different classes of drugs would inherently discriminate against certain populations and we urge CMS to explicitly prohibit this as a valid cost-containment mechanism. We believe that unlimited cost-sharing tiers undermine Congress? stipulation for representation of every drug class within a formulary, and strongly oppose unlimited tiers. We suggest three cost-sharing tiers as an appropriate and acceptable limit to cost-sharing tiers.

On-formulary Drugs

We encourage the final rule to include all beneficiary expenses towards covered Part D drugs to count towards ?incurred costs?, even if the drug was denied coverage by the Part D Plan. On-formulary drugs prescribed by a physician should be explicitly state as counting towards incurred costs in the final regulations.

423.120 (a) Access Standards

We strongly support the provision to require PDP sponsors to meet access standards in each local area as opposed to meeting access standards across a region.

We also strongly support the explicit inclusion of the provision to count only retail pharmacies towards meeting access standards, and the proposed definition of ?retail pharmacy? as stated in the preamble.

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Section 423.153 Cost Management

We strongly recommend that cost containment strategies of individual PDP sponsors are subject other P&T committee. Because their P&T committees exist as an independent entity to protect Medicare beneficiaries, they should be empowered to protect beneficiaries in all aspects. It is unacceptable to allow PDP sponsors? concerns for their profit margins to superseded beneficiaries? well-being. It is also unrealistic to expect sponsors and other businesses associated with the sponsors to willingly emphasis beneficiaries? needs over profits. This must be subject to outside, independent regulation this is more extensive and ongoing than the initial approval by CMS.

Error Rates

The preamble notes that ?In the future, we may require quality reporting that includes error rates?? This should be required immediately, and made public as soon as possible in order to encourage accountability.

Section 423.156 Consumer Satisfaction Surveys

The proposed rules do not enumerate an effective date for consumer surveys. We strongly urge consumer satisfaction surveys to being in conjunction with the beginning of the Part D benefit in 2006.

GENERAL PROVISIONS

Second public commenting period

The first draft of the proposed rules poses many questions, and leaves the rules regarding many areas unwritten. These areas deserve the scrutiny of public comment as much as the regulation proposed in this draft. We urge the consideration of a second commenting period after the unwritten sections of regulations are completed.

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Although we support the intentions in the proposed rule to ensure the independence of P&T committees from PDP-sponsor influences, we feel that the provisions in the proposed rule are wholly inadequate. We strongly encourage the final rule to include the following provisions:

1. P&T committee members must not only be ?free and independent? of the PDP sponsor, but also of pharmaceutical manufacturers. This should be explicitly stated in the final rule.
2. Committee appointments should be public record, and CMS must be required to create a process whereby the ?independence? of a committee member can be challenged and reviewed.
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Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

423.882 Employment-based Retiree Coverage and Subsidies

We are very concerned about the possibility of employer windfalls resulting from the retirement benefit subsidy. Although we believe the cost to the beneficiaries should be taken into account when determining ?creditable coverage?, the subsidy should be based solely on the contributions of the employer. We understand that the accounting and determining of employer subsidies will be a complicated procedure, and we support measures to increase accountability and decrease fraud, including making this accounting public record. We support and encourage involving employee groups and advocates in the monitoring of this accounting, and feel that it could lead to reduced fraud and errors.

423.884 (a) Assuring validity of employer?s actuarial attestation

Information regarding an employer?s actuarial attestation should be made public record so as to allow employee groups and advocates to best work for the protection of their retirees. We also feel that CMS proposed used of random audits to ensure that employment-based retiree coverage meets actuarial equivalence tests in insufficient. We recommend that additional quality control measures be proposed and evaluated as possibilities.

The regulations should explicitly state that employees will not be held responsible for late enrollment penalties in the event that a retiree plan is found to have been in violation of creditable coverage due to error or misrepresentation. Additionally, employees should not be held responsible for late enrollment fees in the event of a failure on behalf of an employer plan to notify retirees of changes in the certification of creditable coverage.

423.890 Appeals

We recommend that third-parties (including employee groups) should be granted the right to appeal a CMS determination regarding actuarial equivalence of an employer?s retiree coverage. We further recommend that CMS be required to provide information regarding their decision on the actuarial equivalence test and how to appeal the decision to all affected beneficiaries and their advocates upon request.

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The Voice of Illinois Consumers

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(Children's Health)
1-888-544-8271
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Website: www.cbhconline.org

Comments on the Centers for Medicare and Medicaid Services' Proposed Medicare Regulations: CMS-4068-P

General

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Subpart D

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Subpart R

Campaign for Better Health Care
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Subpart C

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CMS-4068-P-1206

Submitter : Mr. Scott Melvill **Date & Time:** 10/04/2004 08:10:27

Organization : Healthcare Distribution Management Association

Category : Association

Issue Areas/Comments

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Please see the attached file.

CMS-4068-P-1206-Attach-1.doc

Healthcare Distribution Management Association
Products, Services and Information for Your Health

John M. Gray, President and CEO
Eric Schuss, Chairman of the Board

October 4, 2004

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Via Electronic Submission

Re: Medicare Program; Medicare Prescription Drug Benefit, Section 423.153 (d) [CMS-4068-P]. 69 Fed. Reg. 46632 (August 3, 2004).

Dear Dr. McClellan:

The Healthcare Distribution Management Association submits the following comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed rule, *Medicare Program; Medicare Prescription Drug Benefit*. 69 Fed. Reg. 46632 (August 3, 2004). I am writing to commend CMS for its efforts to implement the Medication Therapy Management Programs (MTMPs) included in the new Medicare Part D benefit, to be codified in section 423.153 of the proposed rule. HDMA believes that MTMPs will be an important addition to the benefits that seniors can receive under the Medicare program and we encourage you to work with the pharmacy community to craft a benefit program that adequately meets the needs of chronically ill beneficiaries.

HDMA is the national trade association representing full-service distribution companies responsible for ensuring that billions of units of medication are safely distributed to retail pharmacies, hospitals, nursing homes, clinics, and other provider sites across the United States. HDMA's distributor members provide services to approximately 141,591 pharmacy settings, including: 17,913 independent pharmacies; 19,824 chain pharmacies; 9,918 food stores; 9,992 hospital pharmacies; 4,872 mass merchandisers; 5,397 long-term care and home health facilities; 62,364 clinics; 1,170 healthcare plans; and 366 mail order pharmacies.[1] It is within these settings that patients interact with their pharmacists and receive important direction regarding their medications.

[1] Table 228 – Class of Trade Analysis – Manufacturer Sales by Customer Categories: 2002-2003.HDMA Industry Profile and Healthcare Factbook, Healthcare Distribution Management Association. (2004).

HDMA has long-believed that appropriate use of prescription drugs not only enhances the patient's quality of life but can also decrease the need for hospitalization or surgery. We believe that disease management and medication therapy management programs will contribute to obtaining favorable patient outcomes. Additionally, when chronically ill patients have access to specialized guidance regarding their medications and their drug therapies are more carefully monitored, it is possible that they can achieve greater results from their course of treatment and perhaps suffer fewer adverse events related to their illness or drug interaction.

It is also important for CMS to recognize the demonstrated value of individualized patient care services and to ensure appropriate and fair reimbursement for the professionals who provide such services. MTMPs involve the collaboration of the pharmacist with physicians, nurses and other healthcare professionals to ensure that medications are used appropriately to improve patient health status, improve the patient's quality of life and contain healthcare costs. CMS should devise appropriate payment mechanisms that acknowledge the important role of the pharmacist and the resources involved in providing individualized guidance for beneficiaries in order to ensure that they receive the most favorable results possible from their prescribed course of treatment.

HDMA distributor members do not serve patients directly, but as part of our role in facilitating patient access to necessary medications, we believe that it is important to support development of MTMPs that contribute to favorable outcomes and that are flexible enough to provide individualized patient care. In addition, MTMPs can lead to an overall reduction in healthcare costs. Therefore, it is critical that CMS develop this benefit in cooperation with the pharmacist and pharmacy communities. In determining the parameters of MTMPs, CMS should consider patient-specific treatment requirements; patient education relative to prescribed medications; the pharmacist's ability to monitor patient progress, and identify and resolve problems that are medication related; in-person consultations between the pharmacist and patient; and reimbursement rates that accurately reflect the resources and expertise that are required to provide effective medication therapy management. HDMA supports development of a MTMP benefit that ensures that the beneficiaries who have the greatest need for such programs are identified and ensured access to these important services.

HDMA appreciates this opportunity to provide CMS with its comments regarding the new Medicare Part D benefit and CMS policy regarding Medication Therapy Management. If we can be of assistance as you continue implementation of Part D regulations, please contact me or Elizabeth Gallenagh, Manager, Regulatory Affairs at 703-787-0000 ext. 234.

Sincerely,

Scott Melville

Scott Melville
Sr. Vice President of Government Relations

CMS-4068-P-1207

Submitter : Ms. Lisa M. Getson **Date & Time:** 10/04/2004 08:10:41

Organization : Apria Healthcare

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

Please reference Apria Healthcare's formal, comprehensive comments in the Word attachment being submitted on this form.

CMS-4068-P-1207-Attach-1.doc

CMS-4068-P-1207-Attach-2.doc

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Re: Comments on CMS-4068-P
The Proposed Rule for the Medicare Prescription Drug Benefit

Dear Dr. McClellan:

On behalf of Apria Healthcare Inc., I am pleased to submit these comments regarding the proposed rule to implement the new Medicare Part D prescription drug benefit. Specifically, these comments pertain to the recent notice published in the *Federal Register* on August 3, 2004.[1]

Apria is a leading provider of integrated home care services and products. Apria offers a full range of home infusion drug therapy, as well as home medical equipment and home respiratory therapy. Through 30 wholly-owned, licensed and JCAHO-accredited infusion pharmacies, Apria serves adult and pediatric patients with a wide range of infectious diseases, nutritional disorders, cancer and chronic illnesses such as Lou Gehrig's Disease and multiple sclerosis. Aside from the thousands of people covered by private managed care organizations who benefit from Apria's home infusion services, the company also cares for a significant number of elderly patients throughout the United States who have complex medical problems and multiple co-morbidities who require home infusion therapy and are covered by Medicare Advantage (MA. formerly Medicare+Choice) plans.

These comments are divided into the following sections:

I. General
II. Dispensing Fees for Home Infusion Drug Therapy
III. Contracting with Home Infusion Drug Pharmacies
IV. Formulary Development

[1] Medicare Program; Medicare Prescription Drug Benefit; 69 *Fed. Reg.* 46632 (Aug. 3, 2004).

I. General

We wish to commend CMS for engaging in the research necessary to understand many of the unique characteristics of home infusion drug therapy. These findings are reflected in the preamble of the proposed rule, which summarizes the various services and functions that are required to provide home infusion drug therapy safely and effectively in the home care setting.

We applaud CMS for recognizing in the proposed rule the clinical and cost benefits of home infusion drug therapy, as well as the essential role this area of therapy plays in the private sector health system and under Medicare managed care programs. The proposed regulation describes an interpretation of the Part D benefit that would include the essential services, supplies and equipment that are integral to the provision of infusion drug therapy provided in the home (see discussion of "Dispensing Fee Option 3" below).

If Dispensing Fee Option 3 is adopted in the final regulation, as we recommend, then the Medicare fee-for-service program can offer coverage of home infusion drug therapy comparable to what private sector health plans and Medicare Advantage plans have offered for years. In doing so, Medicare would realize the significant system-wide savings that come from the provision of infusion drug therapy in the most cost-effective setting.

A. Home infusion drug therapy provides an opportunity for Medicare Part D to replicate the success achieved by private sector health plans and Medicare Advantage plans.

Currently, many of the infusion drug therapies used commonly in the private sector, such as antibiotic therapy used in the treatment of severe infections, are not covered under the Medicare Part B durable medical equipment (DME) benefit. Coverage under the DME benefit is based on the use of an item of DME – in this case, an infusion pump − and extends only to a few designated drugs, most of which are used in the treatment of cancer and intractable pain. As a result, Medicare beneficiaries who could have received infusion drug therapy at home have been forced into far more costly settings, such as acute care hospitals, hospital outpatient departments, hospital emergency rooms and long term care facilities.

In contrast to the limited coverage that exists under Medicare Part B, Medicare coverage of home infusion therapy has worked well under Part C with the Medicare Advantage plans. Many if not most Medicare Advantage plans provide coverage for a broad range of home infusion therapies and related services as a <u>medical</u> benefit. Examples include Aetna US Healthcare, Humana Health Plans, PacifiCare's Secure Horizons plans and Presbyterian Salud in New Mexico. Clearly, these plans would not provide this optional coverage unless they were convinced that coverage of home infusion therapy in the home setting is cost-effective.

For Medicare Advantage plans, home infusion has provided significant system-wide savings by enabling beneficiaries to receive infusion therapy without incurring hospital or nursing facility costs. Medicare Advantage plans cover the homecare pharmacy, nursing and other in-home services, supplies, equipment and same-day, in-home delivery/patient teaching necessary for the provision of home infusion therapy. The effectiveness of home infusion therapy under Part C, and the manner in which Medicare Advantage plans define and cover this therapy, can be a model for infusion coverage under Part D.

B. Specific requirements must be established by CMS to ensure that Medicare Part D makes use of home infusion drug therapy in the same fashion as private sector and Medicare Advantage plans.

Stand-alone Part D prescription drug plans (PDPs), in the absence of specific requirements or direction from CMS, will not embrace drug therapies such as home infusion drug therapy because the PDPs will be rewarded for contributing to system-wide savings on the drugs alone. As a result, the financial incentives that have driven private payer acceptance and use of home infusion drug therapy will not exist for stand-alone PDPs.

As a result, specific requirements and direction from CMS are necessary for the coverage of home infusion drugs to work properly. We urge CMS to ensure that the Final Rule contains provisions relating to home infusion drug therapy on the issues discussed in the remainder of these comments, including such issues as dispensing fees, pharmacy access, formulary provisions and the formatting of claims.

II. Dispensing Fees for Home Infusion Drug Therapy

A. CMS should adopt Dispensing Fee Option 3, which is the only proposed option that would adequately recognize the services and items that are necessary to provide home infusion drug therapy.

Congress' definition of prescription drugs under the statute clearly includes infusion drugs provided in the home, and the proposed rule likewise reinforces the fact that infusion drugs (other than the few drugs currently covered under Part B) are included in the Part D benefit.

However, for the coverage of home infusion drugs to be meaningful for Medicare beneficiaries, CMS also must cover the services, supplies and equipment related to the provision of these drugs. Limiting coverage to the drugs only without the services, supplies and equipment will not produce meaningful coverage of infusion drugs in outpatient settings. This is because infusion pharmacies will be unable to provide infusion drugs without adequate payment for the services, supplies and equipment.

The most appropriate mechanism for such coverage of infusion services, supplies and equipment provided under the proposed rule is the dispensing fee. In the preamble, CMS sets out three options for defining dispensing fees under the new benefit and invites comment on each.

- Option 3 comes closest to accurately recognizing the fundamental elements – including the services, supplies and equipment – that are essential for the provision of home infusion drug therapy. Option 3 is the only option that reflects the fundamental elements of home infusion drug therapy (see additional discussion in subsequent sections of these comments).

- In contrast, Option 1 only provides the perspective of retail pharmacies and does not meet the needs of Medicare beneficiaries requiring home infusion drug therapy.

- Although Option 2 captures the supplies and equipment used in the provision of home infusion drug therapy, this option falls far short of recognizing the essential professional services required to provide home infusion drug therapy because it does not recognize the professional services that are required to provide safe and effective infusion therapy in the home.

B. CMS should adopt Dispensing Fee Option 3 because it is consistent with the well-established standards of practice for home infusion drug therapy.

The major independent accreditation organizations, including the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), have established extensive, detailed standards regarding the patient management, support services, facilities, patient safety, policies, procedures and functions that must be provided by home infusion pharmacies. These standards, which address issues ranging from the requirements for sterile preparation of infusion drugs to the oversight of patient therapy, are significantly different from the standards governing traditional retail pharmacies.

Option 3 is the only dispensing fee option that adequately reflects the content of these national accreditation standards. For example, one major difference between retail pharmacies and home infusion pharmacies is the urgency surrounding the initial referral from a physician or hospital and the resulting home delivery/patient education requirements. Due to the severity of the patient's illness (such as a serious infection which has not responded to oral medications), pressures on hospitals to discharge patients as soon as possible, and stability/refrigeration requirements for many medications, home infusion pharmacy staff frequently have to deliver directly to patients' homes the same day as the referral. This is considerably more expensive than a retail pharmacy model where the patient or caregiver visits the pharmacy in person to pick up the drug. All of this must take place in conjunction with insurance verification, coordination with the nurse who will teach the patient, compounding by a home infusion pharmacist, and eventually, billing third party payors and collecting patient co-pays – all activities that are not applicable to the retail setting.

The well-established understanding of the professional services involved in providing in home infusion drug therapy is not merely an industry definition. Payers, clinicians, clinical societies, providers and accrediting organizations share a common understanding of what is involved in providing these therapies in outpatient settings.

C. CMS should adopt accreditation requirements under Dispensing Fee Option 3 as a straightforward means to protect Part D enrollees.

As the first homecare provider to seek and obtain JCAHO accreditation in the 1980s, Apria has a longstanding commitment to ensuring that the professional services and functions we provide meet a demanding set of quality standards. Apria recently completed its latest triennial survey cycle, with a successful outcome in all infusion pharmacies, respiratory and medical equipment locations. Our company has served as a pilot for innovative survey techniques developed by the JCAHO, and our management has formally served on advisory committees of the organization. Today, our quality standards meet or exceed JCAHO's requirements, which is a requirement of the over 2500 private sector managed care plans with which we contract to provide home infusion services.

In the final rule, CMS should address the qualifications of the infusion pharmacies that may provide the elements of care described under Dispensing Fee Option 3. We recommend that CMS require every pharmacy providing infusion services to be accredited as a home care pharmacy by a recognized national accrediting organization. We also recommend that every entity that provides nursing services to Part D infusion patients be either accredited as a nursing agency as an extension of their existing home infusion accreditation, or be a Medicare-certified home health agency.

Private sector plans require accreditation as a basic assurance that the pharmacists and nurses are experienced and the pharmacies are staffed properly to provide the necessary care. The quality standards required of home infusion pharmacies and nursing agencies by the accreditation organizations have become the community standard for the provision of home infusion therapy.

D. CMS should use a refined version of Dispensing Fee Option 3 to define the full scope of necessary professional infusion pharmacy services.

All infusion patients, whether or not they qualify for the home health benefit, require professional pharmacy services that again differ from those found in the retail setting. The general categories of such services are:

- Compounding medications in a sterile environment
- Dispensing
- Ongoing Clinical Monitoring
- Care Coordination with other agencies involved in patient care

- Provision of Supplies and Equipment
- Multiple Categories of Pharmacy Professional Services, such as pharmacokinetic drug monitoring or parenteral nutrition formula development
- Administrative Services
- In-home delivery, patient and caregiver education
- Third party billing
- Other Support Costs

These services are described in greater detail in a number of accreditation materials and other forums, including a document on the website of the National Home Infusion Association describing the "per diem" model.[2]

We propose a modification to Dispensing Fee Option 3 to more explicitly describe the pharmacy professional services that are needed for home drug infusion therapy. The pharmacy services referenced above in the model per diem definition (and generally described in Dispensing Fee Option 3) should be included in the dispensing fee for all Part D infusion patients. Most of these functions would be captured in the Option 3 definition of dispensing fees.

Both private payers and Medicare Advantage plans use per diem payments that are tied to the intensity level of the particular infusion therapy. For over 20 years, these plans have essentially developed resource-based relative value scales to capture the intensity, in terms of time and resources involved in providing each infusion therapy safely and effectively. Thus, the plans do not use a single per diem amount for all infusion therapies. We recommend that the PDPs follow this approach under Medicare Part D.

E. CMS can establish easily-administered safeguards to avoid any duplicate payments for nursing services

CMS raises a question in the proposed rule regarding how to ensure that the services captured in Dispensing Fee Option 3 are not reimbursed under the home health benefit or otherwise.

The potential area of concern involves the infusion patients who also qualify for the Medicare home health benefit. For this subset of infusion patients who also qualify for the home health benefit, it would be a simple matter to first determine whether a beneficiary qualifies for the home health benefit before reimbursing Part D funds for nursing services. The majority of beneficiaries who require infusion drug therapy do not qualify for the home health benefit, and their nursing services should be paid under the Part D benefit as part of the dispensing fee.

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[2] National Home Infusion Association. National Definition of Per Diem. June 2003. *Available at* www.nhianet.org/perdiemfinal.htm.

Importantly, the home health benefit does not cover any of the pharmacy services described in the preceding subsection of these comments.

By first identifying beneficiaries who qualify for the home health benefit, the nursing component, when medically necessary, should be reflected in the dispensing fee but only for beneficiaries who do not qualify under the home health benefit for nursing services. Importantly, nursing care is not included in the model per diem definition (discussed above) nor in the HCPCS "S" coding structure (discussed below) used by private payers.

Private payers typically separate out nursing from the pharmacy-related costs represented by the per diem. They share the Medicare program's natural concern about nursing costs, and these plans have concluded the best means of tracking and controlling nursing costs is to use a separate payment mechanism for nursing.

F. CMS can establish easily-administered safeguards to avoid duplicate payments under Medication Therapy Management Programs.

CMS asks for comments regarding how to ensure that the Medicare program avoids making duplicate payments if the PDPs pay for infusion-related dispensing fees as well as medication therapy management services.

Generally, the dispensing fee as defined in Dispensing Fee Option 3 will capture most of the services and functions described in our per diem model plus the nursing component, and there will not be a clear need for a separate payment to infusion pharmacies for additional medication therapy management services. We believe that the primary situation where medication therapy management services may be indicated is where an infusion pharmacy has to coordinate the activities of another pharmacy.

However, if CMS does not choose Dispensing Fee Option 3 for defining dispensing fees, then CMS should not consider the medication therapy management program as a substitute for covering the services, supplies and equipment required to provide infusion drug therapy. The limitations on the applicability of the medication therapy management program (*i.e.*, it is limited to patients with chronic conditions and multiple medications) make it a poor vehicle for capturing the clinical monitoring functions required of infusion pharmacies for all infusion patients.

III. Contracting with Home Infusion Pharmacies

A. CMS should establish separate and distinct requirements for PDPs to contract with sufficient numbers of home infusion pharmacies to ensure adequate enrollee access to home infusion drug therapy under Medicare Part D.

CMS should establish specific safeguards for home infusion pharmacies to ensure meaningful enrollee access to home infusion drug therapies. A number of important differences exist between home infusion pharmacies and traditional retail pharmacies that highlight the need to create separate requirements for the two types of pharmacies. For example–

- Home infusion pharmacies provide specific essential services that are not provided by the vast majority of retail pharmacies or mail order pharmacies.

- Home infusion pharmacies must maintain facilities, equipment and safeguards for compounding and storing sterile parenteral drug solutions, which is not common among retail pharmacies.

- Home infusion pharmacies are responsible for the care of their patients 24 hours a day, seven days a week, while retail pharmacies are not.

- Home infusion pharmacies are subject to separate state licensure, regulations and accreditation standards from retail pharmacies.

- The contracts used by private health plans for home infusion pharmacies are structured differently from the contracts used for retail pharmacies.

- The total number of traditional retail pharmacies in the United States far outweighs the total number of home infusion pharmacies.

These differences are echoed in the preamble of the proposed rule, where CMS discusses its findings regarding important distinctions between home infusion pharmacies and retail pharmacies.[3]

To ensure that Part D enrollees have sufficient access to home infusion drug therapy, CMS should adopt its proposal to establish distinct access standards for home infusion pharmacies in the Final Rule. This would be consistent with Congress' general mandate that CMS must ensure enrollees have convenient access to pharmacies, as access to a retail pharmacy does not by itself meet the needs of a beneficiary who requires infusion therapy.

B. CMS should require use of the ASC X12N 837 claims format for infusion drug therapy, consistent with CMS' recent determination, because infusion claims formats are different from retail pharmacy claims.

CMS' Office of HIPAA Standards has carefully reviewed how home infusion therapy is provided, and recently issued a Program Memorandum[4] and a Frequently Asked Question (FAQ)[5] document on the CMS website summarizing its conclusion.

[3] 69 *Federal Register* at 46648 and 46658.

For example, the FAQ document states:

> …Home infusion therapy typically has components of professional services and products that include ongoing clinical monitoring, care coordination, supplies and equipment, and the drugs and biologics administered – all provided by the home infusion therapy provider.

In a letter dated April 8, 2003, Jared Adair, director of the CMS Office of HIPAA Standards, wrote:

> …we have determined that home drug infusion therapy services are different from services provided by retail pharmacies, and that the business model for home drug infusion therapy providers is fundamentally different from a retail pharmacy for dispensing drugs…. We also acknowledge that a requirement to bill home infusion drugs using the NCPDP format would fail to meet the administrative, clinical, coordination of care, and medical necessity requirements for home drug infusion therapy claims." (emphasis added)

As a result, CMS determined that the National Council for Prescription Drugs Program (NCPDP) claim format, which is the HIPAA standard for the processing of retail pharmacy drug claims, is not appropriate for the filing of home infusion drug therapy claims. Instead, CMS instructed that home infusion claims, to be compliant with HIPAA, must be filed under the ASC X12N 837 claims format.

Please note that the description of infusion therapy as described in the FAQ tracks very closely with the language of Dispensing Option 3 in the proposed rule. We recommend that the specific wording already posted on CMS's FAQ be included as the infusion claiming requirement in Part D regulations. To do so will increase the level of administrative standardization in infusion claims transactions per the objectives of HIPAA, while also ensuring that home infusion providers and Part D payers comply with the HIPAA regulation when implementing Part D claiming transactions. If CMS does not require that Part D home infusion therapy claims be submitted on the 837, then it would open up the possibility for some Part D payers to ignore the fundamental differences of home infusion therapy from retail pharmacy and implement only NCPDP claiming—forcing infusion pharmacies to be out of compliance with HIPAA.

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[4] Centers for Medicare & Medicaid Services, Program Memorandum, Carriers, Transmittal B-03-024 (4/11/03), *available at* http://cms.hhs.gov/manuals/pm_trans/B03024.pdf.

[5] Centers for Medicare & Medicaid Services, Frequently Asked Questions (FAQs), "Are Drug Transactions Conducted by HIT Providers Retail Pharmacy Drug Claim Transactions Billed Using NCPDP Formats?" (Answer ID 1880) (3/31/03), *available at* http://questions.cms.hhs.gov.

This would deprive the PDPs and CMS of a valuable tool for tracking important patient-specific data. Consolidated 837 claiming would facilitate the consolidation of all drugs along with the professional pharmacy "per diem" services, equipment and supplies into single claims billed for infusion therapies, easily mapped into patient services utilization data bases for analysis—whereas the possibility of billing infusion drugs separately via the retail NCPDP claim format results in loss of this consolidated data for analysis.

C. CMS should recognize that infusion coding is different from retail pharmacy drug coding.

Since 2002 the Healthcare Common Procedure Coding System (HCPCS) provides approximately 80 "S" codes for home infusion therapy services. Most codes reflect a "bundled" per diem approach in which most or all of the supplies and services provided to a home infusion patient are billed under a single code. This complete system of "S" codes for home infusion therapy services is specifically designed for use by private payers, and are available for use by government payers that adopt this widely used private sector methodology for infusion coding and payment. These codes are not used in coding of retail pharmacy drug claims and are not permitted for HIPAA-compliant use on the NCPDP transaction).

Although CMS does not have a single HIPAA coding standard for drugs, we believe that the PDPs and CMS will find requiring NDC drug coding for Part D claims will provide best opportunity for patient utilization analysis and tracking of total Part D drug costs for CMS's program administration. We believe the Part D regulations should require that all claims for drugs be coded with NDC numbers.

D. Coordination of benefits.

In addition to these reasons for infusion claiming and coding consistency, the COB portion of the Part D program is also best implemented by CMS's establishing a requirement for 837 claiming and use of the established coding systems. The majority of COB will occur with commercial payers such as the Blues and other private health plans. As the private sector has already widely adopted the established coding systems described above, it will be important for CMS to require consistent coding adoption to make COB work, ensuring that the allocation of payment for services between Part D plans and other primary or secondary plans works well.

Since the private payer sector accepts home infusion therapy claims using the HIPAA-compliant X12 N 837 format, for COB to work effectively is another reason that CMS should require PDPs to use the 837 claim format for infusion claims. Because a very large majority of private infusion payers use the HIPAA-complaint *professional* 837 (837P) claim format, to make COB work we believe that CMS's Part D regulations should require PDPs to adopt the HIPAA-compliant 837P format only, excluding both the *institutional* 837 and NCPDP transaction from use.

E. CMS should clarify the any willing provider requirements with respect to home infusion drug therapy.

CMS should clarify that this access safeguard is to be applied to any willing provider of home infusion therapy meeting the infusion-specific quality standards (see below), as distinct from retail pharmacies. Such a requirement is consistent with the statutory language.[6]

In addition, for the purpose of the any willing provider requirements, CMS should clarify that prescription drug plans should have a standard contract for home infusion pharmacies.

These recommendations for the network access standards will help safeguard enrollee access by ensuring that the Medicare Part D benefit reflects common private sector practices for home infusion drug therapy. In addition, the recommended clarifications will not impose significant burdens on PDPs.

F. CMS should recognize that OBRA 1990 standards do not represent the standard of care for infusion pharmacies.

In the preamble, CMS refers to Section 54401 of the Omnibus Reconciliation Act of 1990, stating that the regulations issued pursuant to that section in 42 CFR 456.705 "describe currently accepted standards for contemporary pharmacy practice and our intent is to require plans to continue to comply with contemporary standards." CMS seeks comments on whether these standards are industry standards and whether they are appropriate for Part D.

The OBRA 1990 standards were written for retail pharmacies. The drafters of these standards did not attempt to address the standard of care for infusion pharmacies. Infusion pharmacies that are in compliance with the infusion-specific standards established by accrediting organizations meet the OBRA 1990 standards, but the OBRA 1990 standards do not reflect "contemporary pharmacy practice" for infusion pharmacies. The community standard of care for infusion pharmacies is found in the accreditation standards that are required by virtually every private health plan, as well as numerous MA plans, to participate in their provider networks.

The quality assurance standards followed by home infusion pharmacies—and as required for accreditation--far exceed the OBRA 1990 standards. Due to advances in newly-approved drugs and technology and additional laws and regulations established in the intervening years (such as HIPAA), and development of knowledge surrounding patient safety and medication management at home, the level of patient data collection, assessment and intervention in the infusion clinical model goes far above and beyond the quality standards currently used for Medicaid. Again we respectfully direct your attention to Jared Adair's April 8, 2003 comments concerning the key differences between retail and home infusion pharmacies.

[6] Social Security Act, Section 1860D-4(b)(1)(A).

IV. Formulary Development

A. CMS should mandate that PDP and MA-PD plan sponsors maintain an open formulary for infusion drugs to ensure this population of vulnerable patients has appropriate access to necessary medications.

Much of the MMA is based on the premise that Medicare can take advantage of cost-savings techniques commonly used in the private sector and still deliver quality services to Medicare beneficiaries. CMS should note that although private health plans commonly use restricted or preferred formularies for drugs delivered orally, via patch or other non-invasive methods, private plans rarely apply these formulary restrictions to infusion drugs.

As discussed in greater detail below, there are numerous clinical and operational barriers to establishing formularies for infusion drugs. As a result, with respect to infusion drugs, formularies should remain open.

B. CMS should recognize that PDPs and pharmacy and therapeutics committees are not well situated to evaluate infusion drugs.

It will be difficult for PDPs and traditional pharmacy and therapeutics committees (P&T committees) to evaluate infusion drugs in the same manner that they evaluate orally administered drugs.

P&T committees generally evaluate the relative safety, efficacy, and effectiveness of prescription drugs within a class of prescriptions drugs and make recommendations to a health plan for the development of a formulary or preferred drug list. Frequently, P&T committees focus on the "therapeutic equivalence" of different multisource drugs (*i.e.*, whether one drug will have the same desired clinical impact as another). However, such evaluations are performed in a context where the method of administering the drug is not significant.

In contrast to oral drugs, the method of administration for an infusion drug may have separate and significant clinical and cost implications. All infusion drugs require a device of some type to deliver the drug into the body, including various catheters temporarily or semi-permanently implanted in each patient depending on the anticipated duration of therapy, potential side effects of the drug and the patient's diagnosis itself. Various methods of drug delivery also exist, from IV bags hung on poles to sophisticated external or internal infusion pumps. A patient's clinical condition may determine not only what device is selected for delivery, but also what drug should be used. For instance, many patients receiving infusion therapy are at high risk of infection or complications from infection. Consequently, a physician may need to choose a medication that can be prepared in advance in a pharmacy clean room and administered once a day to reduce the risk of infection from preparation in the home or multiple intravenous access device manipulations.

Similarly, in selecting a medication for a patient, a physician often needs to consider administration access type and what delivery technology will be best suited for use in a particular patient's home. If the patient is capable of managing a portable infusion pump, drugs requiring longer infusion times may become more clinically appropriate. If other technologies are used, such as IV bags hung on poles, the patient may require more frequent nursing visits to monitor the risk of infection.

The typical P&T Committee would usually not have the experience to evaluate the administration technology or professional support requirements, such as nursing visits, in reviewing infusion drugs. Furthermore, such committees do not typically make decisions considering all available treatment options throughout the continuum. Drugs considered ideal in an inpatient setting are often not desirable in the home setting and visa versa, especially where the first dose of the drug is concerned. Examples include Taxol® for ovarian cancer, Lovenox® for deep vein thromboses and certain immune globulins.

In addition, most infusion drugs must be compounded by the pharmacy. Once compounded, these drugs lose stability over time or be impacted by changes in temperature. For oral drugs, the frequency of administration or stability issues usually do not pose challenges for a P&T Committees as they try to determine therapeutic equivalence.

Ultimately, the infrastructure for protecting patient interests in formulary decisions—the traditional P&T Committee—does not have the ability to evaluate the extra-pharmacological considerations that must be taken into account for infusion treatment, including the administration device, drug stability, proximity to a compounding pharmacy, available administration access site and infection risk. Typically, these factors would be addressed by a physician or pharmacist knowledgeable about an individual's patient's circumstances and history when selecting a drug and delivery device.

C. CMS should recognize home infusion patients as a particularly vulnerable population that requires additional protection.

Patients receiving home infusion therapy are one of the truly vulnerable populations of the Medicare population, and as CMS acknowledged in the Proposed Rule,[7] the medical needs of such populations necessitate that they receive special protection under Medicare Part D. Infusion drugs are used to treat some of the most severe illnesses, including cancer, severe infections, pain and loss of gastrointestinal integrity.

Although the Medicare Part D regulations do create an appeals process for patients if their physician's choice of medication is not on formulary, patients with these compromising illnesses are the least capable of exercising an appeals right. If a patient does not have a family member or physician willing to take on the burden of being an advocate, then the patient's care could be compromised.

[7] 69 Fed. Reg. at 46661.

* * * *

We commend CMS for its initial efforts to understand and accurately define home infusion drug therapy under Medicare Part D. There is an important opportunity for the program to replicate the successes achieved by private health plans and Medicare managed care plans. There is also a risk that in the absence of sufficient direction from CMS and some targeted safeguards, the benefits of home infusion drug therapy will be lost for both beneficiaries and the overall Medicare program.

We would be pleased to provide additional assistance regarding these important issues. Please contact Lisa Getson, Apria's executive vice president, at 949-639- 2021 if you have any questions or comments.

Sincerely,

Lawrence M. Higby
President and Chief Executive Officer

CC: Herb Kuhn
Leslie Norwalk

Submitter : Ms. Connie Maranville **Date & Time:** 10/04/2004 08:10:02

Organization : HCR Manorcare

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

HCR Manorcare supports NHIA's position with regard to the issues relating to coverage for home infusion services as part of the Medicare Part D benefit. It is critically important that patients have access to infusion medications and the associated services required to provide them safely.

CMS-4068-P-1209

Submitter : Mr. Jon Rawlson **Date & Time:** 10/04/2004 08:10:59

Organization : PharMerica

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

See Attached Comments

CMS-4068-P-1209-Attach-1.doc

PHARMERICA

October 4, 2004

VIA OVERNIGHT MAIL AND ELECTRONIC SUBMISSION

The Hon. Mark McClellan, MD, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 309-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: CMS-4068-P

Re: Comments On Medicare Program; Medicare- Prescription Drug Benefit, Proposed Rule, 69 Federal Register 46632, August 3, 2004, CMS-4068-P

Dear Dr. McClellan,

PharMerica appreciates the opportunity to comment on the proposed rule *Medicare Program; Medicare- Prescription Drug Benefit, Proposed Rule, 69 Federal Register 46632, August 3, 2004, CMS-4068-P*. PharMerica Inc., is the third largest long-term care (LTC) pharmacy provider in the United States servicing more than 200,000 frail elderly in 2,000 skilled nursing facilities as well as hundreds of other dually eligible residents in similar institutional settings.

In the preamble for the MMA, CMS recognizes the value that LTC pharmacy providers bring to institutionalized residents of nursing facilities. This value extrapolates into enhanced patient care for our frailest, sickest and most unfortunate senior citizens. A synergistic one-to-one relationship has evolved between the skilled nursing and LTC pharmacy provider industries to provide optimal pharmaceutical care to these residents. PharMerica feels strongly that extreme care must be exercised during the implementation of the MMA to ensure that the one-to-one relationship between a skilled nursing facility and a LTC pharmacy provider is not weakened. A diminished one-to-one relationship could result in a decrease in the quality of pharmaceutical care for LTC residents. This

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has the potential to produce cost shifting to other healthcare providers and venues, such as state Medicaid and federal Medicare programs, when LTC residents require hospitalization due to drug related problems.

In order to reduce the potential for drug related problems and medication related errors and incidents, nursing homes and LTC pharmacy providers have invested significant time and resources to develop facility specific standards, policies and procedures, formulary management guidelines, dispensing systems, compliance packaging and other systems designed to decrease process variation and medication errors associated with that variation. Just as many nursing homes once had their own pharmacy within their walls (similar to hospitals), to provide optimal care to their residents; the current external one-to-one relationship has been designed to form a partnership that serves to improve medication therapy and outcomes.

In addition to safety related issues, long-term care pharmacies also work to develop and implement streamlined processes around ordering and delivery of medications. These systems allow nursing home staff to spend more time with direct patient care and less time managing pharmacy processes.

Multiple pharmacies servicing a single nursing home would require nursing home staff to manage multiple processes and systems, which in our experience would be detrimental to resident care. To assure patient safety while optimizing therapy, it is important to assure rapid access to safe and efficacious medications. If a nursing home is forced to interact with multiple pharmacies and PDPs, it is expected that formulary variations will cause confusion and delays in therapy. A delay in the commencement of therapy, in this patient population, could have significant negative results.

Nursing homes now care for the frailest and sickest of our elderly citizens. The litany of diseases and conditions that afflict nursing home residents commonly requires the administration of multiple medications each day. When prescribed and administered properly, medications can prolong survival and enhance quality of life. When prescribed or administered improperly or in error, these medications can cause morbidity and mortality.

Contracting With PDP's

PDPs should be required to contract with LTC pharmacies, and establish standards of access in order to preserve the one-to-one relationship between the LTC pharmacy provider and a nursing facility. Skilled nursing facilities must be able to continue their contractual relationships with their LTC pharmacy provider to maintain the quality and continuity of service for their residents. By requiring a contractual

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relationship between PDPs and LTC pharmacies, LTC pharmacies will be able to maintain the one-to-one pharmacy to facility relationship and ensure that plans have the capacity to meet the specialized needs of all Medicare enrollees in long term care facilities and ensure that long term care facilities meet federal and state quality, licensure and certification standards.

PDP's should also provide standardized long term care pharmacy contracts that recognize LTC pharmacy's essential role in the delivery of needed services to long term care facility residents.

Closed Versus Open Formularies

CMS should mandate an open, broad, geriatric-based formulary for all PDP's. Closed formularies for the geriatric population will result in a negative impact on quality of care and patient outcomes. The geriatric institutionalized patient has unique needs due to differences in drug clearance and metabolism, resulting in varied medication response from patient to patient. Additionally, unique concerns of the long term care resident, such as dysphasia and feeding tubes, require varied dose forms to ease administration (i.e. liquids, medications that can be crushed, injectibles, soluble dose forms). Each skilled nursing facility should have only one formulary to administer to its residents. Dealing with multiple formularies may result in medication errors due to the complexity and restrictions of ordering and administering. If a medication is not covered under a certain formulary, the nursing staff may not have the order changed to a covered item in a timely manner, resulting in a missed dose or possibly borrowing the unavailable medication from another resident. All LTC facilities are inspected at least annually by state and/or federal surveyors, and could be cited and fined for not administering medications according to physician's orders. Multiple formularies may delay the start of therapy – potentially putting the LTC facility at risk for regulatory non-compliance.

Inclusion of the Proposed Formulary Non-covered Drugs

PharMerica recommends that drugs proposed as exclusions in the MMA be covered for institutionalized patients and that payment for these medications be available by appeal for non-institutionalized patients. The draft regulations exclude benzodiazepines, barbiturates, medications used for weight gain, and over-the counter medications. Benzodiazepines are most often used in LTC facilities to treat anxiety, often associated in the adjustment process of being admitted to a facility. Additionally, some benzodiazepines are used to treat status epilepticus, a life threatening condition. Withdrawing benzodiazepines from patients who have been using them for an extended period may result in severe withdrawal symptoms and increased healthcare costs. Barbiturates are also excluded from coverage under the draft guidelines. Barbiturates such as phenobarbital are used to treat epilepsy in the geriatric population, and should be covered. Medications used to stimulate weight gain should also be covered.

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Unintentional weight loss in the elderly may result in unfavorable sequelae, such as a decrease in activities of daily living, and increased chance of depression and infection. Additionally, unintentional weight loss is a federal quality indicator used by federal and state surveyors to assess the quality of care in skilled nursing facilities. Lastly, if over-the-counter medications are categorically not covered, it may result in cost shifting to more expensive prescription medications, when a less expensive over-the-counter alternative is available.

Procedural Requirements for Expedited Coverage

CMS must mandate that PDP's provide an adjudication process that assures timely availability of non-formulary medications to institutionalized residents. If the formulary provisions of this regulation are implemented as proposed, CMS should anticipate an enormous number of formulary appeals. This will be due to that fact that many currently preferred medications for geriatric patients will not be included in PDP formularies because of their costs.

PDP appeal processes for non-covered medications should be streamlined, standardized, and approved by CMS. We also recommend that CMS should mandate that claims be adjudicated at point of sale. Appeal response time should be no longer than 24 hours. To assure that the long term care resident does not miss treatment, PDP's should cover a 3 day supply of the non-formulary medication to treat the resident while the appeal is under review. An appeal should be able to be initiated by the attending physician or the long-term care facility.

Payment for Non-formulary Yet Medically Necessary Drugs

If a PDP refuses or fails to pay for a non formulary medication that is determined to be medically necessary by the treating physician, CMS must establish who will cover these costs for a dually eligible institutionalized Medicare D recipient. Such reimbursement dilemmas are sure to occur unless provisions are included in the final regulations.

Fair Reimbursement Model for LTC Pharmacies.

LTC pharmacies focus on serving the needs of the frail elderly or disabled who reside in institutional settings. The patients we service represent some of the most dependent patients in the Medicare and Medicaid programs. Statistics now show that the average patient serviced is 83 years of age, has 7.8 different medical diagnoses, and takes 8 to 10 medications at any given time. (1)

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The needs of these patients differ vastly from the needs of a typical ambulatory (retail serviced) geriatric patient. To meet these needs a LTC pharmacy provides services greatly in excess of a retail pharmacy. These services include unit dose packaging for medications, emergency services, intravenous therapy, delivery, consulting services and medical records services. These services are necessary to ensure the best possible pharmacy care to these patients.

With the implementation of Medicare Part D the majority of a LTC pharmacy's reimbursement will come directly from a federal program. In order for this industry to continue to ensure the safety and care of LTC patients, reimbursement must be commensurate with the services provided.

Reimbursement should be adjusted periodically for inflation and must take into account the costs of administering the program. Payment terms should be comparable or better than payment terms with current Medicaid programs which vary between 7 - 30 days.

Usual and Customary Fee for A LTC Pharmacy

The dispensing fee paid should reflect the services provided. PharMerica recommends that CMS provide for a dispensing fee under Option 1 that encompasses the services that LTC pharmacies perform such as unit dose packaging for medications, emergency services, intravenous therapy, delivery, consulting services and medical records services. These services are vastly different from a retail pharmacy. A study done by BDO Seidman (see attached) in April, 2002 found that it costs long term care pharmacies, on average, $11.37 to dispense a prescription. This figure did not include a return on equity or a profit margin – it simply reflected the costs of operating a long-term care pharmacy. This study should guide CMS in establishing dispensing fees paid to LTC pharmacies. In contrast, the National Association of Chain Drug Stores (NACDS) estimated in 2000 that it costs a chain pharmacy, on average, $7.05 to dispense a prescription to a retail customer.

It is important to note that without adequate reimbursement, LTC pharmacies will have two options – reduce service levels or close their doors. Either scenario will negatively impact institutionalized patients, the most dependent segment of the Medicare and Medicaid populations.

PDP Assignments for Dual Eligibles

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Upon admission to a long term care facility, CMS should seek ways to limit the auto enrollment of dual eligible beneficiaries into PDP's that includes the LTC pharmacy that is serving the resident's nursing facility. If this is not possible, the beneficiary should be auto enrolled and the servicing pharmacy should have the ability to provide services for the resident as an out-of network provider.

The coordination with the LTC pharmacy will ensure the most efficient drug delivery system for the facility. Admission to a long term care facility should be construed as an address change for the resident and open the administrative option to enact a change in the dual eligible beneficiary's PDP election.

Expand the Definition of LTC

Based upon our experience, as a national provider to all types of facilities where residents and patients require assistance with the administration of their medications, we recommend that CMS expand the definition to cover assisted living facilities, ICFMR facilities, group home facilities and other waiver groups where dual eligibles are serviced. LTC pharmacies exist because of the needs of institutionalized patients. These patients typically require a large number of medications, need assistance with medication administration, and need more pharmacist oversight due to the complexity of their pharmaceutical care.

All of these needs equate to more stringent medication packaging and delivery systems. These requirements are typically met by a LTC pharmacy but in some cases are handled by a retail pharmacy. Any pharmacy that provides these services because of the needs of the institution should be reimbursed for these services. Service level should determine the reimbursement.

Conclusion

In summary, we provide the following list of recommendations to CMS.

- CMS should require, PDP plans to contract with LTC pharmacies by requiring plans serving LTC facilities to abide by a one nursing home – one LTC pharmacy relationship.

- CMS should mandate a broad, open and geriatric – based formulary for all PDP's.

- CMS should work closely with state Medicaid programs to ensure, in the short-term, that benzodiazepines and barbiturates, over-the-counter drugs, and medications used for intended weight loss be covered.

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- CMS should mandate that all PDP's provide a timely adjudication and appeals process to assure availability of medications to all long term care residents.

- CMS should determine adequate coverage and payment for non-formulary medications determined to be medically necessary for a long term care resident.

- CMS should provide for a fair and adequate reimbursement method including separate dispensing fees based on the complexity of dispensing a drug. We recommend a separate dispensing fee which recognizes the costs of specialized packaging, around – the –clock service and delivery, emergency services, services and supplies associated with infusion therapy, and other considerations deemed appropriate.

- CMS should expand the definition of "long-term care facility" to include residents of congregate alternative living arrangements for the elderly that "assist with" or "manage" medication administration for its residents. These facilities include intermediate care facilities for the mentally retarded and hospice, as well as any facilities regulated by State law.

We appreciate the opportunity to comment to CMS and want to express our appreciation to the agency for its hard work during the implementation process. We trust that our comments will assist the agency in developing regulations and policies which will enhance the delivery of medications to the nation's frail elderly residents of nursing homes and ensure their safety and well being.

Sincerely,

Jon B. Rawlson
Vice President, Government Affairs

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(1) D.E.Tobias and M.Sey, *General and Psychotherapeutic Medication Use in 328 Nursing Facilities: A Year 2000 National Survey*, 16 Consult. Pharm. 54 (2001)

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Submitter : Mr. John Hoff II **Date & Time:** 10/04/2004 08:10:20

Organization : Horizon Healthcare Services

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

see attached.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
DEPARTMENT FOR REGULATIONS & DEVELOPMENT

Please note, the attachment to this document has not been attached for several reasons, such as:

1. Improper format,
2. Submitter did not follow through attaching the document properly,
3. The document was protected and would not allow for CMS to attach the attachment to the original message.

We are sorry that we cannot provide this attachment to you at this time electronically, but you can view them here at CMS by calling and scheduling an appointment at 1-800-743-3951.

CMS-4068-P-1211

Submitter : Mr. Michael Wolf **Date & Time:** 10/04/2004 08:10:59

Organization : Horizon Healthcare Services

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

Please see attached

CMS-4068-P-1211-Attach-1.doc

Horizon Healthcare Services is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Horizon Healthcare services the home infusion needs of thousands of patients in south central Pennsylvania every year including many Medicare recipients. Founded in 1984, our highly trained healthcare professionals have the experience and skills necessary to create positive clinical outcomes for the patients we serve while at the same time conserving scarce healthcare dollars by treating patients at home and avoiding costly hospitalizations.

Horizon Healthcare Services appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

* Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm <http://www.nhianet.org/perdiemfinal.htm> .

* CMS should establish specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require specific standards for home infusion pharmacies under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the X12N 837 P billing format for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should mandate that prescription drug plans maintain open formularies for infusion drugs to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Michael F. Wolf, Jr

Account Executive

Horizon Healthcare Services
2106 Harrisburg Pike, Suite 101
Lancaster, PA 17601

CMS-4068-P-1212

Submitter : Mr. Scott Melville **Date & Time:** 10/04/2004 08:10:34

Organization : Healthcare Distribution Management Association

Category : Association

Issue Areas/Comments

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Please see the attached file.

CMS-4068-P-1212-Attach-1.doc

Healthcare Distribution Management Association
Products, Services and Information for Your Health

John M. Gray, President and CEO
Eric Schuss, Chairman of the Board

October 4, 2004

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Via Electronic Submission

Re: Medicare Program; Medicare Prescription Drug Benefit, Section 423.153 (d) [CMS-4068-P]. 69 Fed. Reg. 46632 (August 3, 2004).

Dear Dr. McClellan:

The Healthcare Distribution Management Association submits the following comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed rule, *Medicare Program; Medicare Prescription Drug Benefit*. 69 Fed. Reg. 46632 (August 3, 2004). I am writing to commend CMS for its efforts to implement the Medication Therapy Management Programs (MTMPs) included in the new Medicare Part D benefit, to be codified in section 423.153 of the proposed rule. HDMA believes that MTMPs will be an important addition to the benefits that seniors can receive under the Medicare program and we encourage you to work with the pharmacy community to craft a benefit program that adequately meets the needs of chronically ill beneficiaries.

HDMA is the national trade association representing full-service distribution companies responsible for ensuring that billions of units of medication are safely distributed to retail pharmacies, hospitals, nursing homes, clinics, and other provider sites across the United States. HDMA's distributor members provide services to approximately 141,591 pharmacy settings, including: 17,913 independent pharmacies; 19,824 chain pharmacies; 9,918 food stores; 9,992 hospital pharmacies; 4,872 mass merchandisers; 5,397 long-term care and home health facilities; 62,364 clinics; 1,170 healthcare plans; and 366 mail order pharmacies.[1] It is within these settings that patients interact with their pharmacists and receive important direction regarding their medications.

[1] Table 228 – Class of Trade Analysis – Manufacturer Sales by Customer Categories: 2002-2003.HDMA Industry Profile and Healthcare Factbook, Healthcare Distribution Management Association. (2004).

HDMA has long-believed that appropriate use of prescription drugs not only enhances the patient's quality of life but can also decrease the need for hospitalization or surgery. We believe that disease management and medication therapy management programs will contribute to obtaining favorable patient outcomes. Additionally, when chronically ill patients have access to specialized guidance regarding their medications and their drug therapies are more carefully monitored, it is possible that they can achieve greater results from their course of treatment and perhaps suffer fewer adverse events related to their illness or drug interaction.

It is also important for CMS to recognize the demonstrated value of individualized patient care services and to ensure appropriate and fair reimbursement for the professionals who provide such services. MTMPs involve the collaboration of the pharmacist with physicians, nurses and other healthcare professionals to ensure that medications are used appropriately to improve patient health status, improve the patient's quality of life and contain healthcare costs. CMS should devise appropriate payment mechanisms that acknowledge the important role of the pharmacist and the resources involved in providing individualized guidance for beneficiaries in order to ensure that they receive the most favorable results possible from their prescribed course of treatment.

HDMA distributor members do not serve patients directly, but as part of our role in facilitating patient access to necessary medications, we believe that it is important to support development of MTMPs that contribute to favorable outcomes and that are flexible enough to provide individualized patient care. In addition, MTMPs can lead to an overall reduction in healthcare costs. Therefore, it is critical that CMS develop this benefit in cooperation with the pharmacist and pharmacy communities. In determining the parameters of MTMPs, CMS should consider patient-specific treatment requirements; patient education relative to prescribed medications; the pharmacist's ability to monitor patient progress, and identify and resolve problems that are medication related; in-person consultations between the pharmacist and patient; and reimbursement rates that accurately reflect the resources and expertise that are required to provide effective medication therapy management. HDMA supports development of a MTMP benefit that ensures that the beneficiaries who have the greatest need for such programs are identified and ensured access to these important services.

HDMA appreciates this opportunity to provide CMS with its comments regarding the new Medicare Part D benefit and CMS policy regarding Medication Therapy Management. If we can be of assistance as you continue implementation of Part D regulations, please contact me or Elizabeth Gallenagh, Manager, Regulatory Affairs at 703-787-0000 ext. 234.

Sincerely,

Scott Melville

Scott Melville
Sr. Vice President of Government Relations

CMS-4068-P-1213

Submitter : Dr. Clifford Wong **Date & Time:** 10/04/2004 08:10:34

Organization : MedImpact Healthcare Systems, Inc.

Category : Health Care Industry

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

See attachment for comments

CMS-4068-P-1213-Attach-1.doc

MedImpact Healthcare Systems Inc, Comments for
Medicare Prescription Drug Benefit Proposed Rules Review: File Code CMS-4068 P

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections

Summary: The definition of a covered Part D drug is described, as well as those drugs which are excluded from coverage. Drugs covered under Part A or Part B are excluded from Part D coverage, although there may be potential problems in defining some drugs. The definition of dispensing fee is not yet final and currently there are several options being discussed. The definitions of standard prescription drug coverage and alternative prescription drug coverage are discussed in detail. The definition of incurred costs toward spending against out-of-pocket expenses is also defined. Covered Part D drugs for Part D eligible individuals are not taken into account in "best price" calculations. We will be required to disclose aggregate negotiated price concessions to CMS. PDP plan service areas are being defined and we will need to determine whether our pharmacy network meets the pharmacy access requirements. A model formulary is being developed by USP. We are not required to use the model formulary, but we will need to obtain approval for our current formulary. USP will define therapeutic classes and we are required to have at least two drugs for each therapeutic class. We are required to issue ID cards and conform to a specific standard in designing these cards. Out-of-network pharmacy use must be allowed for certain situations and we need to develop a process to capture out-of-pocket expenses at these pharmacies. The formularies, along with other information, is required to be posted on a public website, accessible to both members and non-members. We are also required to send monthly reports to beneficiaries who use Part D services. These reports will contain individualized information. CMS is proposing to offer waivers for the requirement to always disclose the differential in price of a covered part D drug and the lowest generic version of that drug at the point of service. Confidentiality requirements are similar to those we currently have as a MA plan.

MedImpact Healthcare Systems Inc, Comments for
Medicare Prescription Drug Benefit Proposed Rules Review: File Code CMS-4068 P

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections

FR Page #	*Excerpt*	*Comment/Question*
46646 46646 423.100 C.1.a P 84	*Definition of covered Part D drugs* "… a covered Part D drug must be available only by prescription, approved by the Food and Drug Administration (FDA), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). A covered Part D drug would include prescription drugs, biological products, and insulin as described in specific paragraphs of section 1927(k) of the Act and vaccines licensed under section 351 of the Public Health Service Act. The definition also includes 'medical supplies associated with the injection of insulin (as defined in regulations of the Secretary).' We propose to define those medical supplies to include syringes, needles, alcohol swabs, and gauze.	1. We still don't know which vaccines are required to be covered under Part D. Currently, no vaccines are dispensed from a pharmacy except oral typhoid vaccine. 2. Are orphan drugs considered to be Part D drugs? Some of the drugs in this classification are provided free of charge from the manufacturer, but not all. Would coverage be dependent upon the FDA approval status of the orphan drug? One paragraph on page 46662 (second column, last paragraph) implies that orphan drugs may be considered a Part D drug. 3. Are needle-free insulin injectors covered under Part D? This product costs several hundred dollars and requires the purchase replacement supplies, such as special syringes and vial adapters. 4. As mentioned in previous e-mail, we may want to confirm our presumption that imported drugs are not covered by Part D. 5. The goal to cover the gap for Part B drugs administered pursuant to a physician's visit via Part D has merit but is fraught with operational problems. There may be overlaps where drugs that are administered pursuant to a physician's visit may also be dispensed as an outpatient ambulatory prescription. PBMs administering the drug benefit need as much specificity as possible to build formularies or files for specific adjudication at the point of service. PBMs have no way of coordinating adjudication with drugs that may have been administered or paid via Part B. Concurrently, national PBMs have no way to deal with local medical review board policies in all the different regions. Formularies are plan specific, not regional and certainly not LMRB directed.

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections		
FR Page #	***Excerpt***	***Comment/Question***
46646 46646 423.100 C.1.a P 84	*Smoking cessation agents* "In accordance with section 1860D-2(e)(2) of the Act, the definition of a covered Part D drug would specifically exclude drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid, with the exception of smoking cessation agents."	1. Can we still continue to require proof of patient attendance of smoking cessation classes as a condition of drug coverage? Members currently pay a fee to attend the class and obtain nicotine patches as a covered benefit. Would the cost of the class accrue to the out-of-pocket expense? 2. Some smoking cessation agents are classified as OTC drugs. Would these products require a prescription in order to be covered as a Part D drug or for the costs to incur as part of the out-of-pocket expense? 3. MCO with MA PDs may have varying policies regarding smoking cessation regarding limits to number of courses of treatment and required corresponding education and course work. We would need to allow flexibility in this realm, particularly where PBMs may adjudicate the number of treatments within a given time frame. 4. This section describes the exclusion of drugs restricted under Medicaid, but the concern arises over the grievance process. Will the grievance process allow for coverage of "excluded" drugs? Will the law permit this?

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections

FR Page #	*Excerpt*	*Comment/Question*
46646 46646 423.100 C.1.a P 84	*Excluded Part D drugs* "..the drugs or classes of drugs that may currently be excluded or otherwise restricted under Medicaid include – (1) Agents when used for anorexia, weight loss, or weight gain; (2) agents when used to promote fertility; (3) agents when used for cosmetic purposes or hair growth; (4) agents when used for the symptomatic relief of cough and colds; (5) prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; (6) nonprescription drugs; (7) outpatient drugs for which the manufacturer to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale; (8) barbiturates; and (9) benzodiazepines."	1. This list of excluded Part D drugs is identical to the list provided for the Drug Discount Card. Some of the classes of drugs are fairly straightforward, but some are more difficult to define. The list sometimes defines a class of drugs by its intended use or indication and, at other times, the list defines a type of drug by its chemical and/or pharmacologic classification. Barbiturates and benzodiazepines are fairly straightforward in their definition. However, "drugs used for the symptomatic relief of cough and colds" may be more difficult to define since drugs are often used for multiple indications. For example, guaifenesin tablets are commonly prescribed to treat symptoms of cough and cold. However, guaifenesin is sometimes prescribed off-label for the treatment of fibromyalgia. Would we be responsible for determining whether a given indication is appropriate for an excluded drug in these circumstances? What type of process and documentation would CMS require? 2. For the Drug Discount Card program, CMS provided sponsors with a list of NDC numbers for drugs that fall in the categories of barbiturates and benzodiazepines. We believe this list will be expanded to include all categories but #7 3. If CMS has a specific foundation list of drugs covered under Part B, please provide such that we can build an appropriate file for adjudication. Also, we would like to review the assumptions behind the selection or exclusion of drugs if such is available. 4. If CMS has a specific foundation list of drugs covered under Part B, please provide such that we can build an appropriate file for adjudication. Also, we would like to review the assumptions behind the selection or exclusion of drugs if such is available. 5. Please describe the procedure for instances where a prescription drug becomes OTC during a contract year. This could change the beneficiary coverage and formulary composition and minimum formulary requirements. How would these situations be handled?

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections		
FR Page #	***Excerpt***	***Comment/Question***
	Excluded Part D drugs *(Continuted)*	6. CMS is requesting comments regarding their exclusion of drugs for which there is a manufacturer requirement for lab tests through a manufacturer relationship. CMS is wondering if this is a broad enough exclusion. We should advocate for exclusion of drugs under any manufacturer restricted distribution system due to the administrative burden of repatriating these claims and beneficiary OOP costs back into our accumulator. 7. The concern arises over the exclusion of the 9 specified areas and in the specific circumstance where a drug product is included in a drug class, but it a medically necessary product for valid medical conditions (e.g. diazepam and clonazepam are benzodiazepines, but have valid medical uses for seizure related medical conditions), are these precluded from coverage, even with the grievance procedure?

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46647 46647 423.100 C.1.a P 85	*Exclusion of drugs currently covered by Medicare* "Section 1860D-2(e)(2)(B) of the Act that specifies that a drug prescribed to a Part D eligible individual that would otherwise qualify as a Part D drug cannot be considered a covered Part D drug if payment for drug '* * * *is available* (or would be available but for the application of a deductible) under part A or B for that individual.'" "The Part D drug coverage described in this proposed rule does not alter the coverage or associated rules for drugs that are currently covered by Medicare prior to the MMA, such as those included in the following list….. 1. …Drugs used in immunosuppressive therapy furnished to a beneficiary who receives an organ transplant for which Medicare makes payment. "...We intend to ensure that the Part D benefit 'wraps around' Part B drug benefits to the greatest extent possible. For example, Part D would cover immunosuppressive drugs furnished to Medicare beneficiaries who did not have their transplant paid for by Medicare (e.g. a beneficiary who had his or her transplant paid for by a private insurer when he or [sic] was employed, and the beneficiary has not enrolled in Part B)."	1. CMS is requesting comments on how to avoid coverage gaps between Part B and Part D. This will be somewhat problematic for plans since Part B coverage varies by geographic region. Plans will be left to interpret correct Part B and D coverage based upon the historical Part B coverage interpretation in their geographic area. The fix is obvious in that CMS should rationalize Part B coverage, however, they lack the statutory authority to change existing Part B coverage. 2. In order to properly process prescriptions for immunosuppressive agents, the pharmacy staff will need to know whether 1) if the medication is used for immunosuppression following a transplant and 2) if the transplant was paid for by Medicare. In addition, these medications are usually quite expensive. For patients in the "donut hole", one or two prescriptions could easily surpass the $2850 out-of-pocket expenses and push the patient into catastrophic coverage, so it will be important for the pharmacies to correctly identify whether the drugs are being covered under Part B or Part D.

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	Exclusion of drugs currently covered by Medicare (Continued)	3. The intent to insure that Part D wraps around Part B is positive in intent but likewise creates operational problems. Our broad strategic guidance to CMS is to allow a degree of flexibility to the MA-PD or PDP in this instance. PBMs do not have systems yet developed to coordinate between B & D. The data is not readily available nor easily extracted to be provided to a PBM for quick POS adjudication at a pharmacy. The simplest way, would be for CMS to develop specific lists that allow some product overlap to be covered in BOTH B & D. The PBM has no way of knowing whether transplants are paid by CMS or some other private insurer. The interlink between Part B providers and pharmacy systems does not exist. Is it possible for CMS to become a clearinghouse for such data to cover all CMS regions?
		• How will pharmacists at Point-of-Sale know the medical indication for appropriate billing?
		  ◦ If a transplant was paid for by Medicare, then the claims should be adjudicated under Part B.
		  ◦ Otherwise, the claims should be submitted under Part D.
		• When a beneficiary transfers from a Medicare Employer Group, and is now covered under Part D, how will the pharmacy know if their drug should be covered under a prior Medicare paid procedure or submitted for Part D payment?
		• Currently there is no standard method to communicate medical procedure information to PBM's for appropriate determination of adjudication.

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46647-48 46647-48 423.100 C.1.b P 87	*Dispensing Fees* "Because the statute is ambiguous on the meaning of "dispensing fee," in this proposed rule we are not proposing a specific definition of "dispensing fee," but instead are offering three different options…."	1. CMS has three definitions of dispensing fee. Option 1 allows for the cost of only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead. MedImpact's recommendation would be to follow OPTION ONE. Our systems and contracts with the pharmacy network are built upon this key fundamental financial fact. The notion is that all functions such as phone calls, or pharmacist follow up are included within that negotiated fee. Clearly, pharmacies create additional margin in the spread between acquisition cost and sales price of the drug. Pricing network pharmacy contracted services at an actual acquisition cost plus a fully loaded dispensing fee is a complex issue and not within the Part D scope. 2. Option 2: This option would include supplies and equipment which may be required for or pursuant to administration of a prescribed outpatient drug. Dispensing fee should NOT include these components. Treat the components of supplies and equipment as a a prescription for a product. Have the product as a covered item as a drug or have it sold with an appropriate margin. A dispensing fee for the equipment or supply may then be applied separately for each piece. The equipment and supplies should be treated as prescriptions. 3. Option 3: This option would include Option 2 plus clinical services required to assure safe administration of the drug. This is NOT something that PBMs can currently administer. These are fees which may be paid to nursing or other ancillary staff besides pharmacists. These fees may in fact be included in contracts established between the health plan and the IV therapy vendor. We would have to check the NCPDP capability for providing a different field for services other than dispensing a prescription. Again, keep the products separate from the dispensing, administrative, or clinical service fee. This Option affects PBM network agreements and would require potential renegotiations with 55,000 pharmacies.

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	Dispensing Fees *(Continued)*	4. The crux of the differing definitions is how to limit the payment for clinical services in the outpatient pharmacy through dispensing fees versus the need to pay for appropriate clinical services for home infusion patients. 5. As a PBM, MedImpact would prefer to NOT administer clinical service fees in the home IV arena. PBMS may administer dispensing fees for prescriptions for IV drugs, for each supply item, or piece of equipment given the existence of an NDC for such. Home IV infusion pharmacies could be a part of a pharmacy network. Each IV drug supply should be dispensed as a prescription pursuant to state and federal law. We are not clear on the types of in house pharmacy systems used by home infusion facilities nor are we familiar with their ability to have claims adjudicated via a PBM. They may do medical claims processing to a payor.

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46649 C2a	*Benefit Requirements* PDPs and MA-PDs are required to offer "qualified prescription drug coverage", which is either standard prescription drug coverage (§423.104(e)) or alternative prescription drug coverage (§423.104(f)). These two coverages are illustrated in a chart in the Appendix to this summary. In addition to the benefits discussed below, PDPs and MA-PDs must also make available to their enrollees negotiated prices. • **Standard prescription drug coverage.** Standard prescription drug coverage for 2006 (amounts are indexed by the per capita increase in Part D expenditures) includes a $250 deductible and 25% coinsurance for the next $2,000 of costs for covered Part D drugs. At the point the costs are equal to $2,250, termed the initial coverage limit, the individual is responsible for all of the costs up to the annual out-of-pocket threshold. The PDP or MA-PD may revise the cost-sharing between the $250 deductible and the $2,250 initial coverage limit as long as the cost-sharing is actuarially equivalent to 25% coinsurance. At the point that catastrophic coverage commences, which is when the enrollee has incurred costs of $3,600, enrollees will pay a copayment of the greater of (1) 5% of the cost of the drug or (2) $2 for a generic drug or a preferred drug that is a multiple source drug and $5 for any other drug. PDPs and MA-PDPs may offer tiered copayments provided that the standard for being actuarially equivalent to the 25% coinsurance, noted above, is met. [Note: Medicare Advantage plans may also apply all or a portion of any beneficiary rebates achieved by submitting bids below the benchmark for Part A and B benefits to reducing Part D beneficiary premiums.]	1. CMS would review and approve PDP sponsors', MA-PD proposed prescription drug plans. All will be trying to develop products that are actuarially equivalent to the standard Part D model. It would be helpful if CMS would have its actuaries develop models showing variables as well as CMS assumptions supporting the model. We request that these be developed in detail as examples for the final rules and solicitation forthcoming. This could also save a lot of time and provide valuable guidance for all approved sponsors. What will be the process and infrastructure used by CMS to evaluate for actuarial equivalence? 2. The language requires sponsors to accept without restrictions all individuals who are eligible for an MA plan. What is a capacity waiver? And, why would a PDP not be allowed the same consideration as an MA? 3. C.2.a.1 to 3 46649 describes incurered costs for purposes of applicability towards the beneficiary spending against the OOP limit. The incurred costs must be tracked by a PDP of MA-PD using the standard Part D. The language also describes special circumstances where there are price differentials between mail & retail and OON and usual prices within network. Such OOP differentials count. Also charitable and certain individual costs are allowed to count towards incurred costs. Insurance contributions and wrap around programs are noted to NOT count towards incurred costs. We concur with this policy but wish to comment that tracking such accumulated costs from a multiplicity of sources outside the adjudication process is NOT something within the current capabilities of PBMs. The OOP differentials incurred at a POS Pharmacy may be tracked provided there is adjudication to a benefit design. Contributions from charitable sources and other insurance may not be known to and thus not trackable by PBMs. We would support the notion of a CMS sponsored facilitation center tracking such such incurred costs and providing such data in an NCPD file format to the requesting or designated PDPs, MA-PDs. Tracking accumulator for approved incurred costs will necessitate major systems design and development for enrollment, eligibility, and pharmacy systems and databases. These changes are not minor and require significant time and money resources to accomplish. Such system development will be required prior to adjudicating Plan D benefit designs.

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	Benefit Requirements (Continued) • **Alternative prescription drug coverage**. To qualify as alternative prescription drug coverage, which encompasses basic alternative coverage and enhanced alternative coverage, the following four requirements must be met: 2. Has an annual deductible that does not exceed the deductible for standard prescription drug coverage; 3. Imposes cost-sharing no more than the 5% or $2/$5 amounts stated above at the point the annual out-of-pocket threshold is reached; 4. Has an unsubsidized value that is at least equal to the unsubsidized value of standard prescription drug coverage; and 5. Provides coverage that is designed to provide for payment that is at least equal to the amount that would be paid under standard prescription drug coverage.	
46653 2.b.ii.	• **Enhanced alternative coverage**. A PDP sponsor may offer enhanced alternative coverage if it also provides basic prescription drug coverage in the area. Basic prescription drug coverage is either the standard coverage (above) or alternative prescription drug coverage that is actuarially equivalent to standard coverage. Enhanced alterative coverage is basic prescription drug coverage and supplemental benefits, which includes: 1. Coverage of drugs other than covered Part D drugs: and/or 2. Any of the following changes or combination of changes that increase the actuarial value of benefits: o A reduction of the annual deducible; o A reduction in the cost-sharing; or o An increase in the initial coverage limit.	1. MMA seeks to allow sponsors to develop alternative actuarially equivalent benefits to the basic design that will allow more effective utilization management. The described benefit options will necessitate changes to our enrollment, eligibility and pharmacy systems. Likewise a multiplicity of designs approved for different MA-PDs within the market place decreases PBM efficiency and could increase costs to the PBM or PD administrator. Reality indicates that different MAs and PDPs will NOT have precisely the same benefit designs. Nor will plans have only one product in a competitive market. New benefits, edits, cost shares will be created to be actuarially equivalent. Each may require CMS review. CMS has recognized that actuarially equivalence is difficult to define with specificity and thus may need to allow flexibility in this regard. There are too many variables and untested assumptions in this new arena with the noted potential reduction variables. Modeling from CMS may give additional guidance.

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46649-50 46649-50 423.100 C.2.a P 91 46659	*Costs considered incurred against the out-of-pocket limit* "As a point of clarification, we also propose that beneficiary costs incurred under the following circumstances count as incurred cots consistent with the definition of that term in §423.100 of our proposed rule (with plans explicitly accounting for such price differentials in the actuarial valuation of their coinsurance in their bids): 1. Any differential between a network retail pharmacy's negotiated price and a network mail-order pharmacy's negotiated price for an extended (for example, 90-day) supply of a covered Part D drug, as described in section II.C.4.1 of this preamble, and 2. Any differential between an out-of-network pharmacy's usual and customary price for a covered Part D drug purchased in accordance with the out-of-network access rules described in section II.C.5 of this preamble and the plan allowance for that covered Part D drug." "Thus, as provided under §423.120(a)(6) of the proposed rule, a plan enrollee who chooses to obtain an extended supply of a covered Part D drug through a network retail pharmacy would be responsible for any differential between the network retail pharmacy's and the network mail-order pharmacy's negotiated price for that covered Part D drug.	1. COMMENT: Pharmacy systems vary and do not have the capability at this time to track TrOOP from ALL the various sources CMS has outlined as allowable incurred costs. How would we get costs from SPAP or ADAP & Ryan White? As a PBM, MedImpact recommends that CMS contract with a central TrOOP Facilitator Contractor to provide a NCPDP approved format file to PBMs and PDPs to allow efficient management and reconciliations at the prescription POS and to populate our accumulators. Furthermore adding 340B utilization as contributing to incurred costs towards catastrophic and to insure access to Part D creates an operations challenge which will take significant investments to coordinate. We would assume that ADAP & Ryan White beneficiaries have established retail pharmacy and designated 340B pharmacies for service points. Data from these service points or from 340B reporting may perhaps be provided to CMS for reporting, reconciliations, and financials on a broader basis outside of the existing pharmacy systems. We would look to CMS to bring the data from such sources to a Central Facilitator to distribute to PBMs, PDPs, MA-PDs in a desired NCPDP format to populate our cost accumulators for incurred costs.

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46650 46650 423.100 C.2.a P 91	*Charity contributions incurred against the out-of-pocket limit* "Section 1860D-2(b)(4)(C)(ii) of the Act provides that any costs for which a Part D individual is reimbursed by insurance or otherwise, a group health plan, or other third-party payment arrangement do not count toward incurred costs…"	1. We need to identify which regions have SPAPs as these programs can pay members cost-sharing and it will count as part of their true OOP costs. Again, this speaks to the need for a national facilitator for tracking TrOOP for incurred costs and to allow ALL sponsors the information needed for accurate POS tracking towards the catastrophic benefit. 2. CMS requests comments on coordination of ADAP with Part D: ADAP would be allowed to pay bene premiums for PART D to assure access for AIDS population to Part D as well as deductibles and cost-sharing. The ADAP paid deductibles and cost sharings, however do not count towards incurred costs. Our perspective is that if such costs DO NOT count towards the incurred costs, then we have no position as we will not need to track such on our accumulators. However, if our MA-PD needs such data for adjustments to their own charitable programs, we will not have the capability to provide. Perhaps CMS should provide the actuarial data defining the forecast for how many beneficiaries will reach the $3600 TrOOP and help to assess what systems costs need to be invested to track the various contributing sources to TrOOP. Can an actuarial adjustment be made for AIDS RYAN WHITE patients enrolled in such programs pending development of sophisticated COB systems?

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46654 46654 423.100 C.2.c P 101	*Part D negotiated prices exempt from "best price"* "As required under section 1860D-2(d)(1)(C) of the Act, prices negotiated with manufacturers for: (1) Covered Part D drugs by either a prescription drug plan or an MA-PD plan; or (2) a qualified retiree prescription drug plan, as described in §423.882 of our proposed regulation on the Medicare retiree drug subside, with respect to covered Part D drugs provided on behalf of part D eligible individuals would not be taken into account in making "best price" determinations under the Medicaid program."	1. Currently, MedImpact passes through negotiated prices to the beneficiary at the point of sale in its DDC program. We retain only those administration fees permitted by the negotiate contract with the drug company. Relative to PART D, some of our MA PD clients who negotiate their own drug prices may wish to pass these discounts on to the beneficiary via premium subsidies as well as lower prices at the point of sale. We support these options as provided by MMA. We note that CMS will require reports relative to the aggregated savings. These reports deserve the highest level of confidentiality protection. We would ask CMS to develop rules that allow MA-PD plans to provide those reports direct to CMS with needed utilization data provided by the PBM administering the PD component. 2. Relative to negotiated prices, we recommend that CMS publicly urge the pharmaceutical industry to begin developing its public policy and commitment to the Part D initiative. For DDC, negotiations for discounts were prolonged and difficult due to the uncertainty of the rules, utilization, and application of a new process. Prices were not finalized until after open enrollment in many instances. Thus it was difficult to forecast prices for reporting to CMS. Prices shown on the Price Compare were initially higher pending negotiations with drug companies which take time and resources. Thus, any political pressure that may be asserted to prompt pharmaceutical industry support for Part D may be of great societal benefit. It would also be encouraging if the work done for discounts in DDC could be touted as a strong foundation for moving forward into Part D.

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46654 46654 423.100 C.2.c P 101	*Passing savings from negotiated prices to members* "Section 423.104(h)(3) would require, as stated in the provisions of section 1860D-2(d)(2) of the Act, that PDP sponsors offering a prescription drug plan and MA organizations offering an MA-PD plan disclose to us all aggregate negotiated price concessions – including discounts, direct or indirect subsidies, and direct or indirect renumerations- they obtain from each pharmaceutical manufacturer that are passed through to the Medicare program in the form of lower subsidies or to beneficiaries in the form of: (1) Lower monthly beneficiary premiums, and/or (2) lower covered Part D drug prices at the point of sale."	1. If a MA-PD choose to pass along savings in the form of lower monthly beneficiary premiums negotiated prices need to be determined well in advance of premium announcements. There will have to be an aggressive timeline to finalize contracts with pharmaceutical companies or to forecast potential rebates in order to estimate the reduction in premiums for 2006. This puts our MA PD clients at some risk, particularly if the forecasts for discounts are not achived in drug price negotiations. Adjustments in prescription pricing would then need to be made at the POS to offset lost premium revenue. Again, we speak to the point above. We all want the best possible drug prices and will need CMS assistance and political support to establish an environment which compels effective negotiations with drug industry in the immediate future. PBMs who may be serving MA-PD Plans almost need to begin discussions immediately to allow effective MA PD marketing and premium announcements in the late summer/Fall of 2005.
46655 46655 423.100 C.2.c P 102	*Periodic audits by the OIG on pricing practices* "We would be authorized to conduct periodic audits – either directly or through contracts with other organizations – of the financial statements and records of PDP sponsors and MA organizations pertaining to the prescription drug plans and MA-PD plans they offer."	MedImpact rebate and discount contracts are continuously subject to audit by clients, their accountancy firms, and by pharmaceutical industry. We are confident that we will be able to pass OIG periodic audit reviews.

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46655 C.4 P 138	*Access to covered Part D drugs (§423.120)* NOTE: Congress gave CMS broad authority to waive Part D requirements that duplicate or are in conflict with requirements under Medicare Part C (or under Section 1876 for cost plans and Sections 1894 and 1934 for PACE organizations). • **Assuring pharmacy access.** PDPs and MA-PDs must have a contracted pharmacy network, consisting of pharmacies other than mail-order pharmacies, that meet certain access standards. These access standards apply differently to urban, suburban and rural areas under which a specified percentage of beneficiaries, on average, must live within specified miles of a network pharmacy. The access standards do not apply to an MA-PD plan that provides enrollees with access to Part D drugs through pharmacies owned and operated by the organization. MA private fee-for-service plans that provide coverage for drugs from all pharmacies without differentials in cost-sharing are also not subject to the access standards. • **Any willing provider.** A PDP sponsor or MA organization is obligated to contract with any pharmacy willing to meet its terms and conditions. PDP sponsors and MA organizations may not require a pharmacy to accept insurance risk as a condition of participation. • **Discounts for preferred providers.** The proposed rules allow for a PDP sponsor or MA organization to reduce cost-sharing as part of a non-standard drug benefit plan when the enrollee receives drugs from a preferred pharmacy. Any cost-sharing must not increase CMS payments.	1. MedImpact has potential MA-PD clients who are fully integrated and own their pharmacies. These pharmacies exclusively serve their membership for commercial and MA plans. We recommend that CMS provide waivers to such clients regarding Pharmacy Access Standards. The rule waivers that were provided for DDC should likewise be considered for Part D in that exclusive provider pharmacies were exempt from posting as public pharmacies on the CMS website. There is no business rationale for mandating ANY WILLING PROVIDER to serve exclusive MA-PD beneficiaries. 2. MedImpact has a national network of over 50,000 pharmacies. We meet the current TRICARE standards. Thus, irrespective of the final CMS ruling on how the Regions will be designed, we are confident that our network can solve beneficiaries on a national basis using national retail chains. 3. MedImpact has contracts with national mail order vendors to allow access to remote rural areas. We have the ability to truly provide national service and access. This may serve snowbirds well. Snowbirds may also utilize key participating pharmacies in our network to obtain their prescriptions nationally via a “mail at retail” rate for 90 day drug supplies. We would offer this service and price convenience for our Part D plan.

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	Access to covered Part D drugs (§423.120) (Continued) • **Level playing field between mail-order and network pharmacies.** A PDP sponsor and an MA organization must allow enrollees to obtain a 90 day supply of covered Part D drugs from a network retail pharmacy. In such a case, the enrollee may be obligated to pay the differential between the price of the mail-order pharmacy and the retail pharmacy.	4. LTC PHARMACIES: If CMS proceeds with the notion of including LTC pharmacies within the required network, negotiations would need to be undertaken to define the roles, responsibilities of such LTC pharmacies as well as the price, discounts to be provided to the beneficiary residing at the LTC. The relationship between the LTC Pharmacy and the contracting payer will enter into the process and may thus preclude a practical role for a PBM serving a MA PD. This portion of costs may be best addressed in the payer contract with CMS. Relative to special clinical services provided by a LTC pharmacy, we would recommend keeping that component separate from the dispensing fee for providing the appropriate unit dosed product to the LTC for administration to the beneficiary. A bundled cost does not allow effective negotiation. LTC Pharmacies are required by state and federal law to provide a range of consulting and clinical services somewhat similar but less stringent than an inpatient hospital setting. Negotiation of their prices via a PBM network concept may run contrary to the contract between the LTC FACILITY and the LTC CONTRACTED PHARMACY. There are financial relationships and margins in which the PBM or MA-PD will be viewed as an interloper. There may be opportunities for residents of LTC facilities to have their prescriptions filled OUTSIDE of the LTC Facility/contracted LTC Pharmacy and delivered to the facility in appropriate UNIT DOSE (Unit of use) containers. Potential savings may be achieved therein, but there will be resistance from the LTC facility and pharmacy as it changes their usual processes and will require the contracted LTC pharmacy to examine the drugs to assure they are correct. This is another complex area which has been far removed from public debate.

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	Access to covered Part D drugs (§423.120) (Continued)	5. MedImpact currently contracts with over 50,000 pharmacies nationally. The Service Agreement language is consistent throughout. However, financial terms, reimbursement, conditions required by a plan sponsor, credentialing, state or local legal requirements may compel differences. The Service Areas have not yet been defined by CMS and these SAs may cut across multiple states. It is NOT feasible to have a singular "standard" contract for participation. Also, given the necessity to develop actuarially equivalent benefit designs which suggest total cost equivalence, the PBM or MA-PD must be given the flexibility to use all the tools at its disposal to help manage costs and utilization. The network contract is a financial management tool on behalf of the Plan Sponsor. A MA-PD or PDP may need to have customized networks with tiered pricing and reimbursement in a same Service Area. Credentialing requirements pursuant to Medication Therapy Management may further define capacity to participate within a network. Thus, we support the notion of distinctions between "preferred" and "non-preferred" pharmacies within a network. We support the ideas suggested in the access requirements relative to mail, rural, cost share, and price differentiation within a network. We therefore concur with inclusion of such differential costs towards the incurred costs. 6. With the noted comments above, we can provide focused networks for MA-PD clients requiring such to expand beyond their integrated models. In such instance benefit designs with price differentiation would suffice to allow a balance of choice and cost management.

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46659 46659 423.120 C.4.b P 111	*P&T Committee membership* "The majority of members comprising the P&T Committee would be required to be practicing physicians and/or practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician member would have to be experts in the care of elderly and disabled individuals." "Section §423.120(b)(1)(ii) of the proposed rule also provides that at least one practicing pharmacist and one practicing physician members on a plan's P&T Committee be independent experts. We interpret the statutory language at section 1860D-4(b)(3)(A)(ii) of the Act requiring certain members of the P&T Committee to be 'independent and free of conflict with respect to sponsor and plan' to mean that such P&T committee members must have no stake, financial or otherwise, in formulary determinations."	1. In order to comply with these proposed regulations, the P&T memberships will need to include at least one physician and pharmacist who specialize in the care of the elderly and disabled individuals for each P&T Committee. The key term is "at least one practicing pharmacist and one practicing physician member would have to be experts in the care of the elderly and disabled." This language suggests having geriatricians available to serve on P & T. Disabled is difficult to define as there are a host of disease which create eligibility for disability benefits. W e recommend that a broad interpretation of "expert" be applied in that many internists and family practitioners care for the elderly and would certainly be considered "experts". We would venture to guess that there are not enough board certified geriatricians available to serve on all the P & Ts across the nation. Nor are there likewise enough geriatric specialty pharmacists available. The key focus would be on appropriate dosage and posology for our senior population. The assignment of members to P & T is usually a CMO or Medical Staff process. We are confident that the Chairs of the P & T committees can appropriately assess the membership roster to determine which member has the appropriate "expert" credentials or whether there is a need to expand the membership to ensure such representation. 2. What is the CMS definition of a practicing pharmacist? Pharmacists may be experts in geriatrics care from a wide range of practice settings which include ambulatory clinical, LTC, dispensing to nursing homes, and even pharmacokinetics experts. The latter are experts in metabolism, excretion, and impact of age on the patients' ability to tolerate drugs. We wish to emphasize that practicing is much broader than dispensing. 3. Relative to the terminology "independent and free of conflict with respect to the sponsor and plan", we would like CMS to expand upon the associated term "independent and free of conflict with respect not only to a PDP sponsor and its prescription drug plan or an organization and its MA-PD plan, but also with respect to pharmaceutical manufacturers." Does this mean that MA-PDs must contract or hire consultant pharmacists and physicians to fulfill this role? How is the confidentiality of proprietary data protected? Does employment or contracting with a MA-PD plan preclude a physician or pharmacist from participation in its P & T? We would argue that physicians employed as part of group where the group subscribes to strong principles of responsibility will be much less at risk of financial influence than in other more independent practice modes which lack group guidance and commitment to core principles.

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	P&T Committee membership (Continued)	In our situation, P & T members are NOT compensated for these roles to assure optimal objectivity. We believe that our P & T is free of conflict based upon stringent qualification rules. Total independence would require CONTRACTING and paying for consultants with defined contractual agreements to roles, responsibilities, and confidentiality which increases administrative costs. There is significant preparation time prior to meetings. We would envision such contracted physicians and pharmacists potentially serving competing MA-PDs. Also, nationally recognized physician experts in key therapeutic arenas frequently do presentations or attend advisory boards or panels sponsored by pharmaceutical industry. Does this type of relationship between physicians and pharma preclude participation on a P & T? Seeking physician experts from teaching hospitals and universities may likewise create problems in that research grants are frequently provided by pharmaceutical industry. Does having received such a grant preclude participation on a P & T? It may be interesting to have CMS solicit a panel of experts to develop a strawman or model selection criteria and Principles of Responsibility statement for P & T membership. "No Stake, financial or otherwise, in formulary determinations" for independent P & T members suggests that other P & T members attached to a MA or MA-PD are not capable of appropriate clinical decisions based on quality and affordability.

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	USP model formulary "Although the USP will develop guidelines, under section 1860D-4(b)(3) of the Act PDP sponsors and MA organizations would have the flexibility to develop their own classification schemes." "If, on the other hand a PDP sponsor or MA organization offering an MA-PD plan designs its own formulary using therapeutic classes that vary from the USP classification model, CMS would evaluate the submitted formulary design to ensure that the proposed therapeutic classification system does not substantially discourage enrollment by certain Part D eligible individuals." "We interpret this requirement to mean that a PDP sponsor or MA organization's formulary be required to include at least two drugs within each therapeutic category and class of covered Part D drugs within the PDP sponsor or MA organization's formulary."	1. This section could be problematic for those drugs in which currently only one drug exists, but a "me-too" enters the market. Would we be obligated to add the "me-too" drug to the formulary for the sole purpose of meeting the two drug/class requirement? 2. We envision the USP draft model guidelines as exactly that: Model Guidelines to be finalized. It is up to the PDP and MA-PD to match or enhance this guideline to be competitive in the marketplace with a high quality, affordable, and accessible drug benefit. We would oppose developing stringent mandatory rules and support options and choices for the MA-PD and PDP which will be reflective of their organizations philosophy and commitment to serve the beneficiary population. The beneficiary will make the consumer choice for a PDP or MA PD plan. 3. What will be the CMS process for reviewing formularies to assure actuarial equivalence to Part D standard?
46660 46660 423.120(b)(2) C.4.b P 114	*Formulary coverage of dosages and strengths* "Section 423.120(b)(2) of our proposed rule would also require that the drugs included in each therapeutic class or category include a variety of strengths and doses to the extent that this is feasible."	1. Since we sometimes preferentially use only specific strengths of certain drugs (e.g. Actos 15 mg tablets, Lumigan 2.5 mL bottles), this may be problematic from a contracting perspective if CMS disallows this practice
46661 46661 423.120(b)(3) C.4.b P 115	*Frequency of changes in formulary therapeutic categories and classes* "…PDP sponsors and MA organizations could not change therapeutic categories and classes in a formulary other than at the beginning of a plan year, except as we would permit to take into account new therapeutic uses and newly approved covered Part D drugs."	We believe that this rule will have minimal impact.

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections		
FR Page #	***Excerpt***	***Comment/Question***
46661 46661 423.120(b)(3) C.4.b P 115	*Frequency of formulary treatment protocol and procedure evaluations* "…PDP sponsors and MA organizations offering MA-PD plans would periodically be required to evaluate and analyze treatment protocols and procedures related to their formularies to ensure that their plan members were receiving the best possible care for conditions related to their use of covered Part D drugs. We invite comments as to minimum timeframes for periodic evaluation of protocols and procedures related to a plan's formulary by PDP plans and MA organizations offering MA-PD plans (for example, quarterly, annually)."	1. This statement appears to require us to review all formulary drugs and formulary guidelines on a routine basis. Recommend that the frequency of the review coincide with the annual formulary review (NCQA requirement?).

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections

FR Page #	*Excerpt*	*Comment/Question*
46661 46661 423.120(b)(3) 423.120(b)(5) C.4.b P 115	*Notification to CMS upon removing a drug from the formulary* "…PDP sponsors and MA organizations provide "appropriate notice" to us, affected enrollees, authorized prescribers, pharmacists, and pharmacies regarding any decision to either: (1) Remove a drug from its Formulary, or (2) make any change in the preferred or tiered-cost sharing status of a drug. Section 423.120(b)(5) would implement that requirement by defining appropriate notice as at least 30 days prior to such change taking effect during a given contract year."	1. This requirement will hinder the flexibility of Drug Use Management activities as initiatives may be delayed and the potential to capture maximal cost savings may decrease. 2. Note that the "appropriate notice" is not well-defined. It appears that website postings alone are insufficient for beneficiaries. MedImpact has over 50,000 pharmacies in its networks. We serve several hundred MCOs and employer groups. There are thousands of authorized prescribers contracted to serve the MCOs, TPAs, and employer groups. We anticipate serving a large population of Medicare enrollees. We urge CMS to consider the broad impact of such requirements on systems, communications processes, and costs. Communications to large populations is complex and must rely upon leveraging existing communications within the MCO infrastructure or via electronic mass communications on the internet. We would envision posting updated formularies on a MD-PD website as communications to all enrollees who should have a responsibility to manage their own care and knowledge of services. We would envision constant updates on our adjudication database as our mechanism for real time communication to network pharmacies. It makes NO SENSE to fax paper documents to 50,000 pharmacies. Specific benefit changes relative to tiers and cost share should be communicated as required by state and federal regulations in planned collaterals distributed by MA Plans. PBMs serving as PDPs or MA-PD engines are constantly working with clients to achieve the best possible prices and discounts on drugs. When serving populations, the ability to move quickly to affect the price of millions of prescriptions can save consumers and payers millions of dollars in premiums or direct costs. A formulary is not static. Drugs may be removed for safety reasons such as most recently with Vioxx. Drugs become generic and tiers can change instantly with PBM adjudication systems. If a newly negotiated price on a product available immediately is delayed access to the market, millions of dollars in savings may be lost. Appropriate notice needs to be flexible with reliance upon the MCO or MA PD to undertake business decisions based upon clinical quality and affordability. Benefits designs are usually coordinated on an annual basis for enrollment for the following year.

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections		
FR Page #	***Excerpt***	***Comment/Question***
	Notification to CMS upon removing a drug from the formulary (Continued)	3. For tiered cost sharing status, does this also include drugs that become multi-source or generic? Would members need to wait to take advantage of generic copays until 30 days after it becomes available? 4. For the purposes of tiered cost sharing, we should clearly define the tier for single-source generic drugs (i.e. brand vs. generic copays?). Older generic drugs may become single-source if all other manufacturers elect to discontinue production due to low use and the price for the single-source generic can escalate. CMS needs to be aware that our price files are updated frequently with national database vendors such as FDB.

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections

FR Page #	*Excerpt*	*Comment/Question*
46661 46661 423.36(b)(2) C.4.b P 116	*Prohibition against removing drugs from the formulary around the coordinated election period* "…PDP sponsors and MA organizations would be prohibited from removing a covered Part D drug or changing its preferred or tiered cost-sharing status of a covered Part D drug between the beginning of the annual coordinated election period described in §423.36(b)(2) and 30 days subsequent to the beginning of the contract year associated with that annual coordinated election period."	1. This requirement will hinder the flexibility of Drug Use Management activities as initiatives may be delayed and our capability to capture maximum cost savings will diminish. We would be unable to remove a drug from the Formulary between Nov 15 and Jan 30 (approximately 2.5 months) in a 12 month period of time. 2. Presumably, this requirement was added to prevent "bait and switch" by MA-PD plans. However, if a drug is slated to be removed from the formulary, would the enrollee be less angry/upset if the drug is removed in February versus a few months earlier? 3. The regulatory effort to protect beneficaries needs to balance the prevention of "bait and switch" with the loss of opportunity to achieve savings for beneficiaries and payors. This rule effectively precludes the ability to exercise formulary changes during 21% of the year (November 15th to January 30th). The frequency of bait and switch may be minimal. Would it be more direct and effective if CMS prohibited bait and switch rather than restrict formulary changes for 2.5 months a year? The prohibition as described can have serious cost consequences and effectively delays potential cost savings. Again, the ability for PBMs, MA-PDs, PDPs to rapidly take advantage of cost savings using our adjudication technology is hindered. There needs to be a balance in interpreting media and consumer concerns with the challenges and opportunities for managing the costs for large populations of potentially high utilizers. Drug costs are about 15% of the total medical costs. A beneficiaries decision to choose a PDP or MA-PD during an ACE period may not be totally focused on the formulary. Are there corresponding restrictions prohibiting surgeons from providing high risk surgeries during open enrollment to minimize adverse media complaints about increased morbidity and mortality for a hospital?

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections		
FR Page #	***Excerpt***	***Comment/Question***
46661 46661 xxx.xx C.4.b P 116	*Publication of formularies on public website* "…PDP sponsors and MA organizations can get information regarding formulary changes to beneficiaries via an Internet Web site, as well as via explanations of benefits sent to enrollees who utilize their Part D benefits."	1. This requirement is vague regarding the precise information posted on the website. Do we only need to post drug name, or will we be required to post dosage forms, strengths, package sizes, formulary guidelines etc?
46662 46662 423.124 C.4.c P 117	*Access to out-of-network pharmacies* "…we would require that PDP sponsors and MA organizations offering MA-PD plans assure that their enrollees have adequate access to drugs dispensed at out-of-network pharmacies when they cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy."	1. MedImpact will construct a national network for its MA-PD clients. We anticipate that this network will be more aggressively priced than the cash DDC program. Likewise we are assuming that the network will consist of more than 50,000 pharmacies. We anticipate that OON utilization will be minimal. However, if an emergent situation arises whereby such service is required, we will work with the MA-PD to develop a Direct Member Reimbursement process for the unlikely and rare circumstance. The benefit design and cost share component for this access will be the decision of the MA-PD.

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections

FR Page #	*Excerpt*	*Comment/Question*
46663 46663 423.124 (a) C.5 P 119	*Incurred costs at out-of-network pharmacies* "When an enrollee purchases a covered Part D drug at an out-of-network pharmacy consistent with §423.124(a) of our proposed rule, the cost-sharing he or she pays relative to the plan allowance….counts as an incurred cost…." "…As with the price differential that a beneficiary could incur by purchasing an extended supply (for example, 90 days) of covered Part D drugs purchased at a retail pharmacy rather than a mail-order (discussed in section II.C.4.a of this preamble), the price differential between out-of-network pharmacies' U&C costs and the plan allowance would also be counted as an incurred costs against a beneficiary's annual out-of-pocket threshold." "Under this approach, plans would be required to explicitly account for such price differentials in the actuarial valuation of their coinsurance in their bids."	1. We can capture accumulator costs for TrOOP if network pharmacies are used. Patients going OON with a covered DMR will be providing us with the information needed to add to the TrOOP. However, there is beneficiary responsibility to provide the needed information. It is difficult if not impossible to forecast such OOP OON incurred costs to build into an actuarial forecast or valuation in a MA PD or PDP bid. To "explicitly account for such" suggests that we have OON data for an heretofore unmanaged population. We will need to make assumptions which may or may be financially fair to the MA-PD, PDP, or CMS as the payor for a segment of the risk. 2. We would ask that CMS consider beneficiary responsibility to use the defined network and to go OON only for emergent needs. If a beneficiary chooses OON for convenience, we would argue that these are costs that the beneficiary chooses to accept. It is not reasonable to have systems or costs incurred to manually track and capture such potentially not covered services for the incurred cost accumulator for annual OOP Threshold.
46663-64 46663-64 423.128 (a) C.6.a P 185	*Content of plan description* "The plan description would include information about …. How any formulary used by the plan works, the process for obtaining an exception to a prescription drug plan's or MA-PD plan's tiered cost sharing structure…..	1. The required information seems reasonable. However, we ask that CMS consider the adverse cost impact of suggesting to beneficiaries that exceptions are easily and readily granted. Physicians contracted to a MA-PD are not direct staff or employees and may be subjected to customer pressure to provide prescriptions for which there are equally efficacious and cost effective drugs. Physicians are under pressure and time constraints and wish to please and can yield easily to patient pressure, especially if they are not at risk for the drug cost. We need to have a balance in this arena to allow the MA PD, PDP, to assert a reasonable level of management on drug spend.

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections		
FR Page #	***Excerpt***	***Comment/Question***
466664 46664 423.128 (d)(1)(i)(ii) C.6.c P 188	*Call center access* "We strongly recommend, however, that plans provide some sort of 24-hour-a-day/7 day a week access to their toll-free customer call centers in order to provide timely responses to time-sensitive questions"	1. MedImpact STRONGLY opposes the notion of a mandated 24x7 standard for toll free call center access to time sensitive questions such as how to find an OON pharmacy. We are not convinced that finding an OON pharmacy merits the cost investment for such a service by every PDP, MA-PD, PBM. We would imagine such an emergent situation to be truly a medical emergency and may warrant a visit to an emergency department or 24 hour clinic. In that scenario, the patient would be provided the immediate drugs incident to that emergent need. 2. 3. The website strategy for providing information to beneficiaries for pharmacy access is most efficient. Likewise it is our expectation that beneficiaries need to take responsibility for managing their health and medication needs. True emergent needs may require 911 support.
46664 46664 423.128(d)(2)(ii) C.6.c P 189-190	*Website formulary update requirements and access* " In addition, per §§423.128(d)(2)(ii) and (iii) of our proposed rule, plans would have to post current versions of their formularies at least weekly…." "…Plan websites would have to be available both to current and prospective part D enrollees….	1. Our formularies usually change on a quarterly basis, although the P&T Committees do occasionally make formulary decisions outside of a regularly scheduled meeting. Would it be possible to modify this requirement to state that the website will be updated in conjunction with formulary changes? 2. We would request some flexibility on this issue. Theoretically, if formulary changes are prohibited during 21% of the year, no changes need to be posted during that time frame. 3. CMS clearly has concerns regarding deletions. We find that ADDITIONS are made sometimes on a more frequent basis and may occur weekly. New drug strengths and dosage forms are frequently released for existing formulary drugs. The new dosage forms need to be added. Likewise, release of new drugs may require emergent P & T meetings for approval of an advantageous essential new product. Are the rules structured to prevent changes including additions at designated points? There are the formularies which have the list of drugs available for review. There is the formulary used for adjudication which is constantly monitored by staff other than P& T.

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections

FR Page #	*Excerpt*	*Comment/Question*
46664 46664 423.128(e)(6) C.6.d P 191	*Monthly explanation of benefits* "We would require, under §423.128(e)(6) of our proposed rule, that an explanation of benefits be provided at least monthly for those utilizing their prescription drug benefits in a given month."	1. The explanation of benefits includes individualized components, such as cumulative YTD cumulative incurred costs and applicable formulary changes. This requirement creates significant systems, operations, and cost issues. The current NCPDP 5.1 Transaction record from the pharmacy will not support the data described for EOB purposes. PBMs have not provided EOB reports prior. Monthly generation and mailing of such a report will create significant added administrative costs. The costs estimated for this requirement must far exceed $1 PMPM in materials, mailing, costs, and time. These dollars may be more effectively spent on drugs rather than reports which should be requested on-line or as information requested by telephone. 2. We would recommend that CMS allow MA PDs, PDPs, sub-contracted PBMs to make the prescription profile with use available on-line at the appropriate website for the plan sponsor. The website could provide access to the accumulator for TrOOP. Likewise, the beneficiary could view a current formulary on-line. Technology will allow the beneficiary to print such data as required. 3. Requirement to produce information about formulary changes is broad. Again, costs associated with generating such a document and mailing on a monthly basis may not be the most efficient use of tax payer dollars. 4. We would urge CMS to consider simplified processes or annualized reporting accessed through the network pharmacy where prescription service is provided. The systems at a pharmacy may be able to provide prescription utilization record for tax purposes and should likewise satisfactory as an EOB. 5. The right to receive an itemized statement may also be noted in the EOC at the time the beneficiary registers with a MA-PD, PDP, or other provider. 6. It would also make more sense to provide the drug use data with the EOB statements MA-PDs, PDPs, will be required to provide to beneficiary for medical and other Medicare costs. PBMs could provide a file of prescriptions filled, accumulator for TrOOP status, to the MCO MA-PD for generation of EOB data within existing infrastructure. It would be more cost effective for quarterly rather than monthly statements.

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections		
FR Page #	***Excerpt***	***Comment/Question***
	Monthly explanation of benefits *(Continued)*	7. The comprehensive information regarding cumulative, YTD amount of benefits relative to deductible, initial coverage limit, and the annual OOP thresholds creates added cost structures which ultimately increases administrative costs to the program and the taxpayer. This will require IT systems development between the MA and its PD subcontractor or provider. PBMs who are considering PDP strategies will have to construct this capability.
46665 46665 423.132 c C.7 P 193	*Disclosure of pricing for equivalent drugs* "…we are permitted to waive the requirement that information on differential prices between a covered Part D drug and generic equivalent covered Part D drugs be made available to prescription drug plan enrollees at the point of sale (or at the time of delivery of a drug purchased through a mail-order pharmacy.)	1. This regulation is currently in effect for DDC and network pharmacies should continue to abide by this codified section. Network agreements developed for the Part D networks will incorporate language re full compliance to 42 CFR 423.132. 2. We do not understand the rationale for waiving this requirement for those plans who employ a wide open unrestricted network. 3. We would recommend that LTC pharmacies disclose the drug price differentials in their contracts to the LTC facilitiy, to payers as well as to individuals responsible for the LTC resident.

Submitter : Ms. Mimi Haley **Date & Time:** 10/04/2004 08:10:37

Organization : Group Health Cooperative

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4068-P-1214-Attach-1.doc

Comments on the Proposed Rule on Establishment of the Medicare Advantage Program

CMS – 4068 – P

By

Group Health Cooperative
Seattle Washington

October 4, 2004

Contact: Eileen O'Donnell, odonnell.e@ghc.org, 206.448.6444
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I. Background on Group Health Cooperative

Group Health Cooperative ("Group Health") is a consumer-governed nonprofit healthcare system that integrates health coverage with medical care. About 540,000 residents in Washington State and Northern Idaho obtain medical care through Group Health Cooperative health plans. More than 70 percent of our members receive care in Group Health medical facilities.

Group Health was founded in 1947 by a community coalition dedicated to making quality healthcare available and affordable. As one of the few healthcare organizations in the country governed by consumers, the consumer elected board of trustees works closely with internal management and medical staff to ensure that the organization puts the needs of patients first.

Group Health was one of the original participants in the Medicare Risk Share program, contracting with the federal government since 1976 to provide prospectively paid, capitated, care to Medicare beneficiaries. We currently care for approximately 60,000 Medicare members.

Group Health, as an integrated delivery system, already has extensive experience designing, delivering and financing pharmacy benefit plans. Almost all of our 540,000 members, including almost half of our Medicare enrollees (approximately 30,000 members), currently receive their prescription medications through Group Health owned or contracted pharmacies.

II. Provisions of the Proposed Rule

Subpart B – Eligibility, Election and Enrollment

(Sec.423.34, p. 46639)
Dual eligibles. For full-benefit dual eligible individuals enrolled in MA plans, CMS proposes enrolling them in one of the MA-PD plans offered by their MA organization. CMS further proposes that if the basic premium of the MA-PD plan exceeds the low-income benchmark premium amount, CMS would not permit automatic enrollment in the MA-PD plan.

The regulations appear to drive dual eligibles into the lowest cost plan by limiting enrollment into MA-PDs or PDPs that bid at or below the low-income benchmark. We believe that continuity of care should be a paramount concern for CMS, especially for this patient population. Therefore, we request that dual eligibles currently enrolled in a MA plan be enrolled into that organization's MA-PD plan, regardless of that plan's bid amount.

The proposed rules do not contemplate individuals who are currently enrolled in MA plans at the time of initial eligibility for Medicare benefits. Such individuals should also

be auto-enrolled in a MA-PD plan offered by the MA organization in which the individual is enrolled at the time of initial Medicare eligibility. This ensures continuity of care for individuals and minimizes administrative confusion about enrollment.

Finally, it appears that MA-PDs will be excluded from receiving new enrollments of dual eligibles even if the MA-PD plan bid is at or below benchmark, if that individual was not previously enrolled in a MA plan. For purposes of level playing field and beneficiary choice, we believe that MA-PD plans that bid at or below benchmark should be an enrollment option for all dual eligible individuals.

We request that CMS clarify enrollment rules for full-benefit dual eligible individuals as noted above, with attention paid to administrative efficiency as well as enrollee health and continuity of care needs.

Subpart C – Benefits and Beneficiary Protections

(Section 423.100, p. 46646)
Dispensing Fees. CMS requests comments on the preferred option for dispensing fees.

We believe that Option 3 best represents the operational reality for integrated health systems where the financing and delivery of care are integrated. Group Health's clinical pharmacists perform both health plan functions and clinical functions in the course of performing their jobs on all patients regardless of Medicare eligibility status. For this reason, the total cost of providing both health plan and delivery system functions for integrated MA organizations need to be incorporated into the dispensing fees so that the total cost of care for MA-PD plans can be captured.

(Section 423.120(a)(1), p. 46655)
Assuring pharmacy access. PDPs and MA-PDs must have a contracted pharmacy network consisting of pharmacies, other than mail-order pharmacies, that meet certain access standards. These access standards apply differently to urban, suburban and rural areas under which a specified percentage of beneficiaries, on average, must live within specified miles of a network pharmacy. The access standards do not apply to an MA-PD plan that provides enrollees with access to Part D drugs through pharmacies owned and operated by the organization. MA private fee-for-service plans that provide coverage for drugs from all pharmacies without differentials in cost sharing are also not subject to the access standards.

(p.46656)
Long-term care pharmacy access. CMS is expecting that access to covered Part D drugs would be assured through MA-PD plan contracts with participating long term care facilities. CMS invites comments on a requirement for plan sponsors to contract with some or all LTC pharmacies in their areas, in particular how to balance access needs with reasonable dispensing costs associated with such pharmacies.

(p. 46658)
Any willing provider. A PDP sponsor or MA organization is obligated to contract with any pharmacy willing to meet its terms and conditions. PDP sponsors and MA organizations may not require a pharmacy to accept insurance risk as a condition of participation. CMS seeks comments on the idea of plans using a standard contract for such pharmacies.

We believe the draft regulations in these three areas appear overly prescriptive, calling for redundant systems that add cost but no real value to established MCOs. As such, we believe these provisions should be waived in instances where contracting plans can demonstrate adequate compliance with the intent of the law.

Group Health has a contracting process in place that is carefully crafted to meet customer demand, including a process to respond to both pharmacy and patient requests for network pharmacy expansion. Implementing provisions mandating a network for our population of patients would result in increased administrative costs, challenges in coordinating care, member confusion and potential risk to patients. MA organizations already have access standards in place to conform to existing regulations regarding medical care delivery; these standards should suffice for pharmacy access as well. Any willing provider provisions are antithetical to the essence of managed care systems, interfering with coordinated care and quality outcomes.

We strongly believe Tri-care and any willing pharmacy (AWP) provisions should be waived for MA-PD plans – both for plans with owned and operated pharmacies as well as contracted network pharmacies. We will investigate the need to supplement our existing long term care pharmacy with selected vendors as needed, based on quality, access measures and demand by enrollees in our MA-PD plan.

Group Health's current network of 225 pharmacies allows for appropriate quality review. AWP requirements, in principle, violate the basis of defined network, managed care delivery systems that are accountable for both cost- and medical-effectiveness. We would not endorse a standard contract for any participating pharmacy, as each contract would need to be individually structured to meet myriad market specific issues as well as reimbursement, digital connectivity and account administration requirements.

(Section 423.120, p. 46659)
P&T Committee membership. Under the proposed rules, the majority of members comprising the P&T Committee would be practicing physicians and/or practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician member would have to be experts in the care of elderly and disabled individuals.

This also provides that at least one practicing pharmacist and one practicing physician members on a plan's P&T Committee be independent experts, interpreted by CMS to be 'independent and free of conflict with respect to sponsor and plan' (having no stake, financial or otherwise, in formulary determinations).

CMS seeks comment on whether to limit such outside experts to one each, or to additional physician and pharmacy specialists. CMS also requests comment on whether the determinations of the P&T Committee should be binding on the MA-PD plan.

As with the pharmacy access standards, noted above, the draft regulations in this area are overly prescriptive and propose unacceptable expansion of one of the more troubling aspects of MMA: the composition and scope of MA organization's P&T committees. We believe the regulations should limit themselves to strict interpretation of the law as it is written, and not propose additional representatives to, or binding authority of, the MA organization's P&T Committee.

Group Health has a highly functioning physician led P&T Committee that includes actively practicing physicians and pharmacists from both our integrated group practice as well as our contracted network. It also includes a consumer representative. MMA proposes augmenting MA organization P&T committees with representatives who are independent of the plan and who have highly specialized backgrounds. We believe the degree of specificity related to these additional representatives is a troubling and unprecedented incursion by a payer into MA-PD plan operations. We question the benefit of broadening the current P&T committee composition, which has been an effective and functioning body for current Group Health pharmacy benefit plans and formularies for both commercial and Medicare members. We will seek legislative relief, requesting that this provision be waived for MA-PD plans that demonstrate a well functioning P&T committee with broad committee representation/composition.

In the interim, Group Health requests that the additional representatives proposed for the P&T committee be contracted physicians and pharmacists. Given that all P&T Committee members are compensated for their participation in the committee, we do not believe that "independence" as defined by CMS is operable or necessary for a well-functioning P&T Committee.

(Section 423.120, p. 46660)
Formulary Requirements. CMS seeks to solicit comments on the proposed USP Draft Model Guidelines.

Group Health agrees in principle with the therapeutic categories and classes released in the Draft Model Guidelines. They are an important first step to assist health plans develop formularies that comply with the Medicare Modernization Act. Overall, we believe these Model Guidelines:

1) Give plans the flexibility to drive industry competition and therefore improve affordability of the benefit by allowing either one drug (subdivisions) or two drugs (classes) on the formulary.
2) Allow Medicare beneficiaries a broader array of drugs than two within pharmacologic classes where therapeutics dictate a need for more than two drugs (e.g., insulins).

3) Create choice for both plans and patients choosing plans by allowing flexibility to choose MA-PDs or PDPs with a broader formulary than the model requires so long as the plans adhere to the minimum requirements.
4) Create a reasonable balance of incentives for affordability and choice of drugs available on plan formularies.

(Section 423.124, p. 46662)
Access to out-of-network pharmacies. CMS proposes to require that PDP sponsors and MA organizations offering MA-PD plans assure that their enrollees have adequate access to drugs dispensed at out-of-network pharmacies when they cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. CMS proposes to meet the requirements of this section by establishing a broader out-of-network access requirement.

We are troubled with such an expansion of out-of-network requirements and that CMS has precipitously abandoned the prudent layperson standard for MA enrollees obtaining medications under the Part D benefit. The out-of-network medical benefit for emergent and urgent care is well-established CMS policy, well understood by beneficiaries, and well managed by existing Medicare contracting organizations. We believe that MA-PD plans should be able to continue to apply this standard for purposes of receiving medications out-of-network. CMS should allow managed care organizations the flexibility to tie receipt of out-of-network emergency pharmacy benefits to receipt of emergent or urgent medical benefits, as those benefits are currently administered.

(Section 423.128, p. 46665)
Monthly explanation of benefits. CMS proposes to require that an explanation of Part D benefits be provided at least monthly for those utilizing their prescription drug benefits in a given month.

The explanation of benefits includes individualized components, such as year-to-date cumulative incurred costs and applicable formulary changes. Distributing this information through the dispensing process may be a preferred route, however we request that that the requirements be changed to allow patients to obtain the EOB at any time upon request rather than monthly. In addition, we support allowing MA organizations to use the required toll-free 1-800 number to supply enrollees with status updates on their true out-of-pocket costs.

In addition, we request elimination of the requirement to inform members of the availability of the lowest cost generic alternative when the prescribing physician or other licensed prescriber has requested that no generic be dispensed (i.e., dispense as written). We believe in such an instance that disclosure of the lower cost alternative would be without value, as it could not be dispensed, per the physician's order.

Subpart F – Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

(Section 423.265, p. 46678)
Specification of information (data, methodologies, assumptions, and data elements related to calculating actuarial equivalence, etc.). We concur with the detailed comments related to these proposed regulations made by AHIP, which encourage CMS to collect only information and data that are necessary to accomplish program objectives and requirements.

(Section 423.272, p 46679)
Review and negotiation of bid and approval of plans submitted by potential PDP sponsors or MA organizations planning to offer MA-PD – General Comments. We strongly concur with the detailed comments related to these proposed regulations made by AHIP on behalf of member plans.

(Section 423.272, p. 46680)
Rebate Reallocation for MA-PD Plans. The bid negotiation process will require resubmission of the bid once the outcome of the National Average is known, since it affects the beneficiary premium. After the rebate reallocation, the bid could either be excessive or insufficient to achieve the desired premium level.

While the bid process proposed in CMS regulations refers to it as a negotiation, it is unclear from the regulations whether this would be a two-way or one-way negotiation between MA organizations and CMS. Please clarify the extent of negotiations that would be allowed under these rules.

Part B Only Beneficiaries. The proposed regulations are silent on bid rules for Part B only enrollees in MA organizations. The eligibility rules for Medicare Part D could be interpreted to mean that Part B only beneficiaries are not eligible to enroll in MA-PD plans. Please clarify the enrollment and offering requirements for this subpopulation of grandfathered enrollees.

Subpart G – Payments to PDP Sponsors and MA Organizations offering MA-PD Plans

(Section 423.322, p. 46686)
Data elements and frequency. CMS requests comments on the content, format, and optimal frequency of data feeds for Part D administration, as well as for the risk-adjustment process, reinsurance subsidy payment, risk-sharing and program audit processes.

Similar to the data submission requirements originally contemplated for risk-adjustments that were significantly reduced based on discussion with M+C plans, we believe that CMS should limit data elements and frequency to those strictly required for reconciliation activities. The depth and breadth of new requirements, for both CMS and for participating PPO, MA or PDP-sponsor organizations, envisioned in toto (?) under MMA, beg for CMS to use expediency and minimalism as criteria for data submission. We believe these criteria should be used for both the data elements and the submission frequency requirements proposed by CMS.

(Section 423.343(a), p. 46693)
Retroactive Adjustment (i.e., reinsurance, low income cost-sharing). CMS is requesting comments on how best to make retroactive adjustments and reconciliations to PDP sponsors: in a lump sum or through monthly apportionment in the next year's payments.

We recommend that CMS pay or collect the difference through a lump sum payment, rather than through apportioning over the future payment year. This would be consistent with how CMS is administering retroactive adjustment for risk adjustment and would enable plans to more accurately track current cash flow. An additional option would be for CMS to allow plans an individual choice of making a lump sum adjustment or applying prospective adjustments through future payment year.

Subpart K – Proposed Application Procedures and Contracts with PDP Sponsors

(p. 46707)
Contracting requirements. We do not believe that the provisions specified in this subpart apply to MA-PDs, as they are inconsistent with terms, definitions and requirements of MA organizations in Title II. However, the proposed regulations of this Title I, Subpart K are so ambiguous and vague as to be unclear whether specific provisions apply to all PDP sponsors, including MA-PDs, or just to PDPs. We request clarification about the provisions, if any, in this subpart that apply to MA-PDs.

Subpart M – Grievances, Coverage, Reconsiderations, and Appeals

(Section 423.578, p. 46720)
Exceptions to tiered-cost sharing structure. CMS is considering a set of rules for exceptions to tiered cost-sharing arrangements that may be problematic to enrollees, including specific criteria that should be included in a PDP.

The proposed criteria would require development of a seemingly complex set of rules to manage these exceptions. In addition to adverse effects, a particular drug may be ineffective for a given patient, which would be another appropriate reason to use an alternative drug. The regulations already specify notification requirements and timelines for changes to the MA-PD plan formulary. Given these, we request a simple exception process for Part D members for exceptions to tiered cost sharing, consistent with the existing requirements for plan exceptions for medical benefits.

(p. 46723)
Employer-sponsored benefits and appeals. CMS is soliciting comments on the degree to which parallel appeal procedures under Part D and ERISA might pose a problem for plans, employers and enrollees.

Currently, MA organizations that contract with CMS have elaborate and functional procedures to process routine and urgent appeals from enrollees or their providers about

benefits and coverage determinations made by the plan. We urge CMS to allow MA organization to process appeals under an employer-sponsored plan as any other appeal. Parallel reviews by both CHDR and the employer group create costly redundancies and potential confusion and/or conflicting determinations.

Subpart P – Premium and Cost-Sharing Subsidies for Low-Income Individuals

(Section 423.800, p. 46732)
CMS seeks comment on the process of CMS notification to the PDP sponsor or MA organization that an individual is eligible for a subsidy and the amount of the subsidy. In addition, CMS requests comment on the process the PDP sponsor or MA organization should use to notify CMS that premiums or cost-sharing have been reduced, including the amount of the reduction.

CMS will be the entity tracking and assigning subsidy amounts for low-income individuals eligible for Part D benefits. In addition, CMS will already have on file each MA-PD or PDP plan available to enrollees in any given geography each year. Therefore, we request that CMS eliminate the requirement that MA-PDs and PDPs notify CMS of premium or cost-share reductions for individual enrollees. Instead, it would be administratively more efficient and less time-consuming if CMS retained the authority to track individual enrollee premium and subsidy amounts, and pay MA or PDP organizations accordingly at time of assignment.

In addition, it may be inferred from the proposed regulations that PDP sponsors, including MA-PDs, are required to calculate and submit separate bids for Low-Income Individuals. We strongly discourage such an idea as actuarially invalid and administratively cumbersome. We request, instead, one MA-PD plan and one bid for all enrollees, with premium discounts and subsidies applied to low-income eligibles as determined by CMS at the time of enrollment.

Subpart R – Payments to Sponsors of Retiree Prescription Drug Plans

(Section 423.884, p. 46743)
Data Reporting. CMS requests comments on the approach that employer group sponsors would be required to use for requesting a subsidy payment, including the timeframe for reporting and the proposed information list for submittal.

It is our experience that the timeframes proposed by CMS would be incompatible with the open enrollment season of most employer groups; however, we will defer to comments submitted by such employer sponsors for this proposed requirement.

It is likely that employer groups seeking subsidy payments for prescription drug benefit plans will require that data elements be supplied by the contracted MA-PD or PDP organization. Therefore, we request that CMS limit required data to those minimally necessary to calculate the subsidy amount, consistent with current requirements for risk-adjusters. In addition, we question the ability of employer groups to have access to many

of the proposed data elements without violation of HIPAA privacy and state patient confidentiality laws currently in force and request that CMS ensure compatibility between these proposed regulations and existing federal and state laws.

CMS-4068-P-1215

Submitter : Ms. lillian cardenas **Date & Time:** 10/04/2004 08:10:33

Organization : westchester independent living center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The disabled community has worked hard to get prescription coverage with the medicaid buy-in for working disabled. It's unfair that new laws want to take away prescription coverage for people on both medicare and medicaid. This would be a disincentive for people to go back to work. The disabled community is already at a disadvantage in life. You would be creating more obstacles in our struggle to better our living conditions. I hope you look at other options and help our community. Thank you

CMS-4068-P-1216

Submitter : Mr. Ronald Field **Date & Time:** 10/04/2004 08:10:11

Organization : Volunteers of America

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attached letter from Volunteers of America re: Medicare Prescription Drug Regulations

CMS-4068-P-1216-Attach-2.doc

CMS-4068-P-1216-Attach-3.doc

CMS-4068-P-1216-Attach-1.txt

Wednesday, October 20, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS File Code-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Medicare Program; Medicare Prescription Drug Benefit
Comments on Proposed Rule
69 Federal Register 46632

Volunteers of America welcomes the opportunity to provide comments on the proposed rule. Volunteers of America is a national, nonprofit, faith based housing and human services organization. Through our local affiliates and National Services Board, we serve thousands of low-income persons who rely on prescription drugs as part of their daily regimen, including older adults with chronic care needs and people with mental retardation and other developmental disabilities.

We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are six critical recommendations:

1. **Delay the implementation of the Part D program for dual eligibles.**

Dual eligibles (Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006.

CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the high improbability that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning of the enrollment period to January 1, 2006), we strongly recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

2. **Fund collaborative partnerships with organizations representing people with disabilities are critical to an effective outreach and enrollment process.**

Targeted outreach to Medicare beneficiaries with disabilities, especially those with low-incomes, is vitally important in the enrollment process. We strongly recommend CMS develop a specific plan for facilitating enrollment of beneficiaries with disabilities in each region that incorporates collaborative partnerships with state and local agencies and disability advocacy organizations.

3. **Designate special populations who will receive affordable access to an alternative, flexible formulary.**

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing bed rest, unnecessary hospitalizations and even death, on the other. Often, people with disabilities need access to the newest medications, because they have fewer side effects, and may represent a better treatment option than older less expensive drugs. Many individuals have multiple disabilities and health conditions making drug interactions a common problem.

Frequently, extended release versions of medications are needed to effectively manage these serious and complex medical conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects making it more important for the doctor to be able to prescribe the best medication for the individual. Often that process takes time since many people with significant disabilities must try multiple medications, and only after much experimentation, find the medication that is most effective for their circumstance. The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury, debilitating side effects, hospitalization, or other types of costly medical interventions.

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs, and the enormous potential for serious harm (including death) if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations:

- people who are dually eligible for Medicare and Medicaid;
- people who live in nursing homes, ICF-MRs and other residential facilities;
- people who have life threatening conditions; and

- people who have pharmacologically complex condition such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, and HIV/AIDS.

4. Impose new limits on cost management tools.

In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. We strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization.

We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications, which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

5. Strengthen and improve inadequate and unworkable exceptions and appeals processes.

We are also concerned that the appeals processes outlined in the proposed rule are overly complex, drawn-out, and inaccessible to beneficiaries with disabilities. We strongly recommend CMS establish a simpler process that puts a priority on ensuring ease of access and rapid results for beneficiaries and their doctors and includes a truly expedited exceptions process for individuals with immediate needs. We believe that the proposed rule fails to meet Constitutional due process requirements and fails to satisfy the requirements of the statute. Under the proposed rule, there are too many levels of internal appeal that a beneficiary must request from the drug plan before receiving an independent review by an administrative law judge (ALJ). Additionally, the timeframes for plan decisions are unreasonably long.

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs.

As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already

inadequate grievance and appeals process. We recommend that CMS revamp the exceptions process to:

- Establish clear standards by which prescription drug plans must evaluate all exceptions requests;
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6. Require plans to dispense a temporary supply of drugs in emergencies:

The proposed system does not ensure that beneficiaries' rights are protected and does not guarantee beneficiaries have access to needed medications. For many individuals with disabilities such as epilepsy, mental illness or HIV, treatment interruptions can lead to serious short-term and long-term problems. For this reasons the final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

Thank you for your consideration of our views.

Sincerely,

Ronald H. Field
Vice President of Public Policy

Wednesday, October 20, 2004

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Department of Health and Human Services
Attention: CMS File Code-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Medicare Program; Medicare Prescription Drug Benefit
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69 Federal Register 46632

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Thank you for your consideration of our views.

Sincerely,

Ronald H. Field
Vice President of Public Policy

CMS-4068-P-1217

Submitter : Mrs. Nicole Antonson **Date & Time:** 10/04/2004 08:10:42

Organization : Highmark, Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4068-P-1217-Attach-1.doc

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244 – 8014

Re: Comments on Medicare Prescription Drug Benefit

Highmark Inc. and its wholly owned subsidiary, Keystone Health Plan West, Inc. (collectively referred to herein as "Highmark"), are submitting the following comments on the proposed rule implementing provisions of the Medicare Program: Medicare Prescription Drug Plan.

Highmark is uniquely qualified to comment on the proposed rule. We have been offering MA (formerly Medicare+Choice) products with prescription drug benefits to Medicare eligibles in western Pennsylvania for almost 10 years. Highmark's MA Health Maintenance Organization (HMO), SecurityBlue, is currently one of the largest MA plans in the country with over 180,000 members. Given our experience and success offering seniors prescription drug coverage, we believe that we can provide valuable comments on the proposed rule.

Finally, while we largely agree with the comments the Blue Cross Blue Shield Association and America's Health Insurance Plans have submitted, we feel it is important to comment further in a few key areas.

Subpart B – Eligibility and Enrollment

§423.34 Part D Enrollment Process (§423.34; P: 46638; R: 46811)

Highmark Comment: Dual eligibles should be assigned randomly by CMS, if an eligible does not select a Part D carrier. In addition, if a partnership exists between a PDP and a Medicaid HMO, the PDP should be permitted to provide a smooth transition into its plan for any willing dual eligible.

§423.44 Disenrollment by the PDP (§423.44; P: 46641; R: 46812)

Highmark Comment: Highmark agrees with AHIP concerning members who change their permanent address. If a member permanently moves outside of a region, the member should be allowed to stay with their original plan for a specified amount of time.

However, if the plan does not have the capabilities to provide the member with Part D benefits outside the region, the plan should be permitted to disenroll the member. If the plan decides to disenroll, it must provide the member with 60 days notice.

Subpart C – Benefits and Beneficiary Protections

§423.120 Access to Covered Part D Drugs; Pharmacy Access Standards (§423.120; P: 46655; R: 46818)

Highmark Comment: Contracts with pharmacies cannot be uniform as some pharmacies specialize in particular drugs (i.e., injectables) and are able to offer much lower prices than retail pharmacies. Furthermore, specialty pharmacies are able to deliver additional services such as prior authorizations for these drugs. Because a PDP often only wants to coordinate with one entity for such services, contracting with any willing provider would be administratively burdensome and costly for a PDP. Highmark recommends that contracts with pharmacies do not have to be uniform and available to all willing pharmacies.

§423.128 Dissemination of Plan Information; Disclosure of Information upon Request (§423.128; P: 46663; R: 46819)

Highmark Comment: Highmark agrees that description information regarding Part D plans should be available on a website; however, online application and enrollment should not be mandatory. Until seniors, PDPs, and CMS become more familiar with Part D, mandatory online enrollment may be more burdensome than efficient. In addition, the majority of seniors do not use the Internet.

Subpart D – Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

§423.159 Electronic Prescription Program (§423.159; P: 46670; R: 46821)

Highmark Comment: There is not adequate industry experience to waive the ePrescribing pilot. Until systems in local communities can communicate, ePrescribing should be supported on a voluntary basis. This support could be in the form of incentives and/ or federally funded activities such as educational ad campaigns and pilots.

CMS also requested comments for determining metrics to track the success of ePrescribing. Highmark believes progress should be noted by the number of electronic prescriptions per provider, the amount of increase in generic fill rate and formulary compliance.

Finally, ePrescribing will help CMS mitigate rising drug costs by increasing formulary adherence, increasing generic fill rate, increasing patient compliance where in turn should

decrease hospital admissions, and increase opportunities for patient care coordination through shared data.

Subpart I – Organization Compliance with State Law and Preemption by Federal Law

§423.440 Preemption of State Laws and Prohibition of Premium Taxes (§423.440; P: 46696; R: 46831)

Highmark Comment: Title II of the MMA (Part C, Medicare Advantage) provides for a sweeping federal preemption of state law, replacing the old narrow provision with a broader preemption providing that "State laws are presumed to be preempted unless they fall into two specified categories [state licensing laws or state laws relating to plan solvency]." (Preamble 46904). In contrast, the guidance for the Title I (Part D, drug benefit) preemption provision limits federal preemption, even though the preemption provisions in both Title I and Title II are virtually identical. Title I guidance states that "to the extent there are Federal standards, those standards supersede any State Law." (Preamble 46696). Under Title I, the preemption authority only applies if there is an extant federal rule that trumps an analogous state rule, rather than having all relevant state laws preempted unless they relate to licensing or solvency. This drastically limits the federal preemption on the Title I side as compared to that on the Title II side.

Nothing in the guidance for Title I suggests that Congress intended the preemption under Title I to be narrower than that under Title II. As Congress intended both MA programs and Part D drug programs to operate as federal programs under federal rules, we ask CMS to conform the Title I guidance to that in Title II to support a broad federal preemption in both Title I and Title II.

Subpart J – Coordination Under Part D Plans with Other Prescription Drug Coverage

§423.464 Coordination of Benefits with Other Providers of Prescription Drug Coverage (§423.464; P: 46700; R: 46832)

Highmark Comment: Currently many Health Plans do not include coordination of benefits (COB) within the scope of managing the prescription drug benefit. This is primarily due to the lack of adequate "other insurance data" collected/exchanged/updated from business partners (groups).

While most PBM's can perform COB at the point-of-sale, they need complete/accurate data. Because this is not readily available (e.g., PACE information is only available monthly), implementing such a process would be challenging on a real time basis. Therefore, Highmark supports Option 2 whereby CMS contracts with a TrOOP facilitator. We also support the comments provided by Medco, our PBM, on this matter. In summary, the facilitator would act as the single point of contact for several purposes, such as: matching claims, helping to determine final beneficiary costs. Finally, because

this will be difficult to achieve, plans should be permitted to conduct COB on a monthly or yearly basis.

Subpart M – Grievances, Coverage Determinations and Appeals

§423.590 Appeals; Redeterminations (§423.580; P: 46721; R: 46845)

Highmark Comment: The proposed regulations allow for oral standard appeals. This is a change from current MA regulations and could pose an administrative burden on the PDPs by increasing the number of appeals and also making it difficult to distinguish between appeals and questions. We recommend that appeals be made in the same manner MA appeals are currently handled.

Subpart R– Payments to Sponsors of Retiree Prescription Drug Plans

§423.882 Definitions (§423.882; P: 46737; R: 46858)

Highmark Comment: Highmark receives drug rebate payments an average of 8 months after the incurred date of the claim. Approximately 10% of rebates are paid more than a year after the incurred date of the claim.

The most straightforward solution would be to:

1. Calculate the actual drug payments between the cost limit and threshold for each member and add these amounts at the group level.
2. Calculate a good faith anticipated rebate (percentage of allowances) across the entire book-of-business based on historical data.
3. Calculate the group level subsidy-eligible payments by reducing the aggregate group payment amount by the anticipated rebate.

Although a true-up calculation at a later date may be possible, it is not recommended. A true-up based on actual rebates at the member level is not possible under current rebate arrangements since rebates are not tracked at the member level. A true-up based on actual rebates at the group level would be more costly in terms of administrative expenses, but (assuming the aggregate rebate estimate was accurate) represent a zero-sum gain to the system as a whole. Any reductions in the estimated rebates for some groups would be offset by increases in the estimated rebates for other groups. There would be no net effect on the level of total government subsidies. If the aggregate rebate estimate was incorrect, there are 3 likely scenarios:

1. The aggregate rebate is fluctuating. In this case, overpayments in some years will (for all practical purposes) balance out against underpayments in other years.
2. The aggregate rebate is increasing. In this case, the government will save a small amount of money by paying lower subsidies than it would pay if the aggregate rebate estimate had been more accurate.

3. The aggregate rebate is decreasing. In this case, the government will lose a small amount of money by paying higher subsidies than would have been paid if the aggregate rebate estimate had been more accurate. This problem is self-solving since, unless the downward trend ceases or is reversed, rebates and the problem of how to account for them would eventually disappear.

If the government believes that a true-up is absolutely necessary, then the true-up should be based on an aggregate rebate (percent of allowances) calculated at least 2 years after the incurred date of the claim. This would, however, add significant administrative expenses to the system without adding much value. If a true-up is required, we recommend that it occur infrequently to limit administrative expenses.

§423.888 Payment Methods, Including Provision of Necessary Information; Payment Methodology (§423.888; P: 46745; R: 46859)

Highmark Comment: CMS is seeking comments on the Payment Methodology for disbursing subsidies to plan sponsors. We suggest that Option 3 be removed, as a monthly process creates a significant burden both on plan sponsors and MA organizations assisting them. Option 2, making interim payments throughout the year, is acceptable if payment is quarterly. Option 1 is most preferable, as it would significantly reduce administrative costs and data collection burdens. Regarding periodicity, we suggest that quarterly disbursement be the standard if Option 2 is chosen, as plan sponsors would still be able to receive regular subsidy payments but the administrative burdens would be more reasonable for smaller businesses with fewer employees.

Thank you for your consideration of these comments. We look forward to working with you to determine the most efficient way to roll out Part D. If you need any further explanation or assistance, please contact me at **sandra.tomlinson@highmark.com** or 412-544-7646.

Sincerely,

Sandra Tomlinson
Senior Vice President, Provider Services and Pharmacy Affairs
Highmark, Inc.

Cc: Kenneth Melani, M.D., CEO and President, Highmark Inc.
David O'Brien, President, Keystone Health Plan West, Inc.
James Klingensmith, Executive Vice President, Highmark Inc.
Anne Crawford, Medicare Advantage Compliance Officer, Highmark Inc.
Jane Galvin, Director of Regulatory Affairs, Blue Cross Blue Shield Association

CMS-4068-P-1218

Submitter : Dr. Dean Hakanson **Date & Time:** 10/04/2004 08:10:39

Organization : GlaxoSmithKline

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

GlaxoSmithKline's comments to the Proposed Rule are attached, plus a copy of our comments to the USP Model Guidelines.

CMS-4068-P-1218-Attach-2.doc

CMS-4068-P-1218-Attach-1.doc

October 4, 2004

BY HAND DELIVERY

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-4068-P (Medicare Program; Medicare Prescription Drug Benefit)

Dear Dr. McClellan:

GlaxoSmithKline ("GSK") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Proposed Rule regarding the establishment of a Medicare Prescription Drug Benefit, published in the Federal Register on August 3, 2004 (the "Proposed Rule"),[1] pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").[2] GSK is a world leading research-based pharmaceutical company with a mission to improve the quality of human life by enabling people to do more, feel better, and live longer.

GSK applauds CMS for acting quickly to implement the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"). We are well aware that the MMA has placed an enormous responsibility on the agency to make complex changes to the Medicare program in a short period of time. We appreciate CMS's efforts to appropriately implement the Part D prescription drug benefit. As CMS continues to refine its implementation of the MMA, we hope that it will remain open to comments and dialogue with affected entities and continue to provide clear written guidance to manufacturers on its website or through other means.

Most of our comments focus on protecting patient access to prescription drugs. While the new Medicare prescription drug program holds the potential to greatly increase Medicare enrollees' access to prescription drugs, we are concerned that this access may not be fully realized because of limitations in how the Part D is implemented, most particularly with respect to the design of plan formularies and the limits of a burdensome appeals process.

Following are GSK's detailed comments to the Proposed Rule.

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[1] 69 Fed. Reg. 46632 (Aug. 3, 2004).

[2] GSK also is a member of both the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Industry Organization ("BIO") and fully supports those associations' comments to the Proposed Rule.

I. Subpart C -- Evaluation of a Plan's Design and Formulary Review -- § 423.272(b)(2)

CMS needs to carefully scrutinize formularies and formulary design to ensure that certain groups of Medicare enrollees are not discouraged from enrolling in part D plans.

- **GSK recommends that CMS revise §423.272(b)(2) to establish the two separate types of reviews required by statute—one establishing the general review of plan design for risk avoidance characteristics and the second based on criteria for formulary categories and classes.**

- **Also, CMS needs to clarify that the access criteria in section 423.120 are of no relevance for the general risk selection review of plan design under 423.272(b)(2).**

- **Lastly, GSK urges CMS to establish guidelines to be used for its general risk avoidance review of a plan's design that considers, among other things, clinically recognized treatment guidelines for particular diseases or conditions.**

Congress deemed it critical to the structure and success of the Part D benefit that Part D plans not be able to engage in risk selection. The market mechanism being created for part D will not work either to attract beneficiaries to enroll in this optional benefit or to fairly apportion risk among participating Part D plans if entities are able to explicitly or implicitly discourage enrollment by individuals whose care requires specific and/or multiple medications. Under the plain language of the statute, CMS review of a "plan benefit design" not only must encompass the "design of categories and classes" but also must identify **any** feature that would tend to explicitly or implicitly serve as a risk avoidance mechanism by discouraging patients with specific medical conditions from enrolling in that plan. This means that CMS review must also include the plan's formulary management interventions, including formulary tiers, prior authorization, step therapy, and cost sharing.

In our view, the Proposed Rule does not adequately protect against the risk that certain populations of Medicare enrollees will be discouraged from enrolling in Part D plans. CMS has stated that the agency will evaluate a Part D plan's formulary to ensure that the plan has not designed its formulary to discourage the enrollment of certain groups of Medicare beneficiaries[3] – for example, those with diseases or conditions that require significant prescription drug therapies. However, the Proposed Rule at section 423.272(b)(2) can be read as combining the CMS review of risk avoidance as a general matter, with the criteria for meeting but one of many of the elements to be reviewed, i.e., the single characteristic of plan design (categories and classes).

[3] Proposed 42 C.F.R. § 423.272(b)(2).

GSK recommends that the regulation be changed to conform to the statute by separating out measures that may be used by Part D plans to satisfy the "category and class" element from the general requirement that plan design (including formulary management interventions and formulary tiers) cannot discourage enrollment. CMS must clearly separate the general risk avoidance review and any criteria that CMS may apply from guidelines developed pursuant to the statute (i.e. USP Model Guidelines) for ensuring that the formulary categories and classes satisfy the nondiscrimination requirement. This distinction requires that section 423.272(b)(2) be rewritten to establish the two separate types of review required by the statutory authority – one establishing the general review of plan design for risk avoidance characteristics and the second based on criteria for formulary categories and classes.

The MMA explicitly states:

> "The Secretary may approve a prescription drug plan only if"[4] (among other things) "[t]he Secretary does not find that the design of the plan and its benefits … are likely to substantially discourage enrollment by certain part D eligible individuals."[5]

The statutory language is clear that the "design of the plan" being reviewed by CMS under MMA clause 1860D-11(e) (2) (D) (i) of the law is not limited to a list of covered drugs. The statute explicitly states that the review is of the *plan benefit design*, which may include prior authorization, step therapy, and clinical limitations on coverage of specific drugs, as well as the formulary, its categories and classes, *and* any "tiered formulary structure" for co-payments by beneficiaries. It is an entirely *separate* clause of the statute which provides that "the design of categories and classes within a formulary" cannot be the basis for finding that a formulary and its tiered structure discourage enrollment, if the categories and classes used by the Part D plan are "consistent with" the United States Pharmacopeia ("USP") guidelines.[6] Thus, the language of the statute is clear that the use of USP categories and classes under MMA clause 1860D-11(e)(2)(D) (ii) will satisfy merely one of the multiple points of review that the Secretary is required to make under clause (D)(i).

The explicit requirements of the MMA notwithstanding, the reasons for our recommended clarification to Proposed Rule section 423.272(b)(2) are straightforward and will further Congressional intent. First, formularies are clinical tools that must reflect the current state of science and clinical practice for the diseases that physicians treat. The MMA explicitly requires Part D plans to provide information to prospective enrollees about the plans' formularies prior to enrollment. Thus, the statute clearly contemplates that for a person already receiving

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[4] SSA § 1860D-11(e)(2).

[5] SSA § 1860D-11(e)(2)(D)(i).

[6] SSA § 1860D-11(e)(2)(D)(ii).

medical care for a medical condition, a plan whose design (including formulary, formulary tiers, authorization, and step therapy) does not provide access to drugs consistent with up-to-date medical practice is not a viable option for enrollment. It would be inconsistent with Congress's intent, therefore, to allow a plan to satisfy the requirement that it not be designed "to discourage enrollment by certain part D eligible individuals" simply by using the formulary categories and classes designed by the USP and ensuring that there are a specified number of drugs in each of those categories.

Second, unless CMS clarifies Proposed Rule Section 423.272(b)(2) as recommended above, prospective bidders are likely to be misled about the nature of the risk avoidance review, particularly in light of statements in the commentary to the Proposed Rules[7] and section 423.120(b)(2) of the regulation relating to minimal formulary criteria for assuring access to drugs.[8] For example, in the minimum formulary access provisions (discussed below), CMS has said that it is possible for an adequate formulary to include *only* two drugs per class. If a simple numerical criterion together with use of the USP categories and classes would assure passage of this review, the Proposed Rule would be inconsistent with the statute as a legal matter and would not achieve the stated objective of avoiding the risk that certain populations of Medicare enrollees will be discouraged from enrolling in Part D plans.

Another concern with the current draft of the Proposed Rule is that combining the requirements of sections 423.272(b) (2) and 423.120(b) (3) does not assure clinically sound formularies. The USP categories and classes that are being developed for use by CMS for the review of this one element of plan design may or may not be an appropriate clinical foundation for assuring access to medically appropriate care under part D. GSK understands that the evaluation of the adequacy of the model categories and classes designed by USP is ongoing, and we have urged USP to substantially revise its model guidelines to better reflect accepted medical practice and nationally recognized treatment guidelines. (GSK's comments filed with USP on September 17, 2004, are attached.) Even if there could be agreement on the structure of categories and classes to be used in formulary design, it would not be clinically valid to decide a priori that a specific number of drugs – and the same number for each class – will always be sufficient to provide access to care. Rather, Congress's use of the plural form "drugs" in referring to formulary access is meant to ensure that physicians and patients always have a choice of therapy options, in recognition that medical care in the 21st century is increasingly personalized to meet the specific characteristics of the disease, the patient, and his or her current condition.

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[7] 69 Fed. Reg. at 46660. This portion of the commentary states, "The USP listing would simply serve as a model set of guidelines. As specified in 1860D-11(e)(2)(d)(ii) of the Act, if the therapeutic classifications within a plan's formulary conform to the USP classifications, we could not determine, based on the formulary's therapeutic classifications, that the plan violates the provision at 1860D-11(e)(2)(d)(i) of the Act and section 423.272(b)(2) that prohibits the design of the plan and its benefits (including any formulary and tiered formulary structure) that substantially discourages enrollment by certain Part D eligible individuals."

[8] 42 C.F.R. § 423.120(b)(2).

CMS should clarify in the final rule that the access criteria in section 423.120 are of no relevance for the general risk selection review of plan design under 423.272(b) (2). Rather, the criteria in section 423.120 are minimal guidelines for ensuring a choice of therapy alternatives when developing a formulary. A Pharmacy and Therapeutics Committee should use sound clinical judgment to create the list of drugs covered by the plan, taking into account authorization requirements, clinical guidelines and step therapy, as well as the categories and classes that are used to sort and create preferential coverage and co-payment for the drugs available for treating specific diseases and conditions. Accordingly, we recommend below in our comments regarding section 423.120(b) (Pharmacy and Therapeutics Committees) that CMS clarify that Pharmacy and Therapeutics Committees should take into account clinical guidelines as well as the therapeutic categories and classes when creating preferential coverage and co-payment for the specific drugs.

GSK urges CMS to establish guidelines to be used for its general risk avoidance review of a plan's design that considers, among other things, clinically recognized treatment guidelines for particular diseases or conditions. Specifically, CMS should establish two types of guidelines for evaluating risk avoidance:

(a) Where there are treatment guidelines and protocols established by recognized entities for use in treating the disease or condition, the formulary design must allow for coverage of the full range of drugs needed to use the treatment guideline or protocol and to provide the doctor and patient with therapeutic options and alternatives.

Many among the elderly and disabled population served by Medicare have conditions for which drug treatments may be especially effective, such as Chronic Obstructive Pulmonary Disease (COPD), diabetes, asthma, heart failure, HIV, cancer and depression. Medications for these conditions must be taken for extended periods, and enrollees with multiple problems may require simultaneous administration of multiple medications. [9] In 2001 for example, people 65 and over who reported a prescribed medication expense purchased an average number of 26.5 medications.[10] The elderly population struggles with medication adherence, and their vulnerability is increased by the creation of extremely limited formularies. Such formularies will disproportionately affect the economically disadvantaged elderly and the sickest members.

Nationally and internationally recognized evidence-based clinical guidelines for chronic diseases such as COPD, asthma, HIV, and diabetes, routinely include combination therapies as

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9 Report to the President, "Prescription Drug Coverage, Spending, Utilization, and Prices," From Department of Health & Human Services, April 2000, available at http://aspe.hhs.gov/health/reports/drugstudy/.

10 Pancholi M, Stagnitti M. Outpatient Prescribed Medicines: A Comparison of Use and Expenditures, 1987 and 2001. *Statistical Brief #33.* June 2004. Agency for Healthcare Research and Quality, Rockville, MD. http://www.meps.ahrq.gov/papers/st33/stat33.htm

part of their management recommendations and treatment options.[11,12,13,14] Such recommendations include the simplification of therapy by reducing the number of pills and frequency of dosing, and frequently, a discussion of the potential benefits of such strategies relative to medication adherence, drug interactions and side effects.[14, 16]

Additionally, the effectiveness of combination therapies as a means of simplifying treatment regimens and promoting adherence and compliance has been well documented in the literature.[15,16,17,18,19] Using respiratory tract diseases as an example, combination therapies such as Advair® (fluticasone proprionate and salmeterol) are included in both the NIH/NHLBI guidelines for the treatment of asthma, and the ATS/ERS guidelines for managing COPD.[12, 13,14] Supporting evidence from clinical studies, such as Stoloff et al, demonstrate greater refill persistence with the combination therapy Advair® (fluticasone proprionate and salmeterol) compared with the individual components administered seperately.[18] Based on the consistency of such findings and guideline recommendations, CMS's review of plan design for impermissible risk avoidance issues should consider the importance to Medicare enrollees' of having appropriate access to necessary combination therapies.

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[11] Report to the President, "Prescription Drug Coverage, Spending, Utilization, and Prices," From Department of Health & Human Services, April 2000, available at http://aspe.hhs.gov/health/reports/drugstudy/.

[12] Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: Executive Summary—Updated 2003. Bethesda, Md: NIH, NHLBI; 2003.

[13] National Institutes of Health National Heart Lung and Blood Institute. National Asthma Education and Prevention Program. Executive summary of the NAEPP expert panel report. Guidelines for the diagnosis and management of asthma- update on selected topics 2002. NIH Publication No. 02-5075. June 2002.

[14] . Panel on Clinical Practices for the Treatment of HIV Infection. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. February 2001. Department of Health and Human Services, and the Henry J. Kaiser Family Foundation. Available at http://www.hivatis.org. Accessed November 26, 2001

[15] Celli B, MacNee W, et al. Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. Eur Respir J 2004;23:932-946.

[16] Gurwitz JH et al. Incidence and Preventability of Adverse Drug Events Among Older Persons in the Ambulatory Setting. *JAMA*. March 5, 2003. Vol 289 (9).1107-1116.

[17] Inzzucchi, SE. Oral antihyperglycemic therapy for type 2 diabetes. JAMA.2002; 287; 360-372.

[18] Stoloff SW et al. Improved refill persistence with fluticasone propionate and salmeterol in a single inhaler compared with other controller therapies. *J Allergy Clin Immunol* 2004;113:245-51.

[19] Taylor AA, Shoheiber O. Adherence to Antihypertensive Therapy With Fixed-Dose Amlodipine Besylate/Benazepril HCl Versus Comparable Component-Based Therapy. *CHF* 9(6):324-332, 2003.

(b) CMS should ensure that the cost sharing imposed under any tiered formulary structure that does not prefer drugs integral to treatment protocols or guidelines for a disease or condition does not impermissibly shift costs to any specific patient population.

In other words, CMS must ensure that the actuarial value of the Part D benefit does not selectively reward persons with lower aggregate drug costs while imposing higher costs on persons with a particular disease or condition, such as HIV, cancer, COPD, diabetes, or asthma. Such cost shifting is unfair to most enrollees and inconsistent with the risk selection prohibition in the statute. It also unfairly shifts costs to the federal government because such costs are paid by the government for enrollees under 135% FPL and also count toward TrOOP for purposes of "catastrophic coverage." Furthermore, such cost shifting may unduly burden SPAPs, which may pick up the higher cost-sharing amounts through their supplemental coverage or benefits.

Evidence is mounting that good health and good pharmacoeconomics go hand in hand. Dr. Avi Dor from Case Western and William Encinosa from AHRQ recently demonstrated the profound impact of increasing out-of-pocket costs on adherence and overall medical spending in a working paper prepared for the National Bureau of Economic Research.[20] They demonstrated that, as out-of-pocket costs for medications rise, medication adherence decreases, and anticipated savings to the payor are greatly offset by the increase in costs related to hospitalizations and other medical complications.

Many recent studies using analyses of claims databases linked to benefit design across different populations (private pay and government) consistently have noted that as out-of-pocket costs increase, adherence to essential medications decreases. Since out-of-pocket costs could be a barrier to obtaining recommended and appropriate non-formulary medications, overall health care spending could significantly increase. Most notably, thought leaders from RAND,[21] Harvard University,[22] Case Western Reserve University,[23] the Agency for Healthcare Research and Quality,[24] Cleveland Clinic,[25] and the University of Michigan[26] are adding to the body of evidence

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[20] Dor A, Encinosa WE. NEBR Working Paper Series. Does Cost Sharing Affect Compliance? The Case of Prescription Drugs. National Bureau of Economic Research. http://papers.nber.org/papers/w10738.pdf

[21] Joyce GF, Escarce JJ, Solomon MD, Goldman DP. Employer drug benefit plans and spending on prescription drugs. JAMA. 2002;288(4):1733-1739. - Multi-year study of 25 companies.

[22] Huskamp, HA, Deverka PA, Epstein AM, et al. et al. The Effect of Incentive-Based Formularies on Prescription –Drug Utilization and Spending. N ENJ J MED 2003;2224-32.

[23] Dor A, Encinosa WE. NEBR Working Paper Series. Does Cost Sharing Affect Compliance? The Case of Prescription Drugs. National Bureau of Economic Research. http://papers.nber.org/papers/w10738.pdf

[24] *Id*

[25] Ellis JJ, Fendrick M et al. Suboptimal Statin Adherence and Discontinuation in Primary and Secondary Prevention Populations. Should We Target Patients with the Most to Gain? J Gen Intern Med 2004;19:638-645.

supporting the conclusion that financial barriers (increasing out-of-pocket costs) to essential medications in chronic diseases leads to an overall increase in morbidity and downstream health care costs. [27,28,29,30,31,32,33,34,35,36,37,38,39]

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[26] *Id*

[27] Dor A, Encinosa WE. NEBR Working Paper Series. Does Cost Sharing Affect Compliance? The Case of Prescription Drugs. National Bureau of Economic Research. http://papers.nber.org/papers/w10738.pdf

[28] Joyce GF, Escarce JJ, Solomon MD, Goldman DP. Employer drug benefit plans and spending on prescription drugs. JAMA. 2002;288(4):1733-1739. - Multi-year study of 25 companies.

[29] Berman C. Pitney Bowes: Prescription Drug Value-Based Purchasing. Presented at National Business Coalition on Health; January 22, 2004; Las Vegas, NV.

[30] Cramer JA, Glassman M, Rienzi V. The relationship between poor medication compliance and seizures. Epilepsy and Behavior. 2002;3(4):338-342.

[31] Cranor CW, Bunting BA, Christensen DB. The Asheville Project: Long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc. 2003;43:173-84.

[32] Ellis JJ, Fendrick M et al. Suboptimal Statin Adherence and Discontinuation in Primary and Secondary Prevention Populations. Should We Target Patients with the Most to Gain? J Gen Intern Med 2004;19:638-645.

[33] Goldman, DP, Joyce, GF, Escarce,EJ, Pace, JE, Solomon,MD, Laouri, M, Landsman, PB, Teutsch, SM, Pharmacy Benefits and the Use of Drugs by the Chronically Ill. JAMA. 2004;291:2344-2350.

[34] Huskamp, HA, Deverka PA, Epstein AM, et al. et al. The Effect of Incentive-Based Formularies on Prescription –Drug Utilization and Spending. N ENJ J MED 2003;2224-32.

[35] Pharmaceutical Research and Manufacturers of America. Focus on Health Policy, Winter 2004, pg 1-7. Medicare Beneficiaries Cared for with Prescription Medicines. Available at: http://www.phrma.org/publications/policy//2004-03-23.921.pdf . Accessed May 17, 2004.

[36] Rand Study Finds Patients with Chronic Conditions cut use of Preventive Drugs when Drug Co-Payments Double. Press Release May 18, 2004. Available at: http://www.rand.org/news/press.04/05.18.html. Accessed May 19,2004.

[37] Rundall, T, As good as it gets? Chronic care management in nine leading U.S. physician organizations. Br. Med. J., 2002; 325:

[38] The Hidden Epidemic: Finding a Cure for Unfilled Prescriptions and Missed Doses. December, 2003. The Boston Consulting Group and Harris Interactive. Available at http://www.bcg.com/publications/files/TheHiddenEpidemic_Rpt_HCDec03.pdf. Accessed August 16, 2004.

[39] Wye River Group on Healthcare. An Employer's Guide to Pharmaceutical Benefits. 2003. Available at: http://www.wrgh.org/docs/Book.pdf Accessed May 21, 2004.

II. Comments on Subpart C -- Other Formulary Issues -- § 423.120

a. Inclusion of New Drugs and New Uses – 423.120(b) (3).

GSK recommends that CMS require Part D plans to use the Pharmacy and Therapeutics Committee process to evaluate their formularies at least once each quarter to reflect new drugs and new uses of existing drugs.

GSK strongly supports the provisions in the Proposed Rule that would allow plans to change categories and classes during a calendar year to take into account new therapies or new uses for existing therapies.[40] GSK continually strives to develop new medicines that will fulfill our mission of improving the quality of human life. Because the FDA approves new medicines and new uses for existing therapies throughout the year, the full benefits of continuous medical innovation can be realized only if patients have timely access to innovative treatments. CMS' proposal will help ensure timely patient access to critical therapies by allowing plans to adjust their formularies as medical technology evolves, and it should be implemented in the final rule.

Additionally, we recommend that CMS take further steps to ensure that Part D plans' formularies keep up with the pace of pharmaceutical innovation. Some plans might not take advantage of the opportunity to update their formularies unless CMS requires them to do so. Patient access to life-saving or life-extending therapies could be delayed by plans that fail to update their formularies on a regular basis. *We therefore urge CMS to require Part D plans to evaluate their formularies at least quarterly, using the Pharmacy and Therapeutics Committee process, to reflect new drugs and new uses of existing drugs.*

b. Removal of Drugs from a Formulary and Changes to Cost-Sharing Status – 423.120(b) (5).

CMS should modify the regulation to provide that, upon ninety days notice to physicians, pharmacies, the Secretary, and other financially responsible parties as well as enrollees not yet prescribed a drug, a plan may change the formulary or preference status of a drug. However, such change is not effective as to enrollees with an active prescription for such drug – these enrollees must be ensured continued access to an ongoing therapy during the course of their disease.

The MMA allows Part D plans to remove a drug from a formulary or change its cost-sharing status with "appropriate notice" to certain parties, including affected enrollees, providers

[40] Proposed 42 C.F.R. § 423.120(b)(3).

and the Secretary.[41] In the Proposed Rule, CMS has interpreted this "appropriate notice" provision as permitting a plan to remove a drug from its formulary or change its cost-sharing status with only thirty days notice.[42] We think that this proposal inappropriately confuses appropriate notice to practitioners using the formulary in making treatment decisions for their *new* patients with appropriate notice to Medicare enrollees who have relied on a plan's formulary in making treatment decisions and/or decisions regarding the selection of a Part D plan. Furthermore, we believe that, even for enrollees not currently taking a drug, a thirty day notice is inadequate. As such, the Proposed Rule fails to implement the provisions of the MMA and ultimately ensures a high probability that the Part D benefit will devolve to substandard quality unlikely to meet the medical needs of enrollees

Medical care for the chronic conditions that affect elderly and disabled Medicare beneficiaries is ongoing. For many conditions, care spans many months and even years. Although scientists and clinicians may dispute which of several therapeutic alternates is "best" for *starting* treatment for a patient who has been just diagnosed, there are no principles of good medical practice that would support changing a patient's medications every thirty days if the medication is effectively managing the patient's condition. Yet this is precisely what CMS's proposal would permit.

The entire structure of the Part D benefit depends on enrollees evaluating a plan's design, including its formulary, and through the exercise of choice during each open enrollment period, encouraging plans to improve in quality and coverage to compete for beneficiaries. In fact, CMS has expressly noted that it will be important for beneficiaries to "have the most current formulary information by the time of the annual enrollment period…in order to enroll in the Part D plan that best suits their particular covered Part D drug needs."[43] Yet the Proposed Rule virtually guarantees that this cannot occur. By permitting Part D plans to change which drugs are on its formulary at any time, as many times as it likes, so long as "affected parties" have thirty days notice, CMS would severely undermine the enrollee's plan selection process and the structure of the Part D benefit.

More ominously, the criteria CMS has established would permit a plan to market a clinically rich formulary, modest authorization requirements and clinical guidelines during open enrollment season, and then drop drugs or increase cost-sharing on all drugs after the first 30 day protected period to meet cost containment objectives,[44] so long as the two-drug minimum access

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[41] SSA § 1860D-4(b)(3)(E).

[42] Proposed 42 C.F.R. § 423.12f0(b)(5). CMS has proposed that plans would not be permitted do make such changes during the annual open enrollment period and at the beginning of each enrollment year.

[43] 69 Fed. Reg. at 46661.

[44] Proposed 42 C.F.R. § 423.120(b)(6).

criterion is met.[45] Thus, the 30-day formulary change criterion established by the Proposed Rule not only fails to meet the statutory criterion of "appropriate" notice established by the MMA, but also fails to protect beneficiaries against the very "bait-and-switch" tactics that have been a major focus of concern and action by CMS in connection with implementation of the Medicare Drug Discount Card. Utilizing these tactics, a plan might seek to attract beneficiaries whose condition is stabilized on popular drugs; and, once the patient is locked in and the premium revenue guaranteed for a year, switch the formulary preference. Such bait-and-switch tactics are prohibited under the consumer protection laws of the United States and the States individually as unfair and deceptive to consumers. The Congress established a market-based system to provide a cost-effective drug benefit for Medicare beneficiaries; it did not intend to permit commercial practices that cause beneficiaries to pay a premium and face administrative hassles and confusing messages about the medical care prescribed by their doctors.

We recommend that because the Congress has established a system in which beneficiaries select plans based on their formularies and because beneficiaries are (except in rare circumstances) not permitted to switch from one plan to another more than once in a year, "appropriate notice" to affected parties cannot be a fixed thirty day period. Rather, we urge CMS to require plans to provide *all* enrollees – whether or not they are taking the affected drug – with a 90 day notice before removing a drug from a formulary or increasing the cost-sharing for a drug. Where a patient had an active prescription for a drug for an ongoing or episodic condition when she or he enrolled in a Part D plan or was first prescribed a drug after enrollment in the plan, the Part D plan should not be permitted to exclude the drug or increase its cost sharing for that patient during the course of the patient's disease.

Thus, we recommend that CMS modify the regulation to provide that, upon ninety days notice to physicians, pharmacies, the Secretary and other financially responsible parties as well as enrollees not yet prescribed a drug, a plan can change the formulary or preference status of a drug. However, such change is not effective as to enrollees with an active prescription for such drug – these enrollees must be ensured continued access to an ongoing therapy during the course of their disease.

c. Special Populations -- § 423.120

We recommend that special populations – such as HIV/AIDS, cancer, mental health conditions, long-term care residents, and dual eligibles – be given access to open formularies.

As CMS has acknowledged, Part D enrollees with serious and chronic disease have special needs that may not adequately be met through a restrictive formulary.[46] In addition,

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[45] *See* 69 Fed.Reg. at 46661.

[46] 69 Fed.Reg. at 46661

CMS is concerned that plans might inappropriately discriminate against select Medicare populations. These enrollees – among Medicare's most fragile – tend to require multiple medications and are likely to require individualized treatment plans and specific therapies. Also, because of the nature of the diseases and of the complexity of the pharmaceutical therapies available, the patients will tend to incur high plan costs. It is possible that plans might want to restrict access to select therapeutic areas to discourage these patients from enrollment.

GSK urges CMS to provide these enrollees with access to an open formulary requiring plans to institute special formulary standards for these enrollees that reflect their special medical needs. Such standards may include broad access to the range of therapies required by individuals with serious and chronic illnesses, including access to special dosage forms and a special exceptions process should an open formulary not be implemented.

Below we have identified some reasons why certain Medicare populations – those with AIDS, cancer, or mental health conditions, those in long-term care, and those dually eligible for Medicare and Medicaid – may need these special formulary rules.

Part D Enrollees with HIV/AIDS:

GSK recommends that people with HIV/AIDS be given broad access to a full range of therapeutic and supportive care options based on available scientific evidence.

The standard of care in HIV therapy requires at least three HIV drugs, which are typically in the same class.[47] For example, many HIV patients take two drugs from the nucleoside/nucleotide reverse transcriptase inhibitor category. These drugs are in the same pharmaceutical class and have the same general mechanism of action; yet a specific mutation in the HIV virus may render some of these drugs ineffective. Because several such mutations exist, it is not possible to identify two drugs that would be effective in all patients.[48] Further, changing patterns of viral resistance to the antiviral agents used for HIV treatment mandate an opportunity for the treating physician to readily make changes in the treatment regimen without a burdensome exception process.[49] Transmitted human immunodeficiency virus type 1 carrying the D67N or K219Q/E mutation evolves rapidly to zidovudine resistance in vitro and shows a high replicative fitness in the presence of zidovudine.[50]

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[47] *See, e.g.,* DHHS, Panel on Clinical Practices for Treatment of HIV Infection, "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents," (March 23, 2004) at 13.

[48] *See id.* at 19.

[49] (2004: which HIV-1 drug resistance mutations are common in clinical practice? AIDS Rev. 2004 Apr-Jun;6(2):107-16

[50] J Virol. 2004 Jul;78(14):7545-52.)

Thus, the minimum two drugs per class will not be sufficient to meet the needs of HIV patients. These individuals will need broader access to drugs under Part D to obtain appropriate medical care; the appeals and exceptions process will not be adequate to ensure sufficient access to necessary therapies for this population.

Part D Enrollees with Cancer:

GSK recommends that cancer patients be given broad access to a full range of therapeutic and supportive care options based on available scientific evidence.

We are particularly concerned about whether cancer patients will be able to access the therapies they need through Part D formularies. This will depend in part on whether the USP properly revises its model guidelines to reflect the range of necessary cancer therapies and whether CMS appropriately considers the specific needs of cancer patients in scrutinizing plan formularies.

Current treatment guidelines for cancer management clearly reflect the need for oncologists and cancer patients to have broad access to a full range of therapeutic and supportive care options based on available scientific evidence. These guidelines are frequently updated based on the rapidly evolving nature of the scientific evidence.[51]

It is particularly difficult to provide appropriate cancer treatment within the confines of a plan formulary. Cancer is actually a wide range of diseases requiring therapies from multiple pharmacological classes depending on factors such as tumor type, stage of disease, available biomarkers, proven combination regiments, and patient tolerability. Appropriate cancer treatments may include antineoplastics, hormone suppressants, immune suppressants, and other immunological agents -- as well as supportive therapies for the management of the severe side effects of chemotherapy or radiation therapy. These therapies include antiemetics and treatments for anemia, neutropenia, and thrombocytopenia.

Cancer patients cannot afford the time lost in a lengthy appeals process that may be required to access the care they need. So this population could face significant risk of being discriminated against by Part D plans seeking to contain drug costs

Part D Enrollees with Mental Health Conditions:

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[51] NCCN/ACS Treatment Guidelines for Patients. National Comprehensive Cancer Network. 2004. http://www.nccn.org/professionals/physician_gls/f_guidelines.asp#site

GSK recommends that patients with mental health conditions be given broad access to a full range of therapeutic and supportive care options based on available scientific evidence.

Prescription drugs play a critical role in treating and managing mental illnesses such as depression, schizophrenia, and bipolar disorder. For these conditions, a patient typically must try several drugs in the same class before finding the proper drug and dose. In the Conference Report to the MMA, Congress recognized the special needs of the mentally ill, stating its intent that these Part D enrollees have clinically appropriate access to pharmaceutical treatments for mental illnesses[52] and noting that this is a "unique population with unique prescription drug needs as individual responses to mental health medications are different."[53] There are many legitimate reasons for multiple drug therapy in this population.[54] To fully comply with the MMA, the Part D implementing regulations must appropriately reflect the needs of this population to have broader access to medications. *GSK recommends that patients with mental health conditions be given broad access to a full range of therapeutic and supportive care options based on available scientific evidence.*

Part D Enrollees in Long-Term Care Facilities:

GSK recommends that residents of LTC facilities be considered a "special population" with respect to Part D plan formularies and be granted access to an open formulary that supports their unique medical needs.

Residents of long-term care ("LTC") facilities will be especially vulnerable to adverse consequences that inevitably arise from therapeutic substitutions and administrative inefficiencies in the formulary process. *GSK urges CMS to grant this population access to formularies that include a wider range of drugs than may be offered under the restricted or closed formularies of Part D plans.*

The elderly population, which represents the largest group of patients in LTC facilities, typically requires multiple medications across multiple therapeutic categories and classes; and these drugs often are not interchangeable with other drugs within the class without risking drug interaction and/or other substantial complications. Restricting formulary access to medications will force some of these Part D enrollees to seek approval through the exceptions and appeals processes for the therapies they need. Yet because of their unique needs, many of these

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[52] Conf. Rep at 769-770.

[53] Conf. Rep. at 770.

[54] "Reasons for polypharmacy among psychiatric patients." Pharm World Sci. 2004 Jun;26(3):143-7.

vulnerable enrollees will be unable to meaningfully access the appeals and exceptions processes to appeal the denials and other barriers to access they encounter.

To meet the special needs of this population, GSK recommends that residents of LTC facilities be considered a "special population" with respect to Part D plan formularies and be granted access to an open formulary that supports their unique medical needs.

For a more thorough analysis of these risks and issues, we recommend that you reference the September 17, 2004, Comments to the Draft Model Guidelines submitted by the American Society of Consultant Pharmacists.

Part D Enrollees Dually Eligible for Medicaid:

GSK recommends that CMS establish special formulary rules to provide dual eligibles with continued access to a formulary that is consistent with their current access to prescription drugs under Medicaid.

Dual eligibles are likely to have significant difficulty adjusting to the Part D benefit. Currently, these individuals have access to drugs through Medicaid programs, which generally provide access to medically necessary drugs. Once the Part D benefit begins, these individuals will have access only to those prescription drugs available on their Part D plan's formulary.

It will be critical that CMS establish special formulary rules to provide this population with continued access to a formulary that is consistent with their current access to prescription drugs under Medicaid. Many of these enrollees have special medical needs such as mental health conditions and/or are in long-term care facilities, group homes or other community-based programs that provide long-term care in a setting more conducive to maintaining activities of daily living.

We urge CMS to ensure that these enrollees continue to receive the medications they need by providing them access to medically necessary drugs. Because individuals receiving long-term care in facilities and community settings depend heavily on caregivers for advice and assistance, any transition of these enrollees that requires en masse switching or discontinuation of medicines will be particularly burdensome for physicians (who must participate in exceptions requests and appeals), destructive of the quality of care provided by these community providers, and detrimental to this vulnerable population.

III. Subpart C -- Covered Part D Drugs -- § 423.100

a. Obesity -- § 423.100

Given that numerous Medicare enrollees suffer from health disorders where obesity is a modifiable risk factor, GSK urges CMS to clarify that Part D plans may include in their formularies therapies whose mechanism of action is weight loss when the therapy is medically necessary to improve the outcomes of co-morbid diseases for which obesity is a modifiable risk factor.

Obesity is a modifiable risk factor for a host of diseases including diabetes, heart disease, dyslipidemia, sleep apnea, gallstones, bladder control problems, uric acid nephrolithiasis, psychological disorders, osteoarthritis, and certain cancers.[55] For example, central obesity is one of the risk factors for Metabolic Syndrome – a condition that affects an estimated 20 percent of adults in the U.S., with the prevalence approaching 50% in the elderly.[56] The syndrome is also characterized by dyslipidemia, hypertension, and insulin resistance. Although these combined risk factors do not necessarily manifest in overt symptoms, they are warning signs for increased risk of atherosclerosis, heart disease, stroke, diabetes, kidney disease, or premature death.[57]

Given the recognition and significance by various agencies within HHS of the significance of obesity with regard to health, the number and extent of diseases associated with obesity, and the impact obesity and co-morbidities have on the Medicare population, GSK recommends the following:

GSK urges CMS to consider the significance of obesity and its relation to other co-morbid conditions in the Medicare population and clarify that Part D plans are not prohibited from covering therapies whose mechanisms of action are primarily aimed at obesity, when therapy is medically necessary to improve the outcomes of co-morbid diseases for which obesity is a modifiable risk factor.

Other agencies within HHS recognize the need to combat obesity with regard to improving health. The Food and Drug Administration's ("FDA's") Endocrinologic and Metabolic Drugs Advisory Committee recently held an open meeting to consider changes to the FDA's 1996 guidance document for the clinical evaluation of weight-control drugs and unanimously recommended that indications for the treatment of co-morbidities should not be disqualified simply because the primary mechanism of action was weight loss.

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55 http://www.cdc.gov/nccdphp/dnpa/obesity/consequences.htm

56 http://www.labtestsonline.org/understanding/conditions/metabolic.html.

57 Id.

CMS has revised a long-standing national coverage policy and indicated that "[s]ervices in connection with the treatment of obesity are covered services when such services are an integral and necessary part of a course of treatment for one of these medical conditions."[58] Not only is coverage of therapies that treat obesity clinically sound, but it also translates into cost-savings. According to the 2001 Surgeon General's Call to Action on Prevent and Decrease Overweight and Obesity, the total direct and indirect costs were estimated at $177 billion nationally in 2000.

GSK applauds the agency's recognition that coverage of obesity treatments is warranted when interrelated to other diseases.

b. Vaccines -- § 423.100

GSK is concerned that Part D plans may interpret § 423.100 in a manner that allows them to exclude coverage of certain vaccines that are reasonable and necessary for prevention. Therefore, we recommend that CMS

1. **specify that plans are required to offer coverage for vaccines and**

2. **actively communicate the value of immunizing Medicare enrollees.**

The MMA defines "covered Part D drugs" to expressly include vaccines.[59] CMS mirrors this definition in the Proposed Rule.[60] However, the potential for confusion exists due to other sections of the MMA.

In addition to the express mention of vaccines as covered Part D drugs, the MMA also allows a Part D plan to exclude a covered Part D drug if payment for that drug "would not be made if section 1862(a) applied to this part."[61] Section 1862(a) of the Social Security Act excludes, among other things, from Part B coverage items and services that are not "reasonable and necessary" for the "diagnosis or treatment of illness or injury or to improve the functioning

[58] Medicare Coverage Issues Manual, § 35-26.

[59] SSA §1860D-2(e)(1).

[60] Proposed 42 C.F.R. § 423.100.

[61] SSA § 1860D-2(e)(3).

of a malformed body member."[62] Yet, Part B also covers certain vaccines, including their administration costs, that are reasonable and necessary for prevention.[63]

By explicitly including vaccines in the definition of "covered Part D drugs," Congress clearly contemplated that Part D plans would provide coverage for vaccines. The provision allowing plans to exclude coverage where § 1862(a) would apply was intended to protect plans from being forced to cover drugs that are not "reasonable and necessary." There is no indication Congress intended to allow plans to exclude preventative therapies such as vaccines from the Part D benefit. In fact, the Conference Report for the MMA describes the covered Part D drugs that plans may exclude from coverage as "any drug which would not meet Medicare's definition of medically necessary or was not prescribed in accordance with the plan or Part D,"[64] thus clarifying the intent of the reference to § 1862(a). *Accordingly, GSK urges CMS to specify that Part D plans are required to offer coverage for vaccines.*

Some adult immunizations are already provided under Medicare Part B (e.g., influenza, pneumococcal, hepatitis B to select populations). However, senior adults may need immunizations not currently covered by Part B. For example, Healthy People 2010 includes an objective of reducing levels of hepatitis A from the 1997 baseline of 11.3 new cases per 100,000 people to 4.5 new cases per 100,000 by 2010.

One of the strategies is to target high risk adults over age 40. The availability of hepatitis A vaccine from a plan offering a Part D benefit would make it easier to meet that objective. In addition, Healthy People 2010 contains an objective to reduce cases of hepatitis B from the 1997 baseline of 15.0 cases per 100,000 to 3.8 cases per 100,000 by 2010. Universal immunization of children will go a long way to reaching that objective, but there are many seniors outside of the traditional high risk groups currently eligible for Medicare covered hepatitis B immunization who have never been immunized. This additional population may still be at risk because hepatitis B is a blood-borne pathogen that may be contracted in a variety of circumstances. In fact, hepatitis B can be easier to contract than HIV.[65] Another category of enrollees who should be vaccinated, according to the CDC, are travelers to selected countries. *GSK urges CMS to actively communicate the value of immunizing Medicare enrollees.*

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[62] SSA § 1862(a)(1).

[63] *See* SSA § 1861(s)(10).

[64] H.R.1, Conf.Rep. 108-391 at 442.

[65] Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures. CDC. MMWR, 1991; 40 (RR-8): 1-9.

IV. Subpart C -- Pharmacy and Therapeutics Committees – § 423.120(b)

Under the MMA and the Proposed Rule, plan formularies must be reviewed by Pharmacy and Therapeutics ("P&T") committees.[66] In general, GSK supports CMS's efforts to utilize the P&T committee process in a manner that ensures that plan formularies are designed with appropriate emphasis on clinical considerations. We also appreciate CMS's efforts to make this process more transparent. We have commented on particular P&T committee functions below.

a. P&T Committee Decisions as Binding -- § 423.120(b).

P&T Committee decisions should be binding with respect to the list of drugs on the formulary.

CMS proposes that P&T committee decisions be binding on a plan[67] and suggests that the P&T committee be involved in designing any tiers within a formulary.[68] GSK agrees that P&T committee decisions should be binding, but only with respect to which drugs should be placed on the formulary.

Making these decisions binding on the plan will help to ensure that the formulary represents a clinically appropriate range of drugs that will meet the needs of the Medicare population. These decisions should be binding on the Part D plan even where the plan uses an outside subcontractor as its P&T committee. The plan should be permitted greater participation, however, in the process of assigning formulary tiers to specific drugs. This will appropriately reflect the market-based nature of the Part D benefit and will allow plans to consider their negotiations with manufacturers, while also allowing the P&T committee to have appropriate input to ensure that clinical concerns are properly incorporated.

b. Specialists on P&T Committees – Proposed 42 C.F.R. § 423.120(b)(1)(ii).

Committees should include specialists knowledgeable in the diseases facing the elderly.

P&T committees should include specialists that reflect the prevalent diseases of the elderly such as cardiovascular disease, depression, cancer, and diabetes. We appreciate that CMS is encouraging plans to include such specialists,[69] and *we urge CMS to formalize this by requiring plans to include a range of specialists.*

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[66] Proposed 42 C.F.R. § 423.120(b)(1).

[67] 69 Fed.Reg. at 46659.

[68] Proposed 42 C.F.R. § 423,120(b)(1)(iv); 69 Fed.Reg. at 46659.

[69] 69 Fed.Reg. at 46659.

As a related requirement, the Proposed Rule requires that P&T committees include at least one member who specializes in treatment of the "elderly or disabled."[70] *We urge CMS to clarify what is meant by "disabled" and encourage the adoption of a broad definition to ensure that the needs of Medicare populations with physical disabilities and mental illness are appropriately considered in developing a plan's formulary.*

c. P&T Committee Members Independent and Free of Conflict -- § 423.120(b)(1)(ii).

CMS's proposed extension of the independence requirement to pharmaceutical manufacturers is inconsistent with the intent of the statutory provisions. However, safeguards can be implemented to ensure that physicians or pharmacists with a clear conflict of interest are recused from P&T decisions directly impacted by such conflict.

The MMA requires that at least one practicing physician and one practicing pharmacist on the P&T committee be independent and free of conflict with respect to the Part D plan.[71] CMS proposes to extend this requirement to require these members to be independent and free of conflict not only with respect to the plan[72] but also with respect to pharmaceutical manufacturers.[73] This extension is inconsistent with the intent of the statutory provision, and we are concerned about how this will work in practice.

Congress enacted a number of provisions that seek to ensure that Part D plans will establish formularies that provide a meaningful range of prescription drugs on which elderly patients tend to rely. Congress's apparent intent in setting forth this particular requirement was to provide enrollees with some protection against the possibility that a plan would design its formulary with too much self-interest. In the private market, P&T committees often include members that are independent and free of conflict with respect to the plan. In fact, the recent Merck-Medco consent agreement requires that a majority of P&T committee members be independent of the plan, and members who are not deemed independent have no vote in P&T committee decisions.[74]

CMS's proposed requirement that these members be independent and free of conflict also with respect to pharmaceutical manufacturers will eliminate many of those clinical experts most focused on treatment of the elderly. It is critical to the appropriate development of Part D

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[70] Proposed 42 C.F.R. § 423.120(b)(1)(ii).

[71] SSA § 1860D-4(b)(3)(A)(ii)(I).

[72] Proposed 42 C.F.R. § 423.120(b)(1)(ii).

[73] 69 Fed.Reg. at 46659.

[74] *U.S. et al v. Merck-Medco Managed Care LLC, (Civ. Act. No. 00-737) 2004 WL 977196 (E.D. Penn).*

formularies that P&T committees include members who are engaged in research on new therapies for the elderly. These are exactly the kinds of experts and specialists who should participate in P&T committee decisions regarding a list of drugs that is clinically appropriate for senior citizens. Many physicians and pharmacists participate in some manner in clinical research related to drug development. *We urge CMS to adopt an approach that would not broadly eliminate all physicians or pharmacists previously or currently engaged in such research.*

Safeguards can be implemented to ensure that physicians or pharmacists with a clear conflict of interest are recused from P&T decisions directly impacted by such conflict. For example, CMS could require that P&T committee members with a conflict regarding a particular drug not participate in P&T committee decisions regarding that drug. CMS also could establish a framework for developing criteria to identify those experts who may have a conflict that would be likely to interfere with objective P&T committee decisions. Such criteria could include financial thresholds or other means of determining when members may have a conflict. These types of measures, along with a requirement that a majority of P&T committee members are independent and that each voting member has an equal vote, will help to ensure that the P&T committee process is designed to best consider the prescription drug needs of the Part D enrollee population.

d. P&T Committees and Drug Utilization Management -- § 423.120(b)(iii).

GSK recommends that robust safety and efficacy data be the primary information considered by P&T committees making formulary decisions. If supplemental information is considered, CMS should ensure such information is critically and appropriately assessed.

The Proposed Rule requires that P&T committees base formulary decisions on clinical considerations such as scientific evidence and standards of practice, including but not limited to peer-reviewed medical literature, randomized clinical trials, pharmacoeconomic studies, outcomes research data and other information as it deems appropriate.[75]

Robust safety and efficacy data should be the primary information considered by P&T committees that are making formulary decisions. While other data can be used, it should supplement the primary information. If supplemental information is considered, CMS should ensure such information is critically evaluated.

In particular, information derived from outcomes, pharmacoeconomic, and database studies can be helpful in assessing the effectiveness of a medicine in real world practice and its place within disease/illness management. Pharmacoeconomics is the scientific discipline that assesses the overall value of pharmaceutical health care products, services, and programs. It

[75] Proposed 42 C.F.R. § 423.120(b(iii).

addresses the clinical, economic, and humanistic aspects of health care interventions in the prevention, diagnosis, treatment, and management of disease. Data to conduct pharmacoeconomic evaluations are obtained from clinical trials, databases, outcome studies, health care and insurance data, epidemiology studies, and patients. Pharmacoeconomic studies often assess important patient driven data such as medication tolerability, as well as quality of life and compliance effects.

Results from pharmacoeconomic studies, however, are dependent on the type of evidence and study design that is used; thus the external and internal validity of the study must be critically assessed. *To this end, we urge CMS to take steps to ensure that P&T committees utilize well accepted economic research practice guidelines, such as those provided in the Academy of Managed Care Pharmacy Format for Formulary Submission, developed specifically to assist managed care organizations to appropriately consider pharmacoeconomic studies, outcomes research data, and other such economic information as a basis, in part, for their formulary decisions.*

This document provides guidance on the use of clinical and economic information in the formulary decision-making process, the transparency of study sponsorship, and the use of accepted standards and methods in conducting pharmacoeconomic research. *In addition, GSK recommends that CMS set standards for the education and experience of P&T committee staff to ensure they have the training necessary to review pharmacoeconomic studies.*

In sum, while scientific evidence of safety and efficacy should be the primary driver for formulary decisions, information on the cost-effectiveness or "value" of a medicine can be extremely helpful in considering the impact of a therapy on the total health care system. Pharmacoeconomic studies can help P&T committees assess the value of a medicine and the impact of utilization on the total health care budget, which is much more critical than a narrow focus solely on the impact a drug budget. *CMS should take steps, to ensure that pharmacoeconomic studies are critically and appropriately assessed.*

V. Subpart D -- Drug Utilization Review and Medication Therapy Management Programs -- § 423.153

a. Cost-Effective Drug Utilization Management -- § 423.153(b)

CMS should define the terms necessary to ensure that drug utilization programs are designed to improve health outcomes and total health care costs rather than to limit enrollee access to important drug therapies.

Under the MMA, a Part D plan sponsor or MA-PD plan must establish a cost-effective drug utilization management program. The Proposed Rule describes cost-effective drug utilization management as including incentives to reduce costs when "medically appropriate"[76] through the use of various cost containment tools. The Proposed Rule does not, however, define "costs," "cost-effective," or "medically necessary" – terms central to understanding how a drug utilization management program should work

GSK recommends that CMS clearly define the terms "costs," "cost-effective," and "medically necessary" in a manner that will ensure that drug utilization management does not impair enrollee access to critical drugs.

"Cost" and "cost-effective" are important concepts in designing a drug utilization management program. Although a Part D plan may bear some of the costs of providing prescription drugs to enrollees, other parts of the Medicare program will reap the benefits of appropriate prescription drug use, including decreased spending on hospitalizations, physicians' services, and nursing home care. "Cost" and "cost-effective" should be defined, therefore, to recognize the effect of appropriate use of drug therapies on total health care spending, not just the cost of the drugs themselves

We recommend that CMS define "cost" and "cost-effective" to include all of the expenses and savings for Medicare and the enrollee. To help stand-alone Part D plans with this assessment, we suggest that CMS provide these plans with information on all Medicare costs incurred by their enrollees.

We understand that a single definition of "medically appropriate" is difficult to form, given the constantly changing nature of medicine and the particular needs of an individual patient. The only way to ensure that drug utilization management fully and accurately considers the needs of the patient is to allow the enrollee's physician to determine what is "medically appropriate."

GSK urges CMS to define "medically appropriate" to mean "medically appropriate, as determined by the beneficiary's physician."

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[76] Proposed 42 C.F.R. § 423.153(b)(1).

b. Cost Containment Tools -- § 423.153(b)

Drug utilization programs should not be used to discriminate against certain classes of Part D enrollees. CMS should monitor plans' use of cost containment tools to ensure that such tools are not used to negatively affect beneficiary enrollment or health outcomes.

CMS proposes that cost-effective drug utilization management programs use cost containment tools such as requiring use of multiple source drugs, prior authorization, step therapy, and tiered cost-sharing.[77] GSK appreciates the use of private-sector cost-control devices, but we urge CMS to monitor carefully their use in Part D plans.

We are concerned that cost containment efforts, particularly by stand-alone plans, may lead to underutilization of drugs and increased spending for other types of health care services. For example, a stand-alone plan might seek to control costs by requiring enrollees to use an older, less costly therapy before a newer, more advanced drug would be covered. If the older drug is ineffective or causes unpleasant side effects, the patient may stop taking the drug, prolonging his or her illness and requiring more physician and hospital services. In such a case, a cost containment tool may reduce the plan's expenditures, but increase spending in other parts of Medicare. As we discussed above, Part D plans should take into account all costs and savings associated with appropriate drug use when designing their drug utilization management programs.

To this end, we urge CMS to ensure that cost containment efforts do not impair beneficiary access to appropriate drug therapies.

GSK commends CMS for recognizing that "appropriate drug utilization management programs would have policies and systems in place to assist in preventing over utilization and underutilization of prescribed medications."[78] Part D plans should dedicate as much attention to underuse as to overuse. When patients fail to adhere to their prescribed drug regimens by not taking all of their medications or by reducing their doses, they risk serious consequences to their health. These risks are particularly great for patients with chronic conditions such as congestive heart failure, diabetes, hyperlipidemia, asthma, COPD, and hypertension, which often require costly care in hospitals and nursing homes if not controlled through medications.

We encourage Part D plans to design drug utilization management programs to prevent underutilization of important prescription drugs and to help enrollees avoid painful and costly illnesses.

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[77] 69 Fed. Reg. at 46666-7.

[78] 69 Fed. Reg. at 46667.

Although we generally support drug utilization management programs, we are concerned that they may be used to discriminate against certain classes of Part D enrollees. Plans that direct their cost containment tools toward certain classes of drugs could discourage enrollees who need those therapies from enrolling or remaining in their plans.

GSK urges CMS to monitor plans' use of cost containment tools and direct plans to change their programs if their use affects beneficiary enrollment and health outcomes.

c. Medication Therapy Management Programs (MTMP)

CMS must (i) carefully define targeted populations, (ii) establish clear guidelines to ensure that these programs are used to promote appropriate use of medications and not simply as a cost containment tool, and (iii) ensure that neither program design nor reimbursement structure discourages the enrollment of certain groups of Medicare enrollees or negatively impacts health outcomes.

Under the MMA, a Part D plan must establish a medication therapy management program.[79] CMS proposes to use these programs to "provide services that will optimize therapeutic outcomes for targeted enrollees."[80] GSK supports the suggested uses of MTMPs: to promote the appropriate use of medications and reduce the risk of adverse events, increase enrollee adherence to prescription medication regimens, and detect adverse drug events and patterns of overuse and underuse. [81]

MTMPs are relatively new, and neither CMS nor many private insurers have extensive experience using or reimbursing for their services.[82] *GSK therefore urges CMS to carefully define the targeted populations and establish standards and guidelines for these groundbreaking programs.*

We agree with the Proposed Rule that MTMPs should be targeted toward enrollees with multiple chronic diseases who take multiple Part D covered drugs and who are likely to incur annual costs exceeding a fixed level.[83]

A well designed and implemented MTMP can be very valuable to enrollees with complex conditions. Studies have found that the majority of aged Medicare enrollees have one or more

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[79] SSA § 1860D-4(c).

[80] 69 Fed. Reg. at 46668.

[81] *Id.*

[82] *Id.*

[83] *Id.*

chronic conditions[84] and take more than eight outpatient prescription medications.[85] *Given the complexity of managing the many Medicare enrollees with co-morbidities and multiple medications, we suggest that CMS adopt a "more than one" approach in defining the multiple chronic diseases necessary to be eligible as a "targeted beneficiary."*

This approach is consistent with MMA's use of the term "multiple" to mean more than one. In addition, any other approach may mean that a significant number of enrollees who need medication therapy management services might not be able to take advantage of these programs. For example, based on CMS's own studies, on average, a beneficiary with one or two chronic conditions has approximately 19 filled prescriptions, whereas a beneficiary with three or four chronic conditions has approximately 32 filled prescriptions.[86] *By defining "multiple" chronic diseases to mean more than one chronic condition, CMS will help to assure that MTMP services are available to the enrollees who need them.*

In addition, when providing guidance on MTMPs, CMS should consider that targeted enrollees with multiple chronic diseases may be receiving care through a number of different physicians, any number of whom who may be providing prescriptions for multiple drugs. For example, enrollees with two chronic conditions have, on average, five physicians, while enrollees with four chronic conditions have eight physicians.[87] Effective MTMPs factor in the multiple prescribers and should educate enrollees about the need for effective communication among the enrollee's physicians.

Establish clear guidelines: These patients' health depends on appropriate use of their prescription medications. We recommend that MTMPs provide these patients with one-on-one education and counseling to help them adhere to their drug regimens and prevent harmful underutilization.

Medication adherence is a significant health care dilemma. Research indicates approximately 50% of patients never fill their initial prescription.[88] Twenty to eighty percent make errors in taking their medications.[89] Additionally, thirty to sixty percent of patients stop

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[84] Copeland C, *Prescription Drugs: Issues of Cost, Coverage, and Quality*, EBRI Issue Brief, 1999 Apr; (208):1-21

[85] Wolff JL, et al., "Prevalence, Expenditures, and Complications of Multiple Chronic Conditions In the Elderly," Arch Intern Med. 2002 Nov 11; 162(20):2269-76.

[86] Centers for Medicare and Medicaid Services, CMS Chart Series, *Medicare Program Information: Profile of Medicare Beneficiaries*, found at http://www.cms.hhs.gov/charts/series/sec3-b1-9.pdf

[87] *Id.*

[88] World Health Organization: Adherence to Long-Term Therapies: Evidence for action. Available at http://www.who.int/chronic_conditions/en/adherence_report.pdf

[89] Gotlieb H. Medication nonadherence: finding solutions to a costly medical problem. *Drug Benefit Trends*. 2000;12(60:57-82

taking their medications too soon.[90] Furthermore, eighty-eight percent of prescriptions are filled for chronic conditions, but only twenty percent take the medication as prescribed.[91]

As the *Journal of Clinical Psychiatry* cautions,:

"The consequences of drug noncompliance may be serious in older patients. Estimates of the extent of noncompliance in the elderly vary, ranging from 40% to a high of 75%. Three common forms of drug treatment noncompliance are found in the elderly: overuse and abuse, forgetting, and alteration of schedules and doses. Some older patients who are acutely ill may take more than the prescribed dose of a medication in the mistaken belief that more of the drug will speed their recovery. Such overuse has clearly been associated with adverse drug effects. Forgetting to take a medication is a common problem in older people and is especially likely when an older patient takes several drugs simultaneously. Data suggest that the use of three or more drugs a day places elderly people at particular risk of poor compliance. The use of at least three drugs, and often more, is common in the elderly, with estimates of as many as 25% of older people taking at least three drugs. Averages of drug use among elderly hospitalized patients suggest that eight drugs taken simultaneously may be typical. Problems may also arise when dementia or depression is present, which may interfere with memory. The most common noncompliant behavior of the elderly appears to be underuse of the prescribed drug. Inappropriate drug discontinuation, furthermore, may occur in up to 40% of prescribing situations, particularly within the first year of a chronic care regimen. As many as 10% of elderly people may take drugs prescribed for others; more than 20% may take drugs not currently prescribed by a physician ."[92]

Ensure that neither program design nor reimbursement structure discourages enrollment: GSK recommends that CMS provide clear instructions to Part D plans on reimbursement for MTMP services. We urge CMS to prohibit plans from using reimbursement for MTMP services to direct patients to or away from specific plans or drugs. We also recommend that a plan's reimbursement for MTMP services be included in CMS's review of whether a plan substantially discourages enrollment of certain groups of Medicare enrollees. Finally, although CMS states that it believes payment for MTMP services is separate and distinct from dispensing fees,[93] we recommend that CMS explicitly prohibit any linkage between these payments.

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[90] NACDS and Drug Topics archives (3/3/97).

[91] *Id.*

[92] Salzman C. Medication compliance in the elderly. J Clin Psychiatry. 1995;96 Suppl 1:18-22; discussion 23

[93] 69 Fed. Reg. at 46669.

d. **Cost Control and Quality Improvement (QI) Requirements for Prescription Drug Plans**

GSK recommends that QI standards and systems used by Part D plans

- **include a focus on potential underutilization,**
- **focus on clinical contraindications and adverse drug-to-drug interaction, and**
- **be subject to oversight by the Part D plan's P&T committee**

Due to the specific characteristics of the Medicare population, it is essential that QI standards and systems designed specifically for this population be utilized by Part D plans. The higher rate of physical morbidity and greater chance of receiving multiple prescription drugs[94] increases the risk that older adults will suffer from adverse drug reactions. In addition, biologic and physiologic changes caused by aging may lead to increased sensitivity to differing drug dosages or altered pharmacokinetics.[95] Finally, when examining the patient's perspective in taking prescribed medicines, it is found that physical, psychological, and economic considerations often interfere with their ability to obtain and comply with their medication regimens.[96]

We support the efforts of CMS in evaluating the status of existing QI programs and considering how to modify such programs for the Medicare population. We encourage CMS to update program requirements on an ongoing basis as best practices for this population are identified. We provide some recommendations for consideration below.

1. CMS's proposal to link the QI programs and DUR is an important one. Cost containment mechanisms must be a component of the Part D program. However, there is the potential for underutilization of necessary medications when DUR is applied and only drug costs are considered. *The QI program should include a focus on potential underutilization, providing a necessary balance between the need for cost containment mechanisms and the dangers of underutilization.*

For example, depressive disorders are estimated to affect nearly 1 in 10 adults in America. NCQA's Antidepressant Medication Management HEDIS measure clearly shows that pharmacological management of depression is far below guideline recommendations, particularly for the Medicare population (Acute Phase = 55.3%,

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94 Katona CL, "Psychotropic and Drug Interactions in the Elderly Patient," *Int. J. Geriatr Psychiatry*, 2001 Dec.; 16 Supp I:S86-90

95 Reidenberg, MM, "Drug Interactions and the Elderly," *J Am Geriatr Soc*. 1982 Nov; 30 (11 Suppl): S67-8 [1982]

96 Morris LS, Schulz RM, Medication Compliance: The Patient's Perspective. *Clinical Therapeutics* 1993; 15 (3): 593-606.

Continuation Phase = 39.2%).[97] The State of Health Care Quality 2004 reports there has been no improvement in the Medicare rate for the measure from the previous year. Average Medicare scores continue to lag 5 to 10 points below those reported by commercial health plans.

2. *The quality improvement programs should be subject to oversight by the Part D plan's P&T Committee.* This design would allow the P&T Committee to ensure appropriate access and clinical efficacy while allowing the plans autonomy to determine their best organizational structure.

3. *QI programs should focus on clinical contraindications and adverse drug-to-drug interactions would particularly benefit special needs Medicare beneficiaries and Medicare dual-eligibles*.

[97] National Committee for Quality Assurance; 2004 *The State of Health Care Quality*;©2004 by NCQA.

VI. Subpart C – Patient Assistance Programs and TrOOP -- § 423.100

GSK urges CMS to provide specific guidance in the final rule regarding whether pharmaceutical manufacturers' patient assistance programs ("PAPs") may provide assistance in paying enrollees' out-of-pocket cost-sharing obligations during the doughnut hole, and if so, whether that assistance would count towards the enrollee's TrOOP. In addition GSK urges CMS to seek the input of the Office of the Inspector General ("OIG") to provide manufacturers clear guidance on how PAPs may be allowed to assist enrollees with Part D prescription drug expenditures.

CMS proposes to allow assistance that enrollees receive from certain charitable organizations to count as "incurred costs"[98] for purposes of reaching catastrophic coverage. In doing so, CMS has defined "person" to include bona fide charities "unaffiliated with employers or insurers."[99] The Proposed Rule notes that to be permissible, such arrangements must comply with Federal fraud and abuse laws, including the anti-kickback statute, section 1128B(b) of the Act, as well as the civil monetary penalty provision at section 1128A(a)(5) of the Act. CMS further states that it is "considering whether assistance in paying enrollees' cost-sharing obligations provided through prescription drug patient assistance program sponsored by pharmaceutical manufacturers would be allowed"[100] under these laws.

GSK has a long history of assisting low-income patients. We would like to be able to continue to provide assistance to low-income Medicare enrollees in the doughnut hole who do not qualify for subsidies under Part D. In the first half of 2004, GSK provided more than $162 million worth of medicines to patients through our patient assistance programs. Approximately 35% of the patients enrolled in our programs are Medicare-eligible. Most of those patients have incomes below 135% of the federal poverty level and will receive a full subsidy under Part D, and thus will not be affected by the doughnut hole. However, approximately 10% of our enrollees are Medicare-eligibles with income above 135% of the federal poverty level. They may not be able to bear the burden of paying out-of-pocket for their drugs during the doughnut hole.

We are concerned, based on commentary in the Preamble to the Proposed Rule, that we may not be able to continue to provide assistance under the Proposed Rule and current law. One concern is that the provision of such assistance may result in an enrollee failing to reach a level where they would qualify for reduced cost sharing for all their drugs. In effect, if assistance provided through a PAP does not count toward TrOOP, the individual will still be responsible for paying the full amount of costs for other drugs up to the out-of-pocket threshold for other drugs.

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98 Proposed 42 C.F.R. § 423.100.

99 69 Fed.Reg. at 46650; *see also* Proposed 42 C.F.R. § 423.100.

100 69 Fed.Reg. at 46650.

Also, as CMS has noted in the Proposed Rule, it is not clear whether such assistance would be allowed under the aforementioned Federal fraud and abuse laws.

To continue to help low-income senior citizens who may not be able to afford the cost-sharing required under the Part D benefit, we will need assurances that assistance provided by manufacturers to enrollees is expressly allowed under the Federal fraud and abuse laws in a program where Medicare also is a payer. For manufacturers to be able to provide such assistance, CMS will need to obtain specific guidance on this issue from the HHS Office of Inspector General ("OIG").

We urge CMS to seek the OIG's input in providing manufacturers clear guidance on how PAPs may be allowed to assist enrollees with Part D prescription drug expenditures. We also urge CMS to clarify the types of assistance that manufacturers can provide, and clarify that the provision of such drugs would count toward an individual's out-of-pocket costs for purposes of qualifying for catastrophic coverage

Furthermore, CMS also needs to provide clear guidance on the valuation of the assistance provided by manufacturer PAPs for purposes of counting towards an enrollee's TrOOP.

VII. SPAPs and Part D

CMS should clarify that prices negotiated with a pharmaceutical manufacturer for Covered Part D drugs by a state pharmaceutical assistance program ("SPAP") as defined in Sections 423.4 and 423.464 of the Proposed Rule may be excluded from a pharmaceutical manufacturer's "best price" calculation for purposes of section 1927 of the Social Security Act (the "Medicaid Rebate Statute")

CMS should clarify that prices negotiated with a pharmaceutical manufacturer for Covered Part D drugs by a state pharmaceutical assistance program ("SPAP") as defined in Sections 423.4 and 423.464 of the Proposed Rule may be excluded from a pharmaceutical manufacturer's "best price" calculation for purposes of section 1927 of the Social Security Act (the "Medicaid Rebate Statute"). To do so, CMS must eliminate the confusion created by contradictory definitions of SPAPs in the Proposed Rule and recent guidance issued by CMS in the context of the Medicaid Rebate Statute.

Specifically, the Medicaid Rebate Statute, at § 1927(c)(1)(C)(i)(III) of the Social Security Act, excludes "prices used under a State pharmaceutical assistance program" from consideration in computing a pharmaceutical manufacturer's "best price" for the drug. However, guidance issued by CMS on June 23, 2003, through Medicaid Rebate Program Release No. 59 (restated in CMS State Medicaid Director Release # 124) ("Release 59"), put in place a set of criteria that have caused CMS to conclude that some SPAPs should not be excluded from best price computation, while other states' programs can be excluded from the best price computations. However, the Proposed Rule and Release 59 can be read as having conflicting definitions, as is explained more fully below.

This is problematic because the definition of an SPAP in the Medicare Modernization Act ("MMA") and the rules ultimately promulgated thereunder will not stand alone. Manufacturers will also have to consider the application of relevant CMS releases when considering the 'best price" implications of the prices negotiated with SPAPs for <u>all</u> the populations that may be served by the SPAP. The definition of SPAP for Medicare part D purposes will apply only to the subset of SPAPs that serve individuals who are also eligible for Medicare part D. Nevertheless, SPAPs also serve indigent, unemployed, and other individuals who are not eligible for Medicare, Medicaid, or other insurance programs. Indeed, some SPAPs serve -- and will likely continue to do so -- both Part D eligible and non-Part D eligible populations.

CMS should make it clear that prices offered by pharmaceutical manufacturers under both types of SPAPs should be excluded from a manufacturer's best price computation. Without clarification, it would be difficult, if not impossible, for a manufacturer to know if prices it has offered to an SPAP could be excluded from its best price calculation as a result of the contradictory definitions of SPAPs. SPAPs may not be able or willing to submit separate utilization data to manufacturers for its Part D eligible and non-Part D eligible enrollees. Such a

clarification would also encourage manufacturers to continue to offer discounts to SPAPs that provide pharmaceutical benefits to non-Part D eligible beneficiaries.

For example, CMS suggests in Release 59 that one defining feature of an SPAP is that the SPAP must be "specifically for disabled, indigent, low-income elderly or other financially vulnerable persons." There is no such "low-income" requirement in the MMA definition of an SPAP or under the Proposed Rule. Similarly, Release 59 suggests that to qualify as an SPAP, the program can not be funded with any Federal dollars. In contrast, the Proposed Rule excludes from the definition of an SPAP, among other things, any "program where the majority of the funding is from Federal grants, awards, contracts, entitlement programs or other Federal sources of funding" (§ 423.464(e)(iv) of the Proposed Rule (emphasis added)), thereby suggesting that some amount of Federal funding is acceptable for SPAPs in the context of the MMA.

It would not be in anyone's interest to permit confusion over definitions in a Medicaid rebate program guidance to undermine the coordination of part D benefits and SPAPs. To prevent this result, we propose that CMS define "State pharmacy assistance program" in the final regulations in a way that applies to SPAPs that serve either Part D eligible beneficiaries or non-Part D eligible beneficiaries, or both, and that will serve as an exemption from best price provision of the Medicaid Rebate Statute.

Furthermore, to make the criteria meaningful, we propose that the regulations provide an assurance that pharmaceutical manufacturers can rely in good faith upon an SPAP's representation that it meets the criteria to be excluded from the best price computation under the Medicaid Rebate Statute.

We propose that CMS clarify the provisions applicable to SPAPs by modifying § 423.464(e)(4) "Construction," by placing "(i)" after the title and adding new subparagraphs (ii) and (iii) at the end thereof, to read as follows:

(ii) Definition of an SPAP for purposes of Section 1927 of the Social Security Act. Notwithstanding § 423.464(e)(1), an SPAP operated by or under contract with a State shall be considered a "State pharmaceutical assistance program" for purposes of Section 1927 of the Social Security Act if it:

(A) is a program designed by or on behalf of a State specifically for disabled, indigent, elderly or other financially vulnerable persons;

(B) is not a State Medicaid program, a section 1115 demonstration program, or any other program where the majority of funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding; and

(C) either

(I) directly dispenses pharmaceutical products to its qualified beneficiaries or directly reimburses providers, Medicare-endorsed discount cards, a Medicare prescription drug plan, or a Medicare Advantage prescription drug plan; or

(II) provides assistance with the cost-sharing requirements of a private health plan, a Medicare part D plan or a Medicare Advantage prescription drug plan, or provides a pharmaceutical benefit or discount, either alone or in conjunction with other medical benefits or services.

(iii) *Pharmaceutical Manufacturer's Good Faith Reliance. For purposes of filing price reports under § 1927 of the Social Security Act, a pharmaceutical manufacturer can rely in good faith upon an SPAP's assurance that the SPAP meets the criteria of this part.*

VI. Subpart C.1.a. and Subpart J.6.c. – Coordination of Benefits Under Part B and Part D

To minimize confusion by enrollees and physicians and to ensure that patients obtain appropriate access to medically necessary therapies, GSK encourages CMS to provide seamless coordination of the Part B and Part D benefits

We urge CMS to clarify that the statement in the preamble that "*any drug covered under A or B could not be covered under D, whether it was covered for that individual or not*" applies only to individuals who have declined to enroll in Part B, with respect to drugs for which Part B coverage would have been available for that individual under Part B.

GSK supports CMS's recognition of Part D as a benefit intended to fill gaps in existing Medicare coverage of prescription drugs[101] and to implement Part D in a manner that "'wraps around' existing Part B drug benefits to the greatest extent possible."[102] Medicare Part B provides only limited coverage for drugs provided incident to a physician's service. Part D will provide Medicare enrollees with greater access to the therapies they need.

To minimize confusion by enrollees and physicians and to ensure that patients obtain appropriate access to medically necessary therapies, GSK encourages CMS to provide seamless coordination of the Part B and Part D benefits.

The coordination process should allow physicians to submit claims under Part B for consideration if the product was administered by the physician and arrange for any portion of the claim rejected under Part B to be automatically submitted to the patient's plan. The Part D plan would then reimburse the physician as an out-of-network provider. This process would reduce delays in needed care for these enrollees. Additionally, GSK urges CMS to consider the needs of special populations, including cancer patients among others, whose continuity of care should not deteriorate due to the interaction between Part B and Part D. We specifically address our recommendations with respect to special populations elsewhere in this document.

Additionally, we are concerned that the preamble language to Subpart J.6.c. creates some confusion. CMS states that "any drug covered under A or B could not be covered under D, whether it was covered for that individual or not."[103] This appears to be inconsistent with the provisions of the MMA and the Proposed Rule.

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101 69 Fed.Reg. at 46646.

102 69 Fed.Reg. at 46647.

103 69 Fed.Reg. at 46703.

We urge CMS to clarify that this statement applies only to individuals who have declined to enroll in Part B, with respect to drugs for which Part B coverage would have been available for that individual under Part B.[104]

To highlight some of the potential concerns facing enrollees who may have coverage under both Part B and Part D, we discuss specific examples were the interaction between Part B and D will be complicated. As background, under the MMA and the Proposed Rule, benefits will not be available under Part D for any drug for which payment is available under Part B for that individual.[105]

CMS has clarified that administration and dispensing will include "the setting, personnel, and method involved, and not simply the route of administration."[106] Enrollees will obtain benefits under Part B, where available, unless the Part B coverage criteria are not met. These criteria generally include that the drug is purchased and administered by the physician and that the therapy usually is not self-administered by the patient. If any of these criteria are not met, then the drug will be covered under Part D, as long as the drug is on the formulary or the enrollee has received an exception to the formulary. Thus, Part D coverage will be available in circumstances in which the individual is capable of self-administering a drug that typically is administered in a physician's office or outpatient setting. This interpretation is consistent with the intent of the MMA.

However, there are some products that may not be defined in such a straightforward fashion because they could be covered either under Part B or Part D, depending on the medical use for the product or the medical condition of the individual beneficiary. For example, Zofran® (ondansetron hydrochloride) is a treatment for chemotherapy induced nausea and vomiting (CINV) and for post operative nausea and vomiting (PONV). While the intravenous form of Zofran is clearly covered under Part B, the oral forms of the product can be covered under Part B if it is prescribed for use as an acute anti-emetic used as part of an anti-cancer chemotherapeutic regimen within 48 hours after the time of the administration of the anti-cancer chemotherapeutic agent as a full replacement for the anti-emetic therapy which would otherwise be administered intravenously or under Part D for other uses of the product, including product that is dispensed by the physician for PONV, or as adjunctive therapy to an intravenous anti-emetic. Therefore, if an oncologist uses IV Zofran prior to chemotherapy then the oral product would not be reimbursed for the 48 hour period post chemotherapy for the prevention of delayed nausea and vomiting under the DMERC provisions of the Part B benefit but could be reimbursed under Part D.

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104 We note that the MMA does not require that Part D benefits be unavailable in these circumstances to Medicare enrollees who have chosen not to enroll in Part B.

105 SSA § 1860D-2(e)(2)(B); Proposed 42 C.F.R. § 423.100.

106 69 Fed.Reg. at 46646.

A second example is hepatitis B vaccine. Part B currently covers hepatitis B vaccine furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations). Those regulations do provide definitions of high or intermediate risk, but also exclude patients who have chronic liver disease and others with a medical need for immunization against hepatitis B. Therefore, Part B would pay for hepatitis B vaccine for a patient who is defined as being at high or intermediate risk of hepatitis B but Part D would pay for hepatitis B vaccine for a patient with chronic liver disease.

Lastly, because immunization traditionally is covered as a medical benefit and not a pharmacy benefit, vaccine delivery even for those vaccines that fall entirely within the Part D benefit must be carefully coordinated to ensure that inclusion of vaccines on a plan formulary translates into a meaningful benefit for enrollees. This will require that vaccine administration be included in the definition of dispensing fee as well as clarification regarding how these claims should be processed, since vaccines tend to be purchased and administered by physicians.

VIII. Subpart C -- Dispensing Fees -- § 423.100

CMS should extend the definition of "dispensing fees" to include the administration costs associated with vaccines

CMS has proposed three possible interpretations of "dispensing fees" that would include alternative methods of accounting for costs associated with certain products. CMS is considering limiting an expanded definition of dispensing fees to home infusion therapies in that home infusion represents "the only circumstance we know of where the additional services associated with administering the drug would not already be covered under Medicare Part A or B and would be necessary to ensure effective delivery of the drug."[107] CMS requests comments on whether the administration of other drugs, specifically vaccines, may pose similar access problems for enrollees absent payment for administration supplies and services.[108] It will be important for CMS to ensure that the costs of vaccine administration are properly incorporated into the dispensing fee.

To best ensure Part D enrollees meaningful access to appropriate therapies, CMS should adopt the third option, which would include the costs of supplies, equipment and professional services necessary to administer home infusion drugs.[109] In proposing the third option, CMS recognizes that, absent payment for the supplies and services necessary for administration, certain pharmaceuticals or biologicals may, as a practical matter, be unavailable to many Part D enrollees, undermining the purpose of the Part D benefit.

CMS should, therefore, extend this definition to include the administration costs associated with vaccines. This policy would be consistent with existing Medicare Part B policy regarding vaccines. Part B covers only a limited number of vaccines, but for these vaccines Part B covers both the cost of the vaccine and the cost of administration. This ensures that enrollees for whom a vaccine is covered under Part B have meaningful access to this benefit. Congress clearly intended for the Part D benefit to include vaccines, specifically including vaccines in the statutory definition of covered Part D drugs. Thus, to provide meaningful coverage for vaccines, payment will need to include administration costs. Inadequate coverage of the administration costs will likely have a negative effect on vaccination rates among Medicare beneficiaries.

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107 69 Fed.Reg. at 46648.

108 69 Fed.Reg. at 46648.

109 69 Fed.Reg. at 46647.

IX. Subpart M -- Grievances, Coverage Determinations and Appeals

The exceptions, appeals and grievance processes CMS proposes will not adequately protect Medicare enrollees enrolled in Part D plans and will make it difficult for them to navigate the appeals process to obtain therapies. We urge CMS to redesign its proposed framework to provide Part D enrollees with a clear and reasonable way to obtain the prescription drugs they need. Our specific suggestions are as follows:

1. Reduce the Timeframe for the Appeals Process

CMS must reduce the timeframe in which plans must respond to enrollee appeals or requests for exceptions to provide enrollees with adequate access to the prescription drug benefit.

GSK is concerned that enrollees will experience significant delays in accessing prescription drugs that their treating physician(s) feel are most appropriate because a Part D plan has determined that an appeal must be initiated. The MMA requires that Part D plans follow an appeals process that is consistent with the existing process for appeals of Part C benefits under Medicare Advantage plans.[110] In fact, CMS proposes a process that largely mirrors the Part C appeals process. The MMA does not require, however, that the process for appeals under the Part D benefit incorporate the same timeframes as are set forth for Part C benefits. CMS may shorten the timeframes and still meet the statutory requirement that the appeals process for Part D is consistent with the Part C appeals process.

Reducing the timeframe for appeals would appropriately reflect the difference between prescription medications and other services as well as the manner in which prescription drugs generally are paid. Under Part C, appeals typically relate to payment for physician and hospital benefits after the beneficiary already has received the services. Under Part D, however, an enrollee may be denied a necessary drug at the pharmacy. Thus, under Part D, the enrollee must either go without the drug or pay for the drug out-of-pocket until the appeal is resolved. If an enrollee cannot afford to pay for the drug, the enrollee will need to take a formulary drug that may be less effective or has greater side effects and may not represent the best therapeutic option in the opinion of the treating physician. The enrollee may be forced to go without the therapy altogether while the appeal is resolved. In either case, the enrollee will forgo the therapy that his or her physician deemed most effective.

[110] SSA § 1860D-4(g).

In addition to the therapeutic and financial burdens the length of this process may impose on an enrollee, this process also may require the enrollee to make multiple visits to his or her physician(s) and the pharmacy, thus increasing the burden on frail or elderly patients.[111]

GSK urges CMS to reduce the timeframe of the appeals process to lessen the burden on enrollees and to ensure adequate access to medically necessary drugs. Clearly, the most expedient and beneficial process for the enrollee would be for online, point-of-sale adjudication. Most health plans, or their PBMs, have the ability for online contact with a clinical pharmacist who can make contact with the treating physician to obtain any information necessary to resolve the appeal while the patient is in the pharmacy. Only if a contemporaneous resolution cannot be reached would further appeals processes be implemented.

GSK also recommends that CMS reduce the timeframe for the exceptions process. Given the importance of continuity in how many medications are taken, the timeliness in responding to an exception request is particularly important to the implementation of a meaningful prescription drug benefit. Indeed, Congress recognized the unique challenges that an appeals process may pose for a prescription drug benefit by specifically requiring plans to institute a separate exceptions process. It is not useful to have a separate exceptions process if the timeframe for that process may be as long as for the regular appeals process. *We request that CMS modify the exceptions timeframe to require Part D plans to respond to an exceptions request within 72 hours or at the point-of-sale, if possible. This is consistent with the practice typical in private plans, and will allow enrollees to better access the therapies they need.*

2. Provide Access to an Emergency Supply of Medication

Plans should be required to provide enrollees with an emergency supply of medication while resolving any appeals or exceptions requests.

CMS proposes that a plan be required to provide an emergency supply of medication only for continued coverage of a drug being removed from the plan's formulary, where the plan has failed to act on an exceptions request within a certain timeframe.[112] CMS makes no provision for an emergency supply during the normal course of the exceptions process or during the appeals process.

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111 The financial burden on enrollees here is increased by the fact that enrollees may not have access to negotiated prices for drugs not on the formulary. Under the Proposed Rule, negotiated prices must be available to enrollees if no benefits are payable due to the application of a deductible or 100% coinsurance requirement. 42 C.F.R. § 423.104(h).

112 Proposed 42 C.F.R. § 423.578(c)(2).

GSK recommends that CMS require plans to make an emergency supply of a drug available anytime an enrollee is already taking the drug and an exceptions request or appeal is underway, not simply when a plan has failed to act in a timely manner.

It is not medically appropriate for a patient to simply discontinue an ongoing therapy or switch therapies during an appeals process. This is particularly true for vulnerable populations, including individuals that have multiple medical conditions or need drugs that require very individualized dosing, such as antidepressants or antipsychotics.

Furthermore, proper drug therapy is a function not only of prescribing the correct drug, but also of titrating to the correct dose, especially with agents that have a very narrow therapeutic window. Failure to maintain the patient at adequate dosing could put the enrollee at an increased medical risk. This requirement will provide the enrollee with continued access to an ongoing necessary therapy, as well as provide plans with an appropriate incentive to respond to exceptions requests and appeals in a timely fashion.

3. Clarify that Denial of a Claim is a Coverage Determination

The denial of a claim at the pharmacy should be considered a coverage determination for purposes of enabling an enrollee to begin the appeals or exceptions process.

Under the Medicare program, a denial of benefits generally is considered an adverse coverage determination that triggers a requirement that a notice and an explanation of appeal rights be sent to the beneficiary. Under the Proposed Rule, however, a Part D enrollee – or his or her authorized representative – would need to initiate and seek a "coverage determination" or "exception" from his or her Part D plan; denial of a claim at the pharmacy would not be sufficient.

GSK is concerned that this is inconsistent with the Medicare program and will impede an enrollee's ability to appeal. Failure to maintain proper drug therapy throughout the appeal process could subject the enrollee to untoward medical outcomes.

We request that CMS clarify in the final rule that the denial of the claim at the pharmacy is a coverage determination. This will allow an enrollee to receive information about the appeals process at the point of the denial. This also will eliminate an extra, unnecessary step by allowing an enrollee whose claim has been denied to seek an appeal without first having to request a coverage determination.

4. Allow Appeals When the Enrollee Has No Payment Liability

Eliminate the prohibition on appeals where an enrollee has no financial liability.

Under the Proposed Rule, an appeal right would not exist when the enrollee bears no payment liability.[113] This provision is inconsistent with the goals of Part D, and *we strongly urge CMS to eliminate this provision in the final rule.*

Under the Proposed Rule, an enrollee's authorized representative or prescribing physician may request a coverage determination[114] or an exception.[115] Yet CMS proposes to disallow an appeal where another party – such as a family member, other health insurance, or a State Pharmaceutical Assistance Program ("SPAP") – has paid for the prescription. The MMA specifically contemplates that at least some enrollees will have access to assistance with their prescription drug costs from sources other than Part D. [116] The MMA also expressly requires Part D plans to coordinate with SPAPs.

Prohibiting appeals where a third party has provided payment for a drug is likely to discourage these third parties from providing such payment until a Part D appeal has been exhausted. This will be particularly detrimental to those low-income enrollees who rely on SPAPs to access prescription drugs. Ultimately, the burden of the appeals process will shift to the enrollees least able to manage such a complex process.

In the meantime, such expenditures for non-formulary drugs will not count as "incurred costs" for purposes of reaching the out-of-pocket limit. This will result in enrollees taking longer to reach their catastrophic coverage, which, in turn, will increase the liability of SPAPs and other charitable organizations that assist low-income enrollees with their prescription drug costs. This prohibition also has the effect of relieving Part D plans from their obligations to enrollees. Part D plans will have a strong incentive to shift costs to an enrollee's other health coverage, because the Part D plan will be protected from appeals.

GSK strongly urges CMS to eliminate this provision and clarify that Part D plans are required to pay for drugs consistent with their agreement with CMS and their obligations under the MMA and implementing regulations, regardless of whether an enrollee has secondary coverage.

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[113] Proposed C.F.R. § 423.562(c)(1).

[114] Proposed 42 C.F.R. § 423.566.

[115] Proposed 42 C.F.R. § 423.578(a)(3).

[116] *See, e.g.*, Proposed 42 C.F.R. § 423.452 – 42 C.F.R. § 423.464.

5. Provide Access to Therapies After Mid-Year Formulary Changes

Enrollees taking a drug should be granted continued access to that drug at the same cost-sharing level for the duration of the plan year; alternately, an automatic exceptions process should be instituted for these enrollees upon a formulary change as well as for dual eligibles as they switch from Medicaid to Part D.

CMS proposes that Part D plans be required to establish an exceptions process for situations in which an enrollee is using a drug and the formulary or cost-sharing status changes mid-year or at the beginning of a plan year.[117] *GSK urges CMS to prohibit plans from making changes mid-year that result in removal of a drug from a formulary or increases the cost-sharing required of an enrollee. Otherwise, plans can engage in "bait-and-switch" tactics to the detriment of the enrollee.*

If CMS declines to require plans to limit such changes to the beginning of a plan year, we request that CMS provide a mechanism for automatic exceptions request for enrollees already taking a drug for which the formulary or tiered status is changed. For these enrollees, a plan would need to respond to an automatically generated exceptions request. Otherwise, these enrollees will receive notice of the drug's change in status, have to seek a coverage determination, and then have to initiate an exceptions request. This will result in delays in receiving treatment. For many drug therapies, it is not clinically acceptable for an enrollee to stop and then re-start a prescription while the exceptions or appeals process is resolved. As noted above, such changes may require laboratory tests and physician visits.

We also urge CMS to institute such an automatic exceptions process for dual eligibles when they first switch to Part D. Again, this would enable these enrollees to maintain their current therapies while the exceptions process is underway.

6. Standards for Reviewing Exceptions Requests

The final rule should allow plans to require a prescribing physician to certify that a therapy <u>would not be</u> as effective for an individual.

The MMA requires plans to pay for a nonpreferred drug under the same terms applicable to a preferred drug where the prescribing physician has determined that the preferred drug would not be as effective for the individual for treatment of the same condition, would have adverse effects for the individual, or both.[118] In the Proposed Rule, CMS has established several criteria in addition to the physician's certification required by the MMA that plans must consider during

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117 Proposed 42 C.F.R. § 423.578(a)(1)(i)-(ii); § 423.578(b)(1)(ii).

118 SSA § 1860D-4(g)(2).

review of an exceptions request for a preferred formulary placement. *We urge CMS to remove these additional requirements and revise this regulatory provision to appropriately reflect the intent of the MMA.*

CMS should require a plan to grant an exceptions request where the prescribing physician makes the MMA-required certifications. This would appropriately defer to the prescribing physician as the best determinate of what drug is the safest, most effective, and medically necessary for an individual patient.

GSK also is concerned that CMS has not properly implemented the MMA in implementing the physician certification provision. The MMA permits a Part D plan to require a physician's certification that a preferred drug "*would not be* as effective for the individual or *would have* adverse effects for the individual or both."[119] In the Proposed Rule, CMS allows a plan to require a physician's written certification that a preferred drug "*is* not as effective for the enrollee" as the requested drug.[120] These proposed regulations could be viewed as permitting plans to institute step therapy or "fail first" requirements prior to granting an exceptions request.

We urge CMS to finalize this provision by allowing plans to require the prescribing physician to certify that a therapy would not be as effective for an individual.

7. Therapeutic Equivalence

CMS should not establish a different definition of therapeutic equivalence for the exceptions process than it does for the rest of the Part D benefit, and therapeutic equivalence should be defined in reference to the Orange Book.

The Proposed Rule states that a plan's exceptions criteria should include "[c]onsideration of whether the requested prescription drug that is the subject of the exceptions request is the therapeutic equivalent of any other drug on the sponsor's formulary."[121] Not only has CMS imposed extra criteria on the exceptions process, but in doing so CMS has also inappropriately included a special definition of "therapeutically equivalent" applicable only to this subsection.

For purposes of the exceptions process, the Proposed Rule defines "therapeutically equivalent" as a preferred drug that has "equal effect and no difference when substituted for the requested drug."[122] Yet the definitions section of the Proposed Rule -- § 423.100 -- defines "therapeutically equivalent" as referring to "drugs that are rated as therapeutic equivalent under

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119 Id. at § 1860D-4(g)(2) (*emphasis added*).

120 Proposed 42 C.F.R. § 423.578(a)(4).

121 Proposed 42 C.F.R. § 423.578(a)(2)(iii).

122 Proposed 42 C.F.R. § 423.578(a)(2)(iii).

the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations.'"[123]

GSK supports the definition proposed in § 423.100 as the commonly accepted definition of "therapeutically equivalent." *We urge CMS to avoid establishing a separate definition for exceptions requests.*

X. Subparts C, F, G, K, Q, and R -- Disclosure of Negotiated Price Information

GSK urges CMS to

(1) extend the confidentiality protection of the Medicaid Rebate statute to information obtained by CMS to carry out Medicare payments to Part D plans, data regarding specific drug claims, and other information that CMS deems necessary under various sections of the Proposed Rules, and all negotiated price information submitted to or reviewed by CMS under part D;

(2) make explicit that the Trade Secrets Act[124] applies to pricing or other confidential information that CMS obtains or reviews from plans as it implements Part D;

(3) adopt a regulation mirroring the section of the Federal Acquisition Regulation relating to the protection of confidential and proprietary information; and

(4) provide notice to pharmaceutical manufacturers prior to releasing confidential information under the Freedom of Information Act

1. GSK urges CMS to extend the confidentiality provisions of the Medicaid rebate statute to all of the information that CMS may obtain from plans in the course of administering the Part D benefit.

In the Proposed Rule, CMS specifies the types of information it may require plan sponsors and MA organizations to report. This information includes data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers and passed through to

[123] Proposed 42 C.F.R. § 423.100

[124] 18 U.S.C. § 1905.

Part D enrollees,[125] information necessary to carry out Medicare payments to plan sponsors and MA organizations,[126] data regarding drug claims at an individual level,[127] and other information the agency deems necessary.[128] In addition to these types of information, CMS expects to request detailed pricing information from Part D plans so that it may review the appropriateness of bids, compare bids, and determine allowable costs associated with reinsurance payments, risk corridors and subsidies.[129]

The information that CMS will require from Part D plan sponsors and MA organizations necessarily will include commercially sensitive information that Part D plans obtain from pharmaceutical manufacturers. GSK is concerned that the Proposed Rule does not adequately protect this confidential and proprietary information.

The information that Part D plans will need to submit to CMS is only partially protected under the Proposed Rule. Under Proposed 42 C.F.R. § 423.104(h), the confidentiality protections of the Medicaid rebate statute[130] extend only to the data that plans submit to CMS regarding aggregate negotiated price concessions. The MMA and the Proposed Rule also provide limited protection for the information CMS obtains from plans for the purpose of carrying out payments to plan sponsors and MA organizations.[131] Proposed § 423.322(b) limits the use of this information to purposes consistent with carrying out provisions related to such payments. While this provision does provide some protection against misuse of the information, we are concerned that there is no protection against disclosure of the information. *Extending the confidentiality protections of the Medicaid rebate statute to this information would provide manufacturers with assurances that their confidential and proprietary information will not be inappropriately disclosed.*

CMS also may require plans to submit specific data on drug claims[132] and other detailed data that CMS may deem necessary under § 423.265, § 423.505, §423.863, and § 423.888. The Proposed Rule does not provide any confidentiality protections for any of this information. We are concerned that this lack of protection could result in the inappropriate release of commercially sensitive information that plans obtain from pharmaceutical manufacturers.

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[125] Proposed 42 C.F.R. § 423.104(h).

[126] Proposed 42 C.F.R.§ 423.322(a).

[127] Proposed 42 C.F.R. § 423.329(b)(3).

[128] *Id.*

[129] *See, e.g.*, Proposed 42 C.F.R. § 423.265; § 423.505; §423.863; § 423.888.

[130] SSA §1927(b)(3)(D).

[131] Proposed 42 C.F.R. § 423.322(b). CMS suggests in the preamble that this information may include "the quantity, type, and costs of pharmaceutical prescriptions filled by enrollees." 69 Fed.Reg. at 46686.

[132] Proposed § 423.329(b)(3).

We urge CMS to extend the confidentiality protections of the Medicaid rebate statute to all negotiated pricing information submitted to or reviewed by CMS under Part D, including information obtained under Subparts F, G, K, Q, and R of the Proposed Rule.

We are concerned that the Proposed Rule construes the confidentiality provisions of the MMA too narrowly in extending the Medicaid rebate protections only to aggregate pricing information. While Congress left it to CMS to determine exactly what types of information it would need to properly implement Part D, it seems likely that Congress intended to provide the Medicaid rebate statute protections more broadly to pricing data reported to CMS, and not solely to aggregated pricing information. In fact, the Medicaid rebate statute applies more generally to "information disclosed by manufacturers or wholesalers,"[133] and in effect prohibits the disclosure of pricing information regarding specific drugs. It is this type of specified, disaggregated information that is the most commercially sensitive.

Extending the Medicaid Rebate statute protections will assure manufacturers that their proprietary information will be protected when it is held by CMS. This is particularly important, because, as discussed below, Part D plans may not have sufficient motivation to protect the commercially sensitive information that they obtain from manufacturers.

2. *We urge CMS to clarify in the final rule that the Trade Secrets Act[134] applies to pricing or other confidential information that CMS obtains or reviews from plans as it implements Part D.*

The Trade Secrets Act precludes agency officials or employees from disclosing commercially sensitive information, including certain pricing information. The disclosure of this type of proprietary information would cause substantial competitive harm to manufacturers, as well as to Part D plans. Such disclosure also would impede negotiations between manufacturers and plans. Making clear that this type of specific pricing information constitutes a trade secret would help to protect against the disclosure of such information that CMS obtains from Part D plans and would facilitate the negotiation between these parties.

3. GSK urges CMS to adopt a regulation mirroring the section of the Federal Acquisition Regulation relating to the protection of confidential and proprietary information.[135]

This regulation would apply to all bids submitted by either a risk-bearing plan or a fallback plan and would help to clearly identify confidential and proprietary information.

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[133] § 1927(b)(3)(D).

[134] 18 U.S.C. § 1905.

[135] *See* 48 C.F.R. § 52.215-1(e).

4. *Finally, we urge CMS to provide notice to pharmaceutical manufacturers prior to releasing confidential information under the Freedom of Information Act ("FOIA").*

Federal agencies are required to use "good faith efforts to advise submitters of confidential commercial information" regarding requests for the release of confidential information under FOIA.[136] To that end, the Department of Health and Human Services ("HHS") has adopted a "balanced approach in administering FOIA."[137] Specifically, HHS "recognize[s] the legitimate interests of organizations or persons who have submitted records to the Department or *who would otherwise be affected by release of records*."[138]

Given the unique nature of the reporting requirements under Part D, in which plans report the confidential price information of pharmaceutical manufacturers, it is clear that pharmaceutical manufacturers would be affected by the release of the sensitive price information contained in Part D plan's proposals. Thus, GSK respectfully requests that in addition to notifying Part D plans of a FOIA request, that CMS also provide notice to pharmaceutical manufacturers. This additional notice would allow the entity that would be truly affected by the release of the confidential commercial information the opportunity to review the request and provide the appropriate objection, if necessary.

HHS FOIA regulations currently contemplate the provision of notice to a large number of submitters. Specifically, if CMS "must notify a large number of submitters, [it] may do this by posting or publishing a notice in a place where the submitters are reasonably likely to become aware of it."[139] By posting relevant FOIA requests on a central website, with the ability for submitters to receive e-mail notices of new requests, CMS would provide both Part D plans and pharmaceutical manufacturers sufficient notice to meet CMS FOIA response deadlines or request a time extension. We appreciate CMS's consideration of these specific requests designed to ensure the adequate protection of manufacturers' confidential information.

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136 Executive Order 12,600, 52 Fed. Reg. 23781.

137 42 C.F.R. § 5.2.

138 *Id.* (emphasis added).

139 42 C.F.R. 5.65(d)(1).

XI. Subpart Q -- Non-Interference with Respect to Fallback Plans

GSK recommends that CMS clearly indicate in the final rule that it will not set price benchmarks, create incentive payments, or otherwise interfere with the price structure for Part D drugs, whether provided through fallback plans or not.

Congress explicitly prohibits the Secretary from interfering in Part D negotiations between pharmaceutical manufacturers and plan sponsors and more generally from instituting a particular "price structure for the reimbursement of covered Part D drugs."[140] The Proposed Rule should be clarified to ensure that this prohibition will be observed in the context of fallback plans. While we appreciate CMS's recognition of the risk of running afoul of this non-interference provision, particularly with respect to fallback plans,[141] *we request that CMS clearly indicate in the final rule that it will not set price benchmarks, create incentive payments, or otherwise interfere with the price structure for Part D drugs, whether or not provided through fallback plans.*

It is possible that there will be regions in which one Part D plan or MA-PD is operating alongside a fallback plan. In these situations, it will be especially important that CMS not interfere with the negotiations between a pharmaceutical manufacturer and the Part D plan, MA-PD, or the fallback plan. The Proposed Rule could be interpreted as CMS suggesting that it may seek to influence a fallback plan's negotiations with pharmaceutical manufacturers by scrutinizing the negotiated prices for drugs available through the fallback plan or otherwise instituting a price structure for these plans.[142] *We urge CMS to carefully observe the requirements of the non-interference provisions with respect to fallback plans and to be particularly aware of the non-interference requirements in situations in which a fallback plan is offered alongside an at-risk plan in the same region.*

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[140] SSA § 1860D-11(i).

[141] 69 Fed.Reg. at 46734-5.

[142] *See* 69 Fed.Reg. at 46734-5.

XII. Section 423.159 -- Electronic prescription program

In developing standards for electronic prescribing, CMS must keep as their primary objective the preservation of the physician-patient relationship to facilitate medical choices most appropriate for each patient. Electronic prescribing should support all aspects of the prescribing decision, from choosing the most appropriate drug to resolving all appeals or grievances about that choice. CMS must ensure that the final standards are applicable in the real world with a variety of practice sizes and settings and, therefore, should err on the side of requiring a full demonstration project before the final standards are implemented.

GSK supports the policy of the Medicare Modernization Act to encourage the adoption of electronic prescribing. Widespread adoption of electronic prescribing with the appropriate standards has the potential to (i) enhance patient safety and (ii) improve quality of care, while at the same time realizing significant efficiencies in the delivery of care and reducing overall health care costs.

There are literally hundreds of highly technical issues surrounding the development of electronic standards, interoperability, terminology, privacy, etc. If the critical goal of improving quality of care is to be preserved, CMS must not lose sight of the overarching consideration in implementing this new technology: the importance of the physician-patient relationship and the ability of the physician and patient to make the most appropriate medical choices. Those choices relate both to the decision on which drug will most effectively treat the patient's disease and to the patient's options for filling that prescription.

Within the health care system, in addition to appropriate treatment considerations, there are also financial incentives for payors, pharmacies, drug manufacturers, and other participants to encourage or select the use of certain drugs. While the electronic prescribing system must operate within the context of a specific drug benefit plan in which costs are a relevant consideration, its primary focus should be ensuring safety and improving patient quality; it should not be used merely as a cost-savings tool. *The standards must ensure that the ultimate decision on what drug to prescribe – if any – and how to get drugs dispensed remains in the hands of the patient and the physician or other practitioner.*

There are many examples of how electronic prescribing can help save costs while at the same time ensuring quality of care through preservation of physician and patient treatment choice. For example, the electronic prescribing initiative has the potential to greatly simplify the process of satisfying health plan prior authorization, physician "dispense as written" orders, physician attestation regarding appropriate use, drug interaction alerts, step therapy, co-payment appeals, and denial of coverage appeals. These processes are typically performed manually at great cost to the plan and physician and great inconvenience to the patient. In the current system, these well-intentioned efforts actually dissuade patients from filling their prescriptions, thus contributing to poor outcomes and increased health care costs. *The inclusion of electronic*

"Point of Care" fulfillment processes for each of the above mentioned interventions, therefore, should be an essential feature of an electronic prescribing system.

It is easy to get carried away with the prospect of a "perfect" electronic prescribing environment in which physicians will ideally have all of the information they need to prescribe the medicine that is the most clinically effective and cost effective for the patient and in which the prescription will be transmitted quickly and without error to the chosen dispenser, whether that be a physical pharmacy or a mail-order facility. However, CMS must not lose sight of the reality that underlying this electronic communications system are real patients with less–than-perfect memories, who often face obstacles to filling and complying with their prescriptions.

For example, one of the stated advantages of electronic prescribing is doing away with the paper prescription that the patient must deliver to a pharmacy. Paper prescriptions are often the cause of errors, non-compliance, and inefficiencies due to handwriting errors and obstacles to the ability of patients to have their prescriptions filled. The resulting underutilization and non-compliance are major sources of inefficiencies and costs in the system.

However, in many cases it is the prescription – the piece of paper -- that helps patients remember to get their prescriptions filled. In implementing an electronic prescribing system that eventually could obviate the need for paper prescriptions, we must keep in mind the human elements in play and ensure that there are still adequate incentives and tools available to help patients follow through in getting prescriptions filled, either for themselves or those for whom they are responsible.

We encourage CMS to also consider the other real-world factors that will influence the use of electronic prescribing technology. That is, standards for electronic prescribing must be flexible and scalable to be applicable in the wide variety of clinical settings and specialties, from small to large health care organizations, and low to high volume prescribing practices. *The system must be flexible to support varying physician and patient needs.*

For example, a physician may write a prescription for a long-term medication that the patient chooses to receive by mail order. If the mail order medication will take several days to a week to be delivered, the physician may want to split the prescription and write a prescription for one week's worth of medicine so it can be filled locally. The standards must be sufficiently flexible to support situations like this that vary from most common practices.

The standards must be written with the understanding that electronic prescribing is not just a stand-alone application but must become a collective part of a full electronic health record. *Ultimately, it must have interoperability so that each physician can have the full patient medical history and other information he or she needs in a reliable and user-friendly form.*

Finally, the law requires the Secretary to conduct a pilot project once the initial standards have been adopted; the law allows the Secretary to by-pass the pilot project if there is already

adequate industry experience with the standards the Secretary is planning to adopt. We encourage CMS to exercise caution in this regard.

With the introduction of a new technology that is complex and uncertain, yet so critical to patient safety and the delivery of quality care, we encourage the Secretary to exercise the power to forego a pilot project only if there is extremely high confidence level in the industry experience with the proposed standards. The Secretary should err on the side of requiring further demonstrations to ensure the effectiveness and quality of all aspects of the new standards in a variety of real-world settings.

Conclusion

As CMS prepares the final rule and other regulations to implement the MMA, we ask the agency to remain focused on the statute's greater purpose: to provide Medicare enrollees with important drug therapies in clinically appropriate and cost-effective settings. Patients' access to advanced therapies depends upon Medicare's appropriate reimbursement to providers for those therapies. GSK appreciates the opportunity to comment on the issues we have identified in this comment letter, and we look forward to working with CMS to create a Part D prescription drug benefit that ensures Medicare enrollees meaningful access to vital drug therapies. Please feel free to contact me at (215) 751-4557 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Dean Hakanson. MD
Vice President
GlaxoSmithKline

Attachment

September 17, 2004

BY EMAIL AND OVERNIGHT DELIVERY

Lynn Lang
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Comments of GlaxoSmithKline on the Draft Model Guidelines

Dear Ms. Lang:

GlaxoSmithKline ("GSK") appreciates this opportunity to comment on the draft document entitled "Medicare Prescription Drug Benefit Model Guidelines" (the "Draft Guidelines") that the United States Pharmacopeia ("USP") recently released. GSK is a world leading research-based pharmaceutical company with a mission to improve the quality of human life by enabling people to do more, feel better, and live longer.

GSK supports the implementation of the new Medicare prescription drug benefit ("Medicare Part D") and the delivery of that benefit through competing private-sector prescription plans. GSK applauds USP for acting quickly to produce the Draft Guidelines and appreciates the substantial effort invested by the USP Panel in undertaking this complicated task. We believe the final USP model guidelines ("Model Guidelines"), if developed consistent with USP's mission envisioned by Congress in the Medicare Modernization Act ("Statute"), can be an important component in the successful implementation of Medicare Part D.

EXECUTIVE SUMMARY

Medicare Part D prescription drug plans ("PDPs") with formulary structures (categories and pharmacologic classes) consistent with the Model Guidelines are subjected to <u>less review and scrutiny</u> by the Centers for Medicare & Medicaid Services ("CMS"). In our view, this requires USP to be especially vigilant in its development of the Model Guidelines to ensure that the categories and classes in the Guidelines are sufficient to protect vulnerable Medicare beneficiaries from discrimination by PDPs and to ensure access to a meaningful range of safe and effective medicines for all beneficiaries -- a large, diverse population with a wide spectrum of health conditions, comorbidities and treatment needs. Upon a thorough

review of the Draft Guidelines, GSK believes that the Draft Model Guidelines fall far short of this critical role envisioned by Congress.

For example, the USP proposed "Respiratory Tract Medications" Therapeutic Class contradicts the nationally accepted NIH/NHLBI/NAEPP practice guideline. The practice guideline specifically lists three different medication classes patients must have. However the proposed Model Guidelines places all three into a single pharmacologic class, which would have the effect of discriminating against Medicare beneficiaries with asthma, particularly the sicker beneficiaries.

Another example is the model Blood Glucose Regulating Agents therapeutic category where all oral hypoglycemic agents are placed in one class. Practice guidelines, published research and standard of practice recognize the natural progression of Type 2 Diabetes over time, resulting in a decrease in pancreatic beta cell function and reduced secretion of insulin. There may also be an increase in insulin resistance. The result is loss of glycemic control over time regardless of the treatment used (diet, sulfonylureas, metformin or insulin). During the course of diabetes treatment, physicians typically add therapies without dropping current therapies to meet escalating patient needs (from monotherapy to increasing use of oral polytherapy to oral polytherapy plus insulin). Because the proposed Model Guidelines do not assure coverage for polytherapy for diabetes, the sickest diabetic beneficiaries would be discouraged from enrolling in plans that adhere to the Model Guidelines.

Accordingly, in finalizing the Guidelines, we urge USP to ensure that the Model Guidelines accomplish the purpose that Congress intended - to prevent PDPs from discouraging sicker and more costly beneficiaries from enrolling due to the plan's formulary design and to ensure beneficiaries access to the drugs they need. To achieve that result, GSK recommends (i) that the "recommended subdivisions" in the Draft Guidelines be moved into pharmacologic classes and (ii) that various categories, classes and the currently proposed "recommended subdivisions" be modified so that, when final, the Model Guidelines are more closely aligned with currently accepted clinical practice as discussed below. Moreover, based on our assessment of the literature and accepted medical practice, we have identified a need for additional categories or classes for products that USP appears to have overlooked. [1] In addition, we believe that USP should identify how it will react to newly approved drugs and changes in indications for already approved drugs, and how it will review existing categories and classes to ensure that they remain consistent with current clinical practice.

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1 While we include a discussion below about a number of products that were seemingly overlooked, it would be helpful to see the list of drugs by category or class that USP is supposed to prepare for CMS as soon as possible to further our understanding of how USP believes the categories or classes are populated.

ASSESSMENT OF THE MODEL FORMULARY GUIDELINES

I. Ensuring that the Model Guidelines Serve Their Intended Purpose

The new Medicare prescription drug program holds the potential to greatly increase Medicare beneficiaries' access to prescription drugs not currently covered by Medicare. GSK is concerned, however, that the substantial benefits of Medicare Part D will be jeopardized by how some prescription drug plans ("PDPs") implement the program, particularly with respect to the design of their formularies. Congress shared this concern and included in the statute several significant and independent beneficiary protections regarding formulary structure and development. CMS may approve a PDP only if the PDP satisfies these important requirements. [2]

One such key patient protection provision developed by Congress (and placed among the provisions labeled "Beneficiary Protections for Qualified Prescription Drug Coverage") is the requirement that patients have access to multiple "drugs" (at least two drugs) within each "therapeutic category and class" of the formulary. Given this requirement, the formulary categories and classes that a PDP uses to structure its formulary are critical in determining what types of drugs are available to beneficiaries covered by the formulary. The Statute also requires that upon review of the plan, CMS "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan." [3] In other words, CMS must determine that the PDP and its benefit ensures access to a meaningful range of drugs necessary for treatment of beneficiaries and that the PDP's therapeutic category and class structure does not discriminates against the sickest and costliest beneficiaries by failing to assure them this access to the types of drugs that they need.

Under the Statute, approval of individual PDPs is generally left to CMS following its careful review of the PDP's application. However, Congress directed CMS to seek the assistance of the USP in the development of a list of categories and classes that may be adopted and used by PDPs (*i.e.*, the Model Guidelines) in structuring their formularies. If a PDP's formulary structure is consistent with the categories and classes in the Model Guidelines, CMS may not find that the design of

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2 Social Security Act ("SSA") § 1860D-11(e)(2).

3 SSA § 1860D-11(e)(2)(D)(i).

the plan's formulary categories and classes violate the requirement not to "to substantially discourage enrollment" by eligible beneficiaries through its plan design and benefits. This insulates a PDP from some scrutiny of its formulary. On the other hand, the Statute does not require plans to follow the Model Guidelines. PDPs with formularies using categories and classes different from the Model Guidelines may obtain approval from CMS only upon the agency's review of its categories and classes, in addition to all formulary and other requirements required by the Statute and CMS regulations.

This Congressional mandate and role for guidelines from USP has led some to refer to the Model Guidelines as a "safe harbor" for PDPs. While this characterization may be an overstatement in that consistency with the Model Guidelines does not insulate the plan entirely from review of its formulary by CMS, the fact that the Model Guidelines provide even a partial "safe harbor" from CMS' ability to police the effect on patient access of category and class designs in PDP formularies, in our view, bestows a significant responsibility on USP. That is, USP has the responsibility to ensure that the categories and classes in the Model Guidelines ensure access and are not transformed into a means for PDPs to effectively deny access to medications to select groups of Medicare beneficiaries.

Unfortunately, there is evidence that the Draft Guidelines have been shaped by a desire on the part of USP to balance the number of categories and classes against the position of many prospective PDPs that fewer categories or classes are needed to give them flexibility to, among other things, design their plans to ensure "cost effectiveness." [4] The decision to create numerous "recommended subdivisions" rather than having such groupings included as categories or classes likewise illustrates USP's departure from its charge from Congress and its misplaced focus on balancing the protection of beneficiaries with the desires of plans. The result of this focus is a less granular set of categories and classes that would, in effect, allow a PDP to evade review by CMS whether the categories and classes in its formulary would discourage sicker and more costly beneficiaries from enrolling in its plan. At the same time, as illustrated with numerous examples in our analysis below, it is evident that the categories and classes in the Draft Guidelines are structured in a manner that would allow plans not to provide numerous, critically needed drugs to treat the Medicare patient population consistent with accepted medical standards and nationally recognized treatment guidelines.

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4 *E.g.* Draft Guidelines at 7 (discussing the "challenge of balancing access to needed drugs with the need for the Model Guidelines to be practical for" drug plans).

GSK is also concerned that USP has given insufficient consideration to the unique and distinct drug needs of the elderly and disabled patient population that will enroll in Medicare Part D. The "environmental scan" performed for USP in support of its efforts to develop the Draft Guidelines and on which the USP heavily relied, focused almost exclusively on the employer group health plan population, not the Medicare population. However the Medicare patient population is a very different population from enrollees in employer group health plans with respect to the use of drug therapies. The Medicare population typically has multiple chronic conditions and requires a wider variety of medications. Indeed, elderly Medicare beneficiaries often require drug treatments for chronic conditions such as osteoporosis, hypertension, diabetes, cardiovascular disease or depression – conditions that require simultaneous administration of multiple medications that must be taken for extended periods of time.[5] Elderly patients with chronic diseases are more susceptible to medication adverse events than the general population. Therefore, access to adverse-event reducing drugs is essential for these beneficiaries. Physicians must have access to the wide range of medicines needed to treat appropriately this population's often complex medical conditions, especially in light of the elderly patient's greater sensitivity to drug interactions and side effects.

GSK urges USP to provide a matrix of categories and classes that, if followed by a PDP, would ensure that the plan makes available to enrolled Medicare beneficiaries and their treating physicians all of the drugs that they would need.[6] This matrix must be developed by carefully reviewing the clinical and scientific evidence regarding the set of drugs needed by the Medicare patient population, not by balancing that evidence with the cost concerns of PDPs. Any such balancing will be the job of CMS in implementing the new prescription drug program. Because the Model Guidelines will provide a means for plans to avoid some level review by CMS, it is imperative that there be no room within the Model Guidelines to allow plans to discourage beneficiary enrollment. While this might appear to create a higher burden for plans, they have the option of adopting different categories and classes and having them reviewed by CMS.

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5 See Report to the President, "Prescription Drug Coverage, Spending, Utilization, and Prices," From Department of Health & Human Services, April 2000, available at http://aspe.hhs.gov/health/reports/drugstudy/.

6 We also request that USP identify how it will perform the congressionally mandated function of updating the Model Guidelines to reflect changes in the uses of drugs and the addition of new drugs. There needs to be a predictable mechanism for doing so in a timely fashion. For newly approved drugs, in particular, GSK believes that there needs to be a prompt mechanism for determining whether a new category or class must be added.

II. Assessment of Current Categories, Classes and Subdivisions

Based on our review of the Draft Model Guidelines, considerable changes need to be made to the list of categories and classes to ensure that plans following the Model Guidelines will not be able to discourage enrollment by certain types of Medicare beneficiaries and that the enrollees have access to the range of medicines needed to appropriately treat their medical conditions. Avoiding adverse events should be a specific consideration in establishing pharmacologic classes. Even drugs in the same therapeutic category and pharmacologic class will have different side-effect and adverse event profiles. This is particularly necessary for patients with chronic conditions because they are more susceptible to medication adverse events than the general population. This means that pharmacologic classifications should include classes that allow avoidance of adverse events and not just traditional chemical class or mechanisms of action. A starting point would be to include all of the currently "recommended subdivisions" in the Draft Guidelines as pharmacologic classes in the final Model Guidelines. However, that alone would not be sufficient, as there would need to be changes to the categories, classes and subdivisions that appear in the Draft Guidelines We address these changes below.

A. Analgesics Therapeutic Category

By offering Opioid Analgesics and Non-opioid Analgesics as the only options in the Analgesics Pharmacological Classification, the proposed Model Guideline conflicts with leading peer-reviewed arthritis treatment guideline recommendations and associated pharmacologic classifications and potentially limits patient access to safe and effective alternatives for pain relief. For this reason, GSK recommends that COX-2 selective inhibitors be added as a Pharmacologic Class in this category.

Key goals of the American College of Rheumatology Osteoarthritis Guideline include control of pain and avoidance of toxic effects from therapy.

> *"The goals of the contemporary management of the patient with OA continue to include control of pain and improvement in function and health-related quality of life, with avoidance, if possible, of toxic effects of therapy."*[1]

When describing the pharmacologic options, the intent of these guidelines clearly is to separate the COX-2 selective inhibitors from the non-selective NSAIDs. As described, COX-2 selective inhibitors are first line therapy for patients who fail to manage their pain with adequate doses of acetaminophen.

> *"Toxicity is the major reason for not recommending the use of NSAIDs as first-line therapy for patients with OA of the hip. Data from epidemiologic studies demonstrate that among persons ages 65 and older, 20-30% of all hospitalizations and deaths due to peptic ulcer disease were attributable to NSAID therapy."*[2]

The importance of this recommendation is highlighted by the incidence of major complications and death from gastrointestinal bleeds due to non-selective COX inhibitors (NSAIDs). This represents a public health problem for patients requiring the management of chronic pain. Hospital admissions arise in 0.25 - 1.58% of users per year and deaths occur in 7,000 US patients annually. [1] In many cases of major GI bleed due to NSAIDs there is no prior warning.

Table 3. Pharmacologic therapy for patients with osteoarthritis*
(Taken from ACR OA Hip & Knee Guideline)

Oral
Acetaminophen
COX-2-specific inhibitor
*Non-selective NSAID plus misoprostol or a proton pump inhibitor***
Nonacetylated salicylate
Other pure analgesics Tramadol

Opioids Intraarticular
Glucocorticoids
Hyaluronan
Topical
Capsaicin
Methylsalicylate

- *The choice of agent(s) should be individualized for each patient as noted in the text. COX-2 = cyclooxygenase 2; NSAID = nonsteroidal anti-inflammatory drug.*

***Misoprostol and proton pump inhibitors are recommended in patients who are at increased risk for upper gastrointestinal adverse events.* [1]

Subsequent to the writing of the guidelines noted above, several large outcome studies have been published confirming that COX-2 selective inhibitors can reduce GI morbidity 50% to 80% vs. non-selective NSAIDs. The VIGOR study [3] showed a 50% reduction in GI risk for patients taking rofecoxib versus an NSAID. The TARGET study shows an even greater reduction of approximately 80% for lumaricoxib. [i] Short-term endoscopy studies for all available COX-2 drugs show substantial risk reductions for endoscopic ulcers. [4]

The American Pain Society (APS) recently released a clinical guideline on the treatment of acute and chronic pain associated with arthritis. This multidisciplinary, evidence-based guideline was developed by a panel of experts in arthritis pain management confirms the use of COX-2 specific inhibitors prior to the use of the non-selective NSAIDs.

> *"For persons with moderate to severe pain from osteoarthritis and rheumatoid arthritis, COX-2 nonsteroidal anti-inflammatory drugs (NSAIDs) are the best choice for their pain-relieving potency and lower incidence of gastrointestinal (GI) side effects. Use of non-selective NSAIDs should be considered only if the patient does not respond to acetaminophen and COX-2 drugs, and is not at risk for NSAID-induced GI side effects. Because of the high cost of COX-2 agents, some patients may benefit from non-selective NSAID therapy combined with a medication to moderate GI distress."* [4]

Early concerns that rofecoxib-specific increases in cardiovascular risk may represent a class effect have been negated by the benign CV profile shown in the TARGET study. [5]

The American College of Rheumatology guidelines for the management of rheumatoid arthritis points out that patients with RA are twice as likely as OA patient to have a

serious complication from non-selective NSAID therapy. Strategies to avoid the GI toxic effects of non-selective NSAIDs, include the use of a highly selective COX-2 inhibitor.[6]

These data, taken together, shows that the COX-2 drugs are sufficiently different in their safety profile from ns-NSAIDS as to represent a distinct class of medications, offering patients a distinct benefit over ns-NSAIDs. These drugs should be considered as separate therapeutic options for patients at risk of serious GI bleeding (advanced age, chronic use and other risk factors).

For these reasons, GSK recommends that the Analgesics Therapeutic Category be revised as follows.

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	*Recommended Subdivisions*
Analgesics	Opioid Analgesics	
	Non-opioid Analgesics	
	COX-2 Inhibitors	

1. Altman RD, Hochberg MC, Moskowitz RW, Schnitzer TJ. Recommendations for the Medical Management of Osteoarthritis of the Hip and Knee. American College of Rheumatology Subcommittee on Osteoarthritis Guidelines. *Arthritis & Rheumatism*. 2000; 43;1905-1915.

2. Hochberg MC, Altman RD, Brandt KD, Kenneth D, Clark BM, Dieppe P, Griffin MR, Roland W, TJ Schnitzer. Guidelines for the Medical Management of Osteoarthritis, Part I. Osteoarthritis of the Hip. Arthritis & Rheumatism. *Official Journal of the American College of Rheumatology*. 1995;38;1535-1540.

3. Bombardier C, et al. Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis. *New England Journal of Medicine*. 2000; 1520 – 1528.

4. Schnitzer TJ, Burmester GR, Mysler E, Hochberg MC, Doherty M, Ehrsam E, Gitton X, et al. Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), reduction in ulcer complications: randomised controlled trial *Lancet*. 2004; 364: 665–74.

5. US package inserts: BEXTRA, CELECOIB, VIOXX.

6. Farkouh ME, Kirshner H, Harrington RA, Ruland S, Freek WA, et al. Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), cardiovascular outcomes: randomized controlled trial. *Lancet* 2004; 364: 675–84

B. **Antibacterials Therapeutic Category, All Pharmacologic Classes (Nos. 5 – 13)**

The proposed antibacterials pharmacologic classes are not aligned with accepted medical practice and treatment guidelines. According to the CDC, drug-resistant infections require accurate detection and appropriate treatment as they pose a significant threat to public health[1].

Community-acquired infections and the number of medications to which they are resistant is increasing[2]. Organisms that are resistant to multiple anti-bacterial medications are increasing, therefore access to the most specific and potent antibacterial medications is essential.

The currently defined subdivisions are actually antibacterial classes and should be listed as such. Each formulation and derivation is unique and specific to their antibacterial actions, effectiveness and benefits. These drugs are not interchangeable because they combat different types of bacterial infections (gram negative vs. gram positive, broad spectrum vs. specific). In addition, an individual patient might need more than one agent at a time.

Therefore, GSK proposes that the following classification be used for the Antibacterials Therapeutic Category.

Therapeutic Category	Pharmacologic Class	Recommended Subdivisions
Antibacterials	Beta Lactam, Penicillins	
	• Penicillin G-related Penicillins	
	• Penicillins, Amino Derivative	
	• Penicillinase-resistant Penicillins	
	• Extended Spectrum Penicillins	
	Beta-Lactam, Cephalosporins	
	• Cephalosporins, 1st Generation	
	• Cephalosporins, 2nd Generation	
	• Cephalosporins, 3rd Generation	

	• Cephalosporins, 4th Generation	
	Beta-Lactam, Other	
	• Carbacephems	
	• Carbapenems	
	• Cephamycins	
	• Monobactams	
	Quinolones	
	• Quinolones, Fluorinated	
	• Quinolones, Non-fluorinated	
	Sulfonamide/Related Antibacterials	
	Aminoglycosides	
	Macrolides	
	• Erythromycins	
	• Macrolides, Other	
	Tetracyclines	
	Antibacterials, Other	
	• Antifolates	
	• Glycopeptides	
	• Lincomycins	
	• Nitrofurans	
	• Oxazolidinones	
	• Polymyxins	
	• Streptogramins	
	• Other	

References
1. Centers for Disease Control (CDC) Second Annual Progress Report: Implementation of *A Public Health Action Plan to Combat Antimicrobial Resistance. Part 1: Domestic Issues*. June 2004. Executive Summary. http://www.cdc.gov/drugresistance/actionplan/2003report/executivesummary.pdf. Accessed September 16, 2004.

2. Goossens, H. Sprenger, MJW. Community acquired infections and bacterial resistance. *BMJ*, 1998;317:654-657.

C. Anticonvulsants Therapeutic Category (No. 14)

GSK recommends adding four (4) pharmacologic class listings titled "sodium channel blocker", "calcium channel blocker", "GABA systems" and "glutamate receptors" to the therapeutic category titled "anticonvulsants".

Various types of seizures respond differently to anticonvulsant agents with response rate often based on a drug's mechanism of action. Furthermore, selection of an antiepileptic drug depends on if the treatment is for new onset or refractory epilepsy. In accordance with the American Academy of Neurology (AAN)/American Epilepsy Society (AES) treatment guidelines, broad access to anticonvulsant agents is required to treat the multiple forms of epilepsy, to accommodate disease response variability and to account for the vast differences in drug side effects, toxicity, and adverse event profiles among the many agents. [1,1] Access to anticonvulsants with different mechanisms of action is particularly important for patients with refractory epilepsy. According to the AAN/AES treatment guidelines, the average number of failed anticonvulsants in studies involving refractory patients was often eight or more.

The Model Guidelines present potentially serious problems for Medicare part D patients including:

- Placing patients at undue risk by failing to ensure access to newer agents which often have fewer safety concerns, better side effect profiles and a broader therapeutic concentration range
- Not ensuring coverage of medications to treat each type of seizure including partial (focal or local) seizures, generalized seizures and unclassified epileptic seizures
- Reducing the likelihood that patients with refractory disease will find one anticonvulsant or a combination of anticonvulsants that will control their seizures.

The Model Guidelines make it possible for a PDP to cover only older agents, those that can have higher toxicity profiles, those with a high likelihood for a side effect or to cover agents that address just one or two mechanisms of seizure activity. In addition, even if limiting coverage of anticonvulsant medications addressed the goal for seizure control for all types of seizures, even in refractory patients, it would not recognize the additional, but equally important, goals of therapy that impact a patient's quality of life including optimal cognitive, physical and psychological functioning.[2]

Drug therapy selection is based on the seizure type, disease duration, mechanism of drug action and the side effect or adverse event profile. The elderly beneficiaries covered by Medicare part D may be especially vulnerable to drug side effects as are most patients with increasing age. Therefore, limiting drug coverage by narrowly

defining the anticonvulsant therapeutic category could result in excessive adverse event and toxicity burden in this already high risk population.

For these reasons GSK proposes the following change to the Model Guidelines.

Reference Line	Therapeutic Category	Pharmacologic Class	Recommended Subdivisions
14	Anticonvulsants	Sodium Channel Blocker	
15		Calcium Channel Blocker	
16		GABA Systems	
17		Glutamate Receptors	

References:

[1] French JA, Kanner AM, Bautista J, et al. Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new onset epilepsy. Report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. 2004;62:1252-1260.
NOTE: the guideline reference is available online at http://www.neurology.org/cgi/reprint/62/8/1252.pdf

[2] French JA, Kanner AM, Bautista J, et al. Efficacy and tolerability of the new antiepileptic drugs II: Treatment of refractory epilepsy. Report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. 2004;62:1261-1273.
NOTE: the guideline reference is available online at http://www.neurology.org/cgi/reprint/62/8/1261.pdf

D. Anti-depressants Therapeutic Category, Reuptake Inhibitors and Other, Pharmacologic Classes_ (Nos. 15, 16, 17)

GSK recommends that subdivisions for anti-depressants be made pharmacologic classes, which is consistent with APA Practice Guideline for the Treatment of Patients with Major Depressive Disorder.

Of the nearly 35 million Americans age 65 and older, an estimated 2 million have a depressive illness (major depressive disorder, dysthymic disorder or bipolar disorder.)[1] Chronic medical illness afflicts eighty eight percent of people aged 65 or older, and those with chronic illnesses have a high prevalence of major depressive illness[2]. Depression associated with chronic medical illness may also lead not only to increased health care utilization and morbidity but also to increased mortality[3]. The National Institute of Mental Health considers depression in people age 65 and older to be a major public health problem[1].

The American Psychiatric Association guideline for treatment of patients with major depressive disorder emphasizes the necessity of continuation of medication through acute and maintenance phases. The goal is to treat the symptoms acutely (1-2 months) to achieve response. To reduce the likelihood of relapse, this response should be maintained for an additional 2-6 months[4]. Thus, depressed patients should be treated with an antidepressant for at least 4-9 months. More than 40% of these patients, however, discontinue therapy within the first three months of treatment due to poor tolerability[5].

In order to assure continuous treatment, a range of anti-depressant medication options are needed for initial therapy as well as for replacement medication. CMS will realize medical cost savings as medication adherence improves because total cost of care decreases significantly. Additional drug cost is more than offset by medical cost savings. Patients who stay on therapy for more than 90 days not only have an improved chance of recovery, but their annual medical costs can be reduced by more than $2,000.[6,7]

The proposed pharmacologic classifications under the antidepressant therapeutic category inappropriately link different mechanisms of action under a single heading. It also links medications that have considerable differences in safety as well as side-effect profile.

We recognize that USP will be looking at which specific drugs would fit into each classification/subdivision, but we would like to clarify that buproprion does not fit into the specific categories and would be considered antidepressant, other, or a new pharmacologic classification would need to be added.

Therefore, GSK proposes that the following classification be used for the Antidepressant Therapeutic Category.

Therapeutic Category	Pharmacologic Class	Recommended Subdivisions
Antidepressants	Monoamine Oxidase Inhibitors	
	SNRI	
	SSRI	
	Tricyclics	
	Antidepressants, other	

References:

1. Older adults: Depression and suicide facts. National Institute of Mental Health. http://www.nimh.nih.gov/HealthInformation/elderlydepsuicide.cfm. Accessed September 15, 2004.
2. Katon, WJ. Clinical and health services relationships between major depression, depressive symptoms, and general medical illness. Biol Psychiatry. 2003; 54:216-226.
3. Katon, W. Sullivan, MD. Depression and chronic medical illness. J Clin Psychiatry. 1990 Jun; 51 Suppl:3-11.
4. American Psychiatric Association practice guideline for the treatment of patients with major depressive disorder. Am J Psychiatry 2000 Apr;157(4 Suppl):1-45.
5. Bull SA, Hunkeler, EM, Lee, JY, et al. Discontinuing or switching selective serotonin-reuptake inhibitors. Ann Pharmacother, 2002;36:578-584.
6. Thompson D, Buesching D, Gregor KJ, et al. Patterns of antidepressant use and their relation to costs of care. *Am J Managed Care.* 1996;2(9):1239-1246.
7. Tseng, CW, Brook, RH, Keeler, E, et al. Cost lowering strategies used by Medicare beneficiaries who exceed drug benefit caps and have a gap in drug coverage. JAMA 2004;8:952-960.

E. Antidotes, Deterrents and Poison Control Therapeutic Category, Antidotes Pharmacologic Classes (No. 18)

The term "opioid antagonist" in the current subdivision of antidotes has become outdated and should be changed to specify "centrally acting opioid antagonists." A new opioid antagonist pharmacologic classification "peripherally acting opioid agonist" should be added to the Gastrointestinal Medications section for differentiation.

The new class of agent is peri registration for the treatment of Post Operative Ileus and under development for other gastrointestinal conditions. The two distinct mechanisms of action and clearly different potential indications should be differentiated in the USP model guidelines.

GSK recommends the following change to the Draft Model Guidelines

Therapeutic Category	Pharmacologic Classification	Recommended Subdivisions
Antidotes, Deterrents, and Poison Control	Antidotes Centrally Acting Opioid Antagonist	
	Antidotes: Antivenins	
	Antidotes: Ion Exchange Resins	
	Antidotes, Other	
	Antidotes:Heavy Metal Antagonists	

F. Antiemetics Therapeutic Class, New Pharmacologic Class for NK1

The National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemetics (v.1.2004) guidelines now identify NK1 inhibitors for use as prophylaxis with highly emetogenic chemotherapy regiments in combination with a 5HT3 antagonist.[1] They are also recommended for use as an option for moderately emetogenic chemotherapy in combination with dexamethasone for the prevention of delayed nausea and vomiting.

Therefore, GSK requests that this new class be added to the proposed formulary listing.

Therapeutic Category	Pharmacologic Classification	Recommended Subdivisions
Antiemetics	NK1 inhibitors	
	5-HT3 Antagonists	
	Antiemetics, other	

Reference:

1. Practice Guidelines in Oncology – v.1.2004. National Comprehensive Cancer Network, Inc. Available at http://www.nccn.org/professionals/physician_gls/PDF/antiemesis.pdf

G. Antihistamines Therapeutic Category, H1 Blockers and H2 Blockers Pharmacologic Classes (Nos. 28, 29)

The antihistamine therapeutic category and classes are too narrowly defined and do not incorporate recognized practice guidelines for the treatment and management of allergies, which include a broader range of conditions and recommended treatments.

Of all allergy-related conditions and symptoms, allergic rhinitis is of major concern. Allergic rhinitis affects up to 40 million Americans and is the sixth most prevalent chronic disease in the United States[1]. In 1995, it was estimated that the direct and indirect costs for the management of this condition was 2.7 billion dollars, excluding costs for accompanying asthma and sinusitis. In 1996, Ray et al, estimated that the direct medical costs for allergic rhinitis, as a primary or secondary diagnosis, at 5.9 billion dollars accounting for airway related diseases[2].

Allergic rhinitis is defined as inflammation of the nasal mucosa precipitated by exposure to inhaled allergens producing a specific immunologic response[3]. "Untreated allergic rhinitis develops into a chronic state of inflammation and nasal obstruction that frequently leads to much more serious diseases in both the upper and lower airways. Allergic rhinitis is closely associated with, and may be a causative factor in, asthma, sinusitis, otitis media with effusion (OME), and polyps."[4,5]

Antihistamines work by blocking the H_1-receptor site and inhibiting the effects of histamine. Antihistamines relieve rhinorrhea, sneezing, itching and ocular symptoms; however in general, they do not effectively relieve nasal obstruction[6].

Decongestants constrict blood vessels in the nose and reduce mucosal edema to relieve nasal obstruction. They are less effective for rhinorrhea, sneezing and itching. Decongestants are available in topical and oral formulations. Decongestants are often combined with antihistamines to provide relief of all nasal symptoms[7].

Intranasal corticosteroid preparations relieve all major nasal symptoms of allergic rhinitis, including nasal obstruction, rhinorrhea, sneezing and itching. These preparations are applied directly to the site of inflammation and inhibit the activity of inflammatory cells and their mediators: histamine, leukotrienes and prostaglandins. The Joint Task Force states "…nasally inhaled corticosteroids are the most effective medication class in controlling symptoms of allergic rhinitis."[6]

Leukotriene modifiers are a class of drugs used to treat asthma. Of the three leukotriene modifier agents available, only montelukast is indicated for the relief of symptoms of seasonal allergic rhinitis. It inhibits one of the many classes of

inflammatory mediators, leukotrienes, by binding to leukotriene C_4, D_4, and E_4 receptors[7].

Mast cell stabilizers treat allergies by blocking the release of histamine and preventing mast cells from degranulating. Intranasal cromlyn sodium is used for the prevention and treatment of the nasal symptoms of allergic rhinitis. Although its mechanism is thought to involve degranulation of mast cells, it has not been fully elucidated[8].

Anticholinergic agents such as intranasal ipratropium bromide is indicated for the symptomatic relief of rhinorrhea associated with allergic and non-allergic perennial rhinitis in adults and children 12 years of age and older. It does not relieve nasal congestion, sneezing or post-nasal drip.

GSK recommends that the Therapeutic Category "Antihistamines" be updated and renamed "Anti-allergy." The proposed H1 and H2 blocker pharmacologic classes should be replaced with the new classes, which reflect Joint Task Force guidelines for appropriate treatment of allergy symptoms, including allergic rhinitis:

- antihistamines,
- decongestants
- intranasal corticosteroids
- leukotriene modifiers
- mast cell stabilizers
- anticholinergics

For these reasons GSK recommends the following changes to the Model Guidelines.

<table>
<tr><th>THERAPEUTIC CATEGORY</th><th>PHARMACOLOGIC CLASS</th><th>Recommended Subdivisions</th></tr>
<tr><td rowspan="2">Anti-allergy</td><td rowspan="2">antihistamines,
decongestants
intranasal corticosteroids
leukotriene modifiers
mast cell stabilizers
anticholinergics</td><td></td></tr>
<tr><td></td></tr>
</table>

References:

1. Dykewicz MS, Fineman S, Skoner, et al. Diagnosis and Management of Rhinitis: Complete Guidelines of the Joint Task Force on Practice Parameters in Allergy, Asthma, and Immunology. Ann Allergy Asthma Immunol 1998; 81: 478-518/ Naclerio RM. Allergic rhinitis. N Engl J Med 1991;325:860-869.

2. Ray NF, Baraniuk JN, Thamer M, et al. Direct Expenditures for the Treatment of Allergic Rhinoconjuctivitis in 1999, Including the Contribution of Related Airway Illness. J Allergy Clin Immunol 1999;103:401-407.

3. Dykewicz MS, Fineman S, Skoner, et al. Diagnosis and Management of Rhinitis: Complete Guidelines of the Joint Task Force on Practice Parameters in Allergy, Asthma, and Immunology. Ann Allergy Asthma Immunol 1998; 81: 478-518/ Naclerio RM. Allergic rhinitis. N Engl J Med 1991;325:860-869.

4. Dykewicz MS, Fineman S, Skoner, et al. Diagnosis and Management of Rhinitis: Complete Guidelines of the Joint Task Force on Practice Parameters in Allergy, Asthma, and Immunology. Ann Allergy Asthma Immunol 1998; 81: 478-518.

5. Rachelefsky GS. National guidelines needed to manage rhinitis and prevent complications. Annals of Allergy, Asthma, & Immunology. 1999;82(3):296-305.

6. Naclerio RM. Allergic rhinitis. N Engl J Med 1991;325:860-869.

7. Naclerio RM. Allergic rhinitis. N Engl J Med 1991;325:860-869.

8. Dykewicz MS, Fineman S, Skoner, et al. Diagnosis and Management of Rhinitis: Complete Guidelines of the Joint Task Force on Practice Parameters in Allergy, Asthma, and Immunology. Ann Allergy Asthma Immunol 1998; 81: 478-518.

9. HON Dossier – Allergy Glossary-Leukotreine. Available at: http://www.hon.ch/Library/Theme/Allergy/Glossary/leukotriene.html. Accessed on September 16, 2004.

10. Naclerio RM. Allergic rhinitis. N Engl J Med 1991;325:860-869.

11. HON Dossier – Allergy Glossary–Anti-cholinergic. Available at: http://www.hon.ch/Library/Theme/Allergy/Glossary/anti-cholinergic.html. Accessed on September 16, 2004.

H. Anti-Inflammatory Therapeutic Category

By combining COX-2 Inhibitors, Salicylates and Other Nonsteroidals as subdivisions of the Nonsteroidal class in the Anti-inflammatories Therapeutic Category, the proposed Model Guildeline conflicts with leading peer-reviewed arthritis treatment guideline recommendations and associated pharmacologic classifications and potentially limits patient access to safe and effective options for pain relief. For this reason, GSK recommends that COX-2 Inhibitors, Salicylates and Other Nonsteroidals be listed as separate Pharmacologic Classes.

Key goals of the American College of Rheumatology Osteoarthritis Guideline include control of pain and avoidance of toxic effects from therapy.

> *"The goals of the contemporary management of the patient with OA continue to include control of pain and improvement in function and health-related quality of life, with avoidance, if possible, of toxic effects of therapy."*[1]

When describing the pharmacologic options, the intent of these guidelines clearly is to separate the COX-2 selective inhibitors from the non-selective NSAIDs. As described, COX-2 selective inhibitors are first line therapy for patients who fail to manage their pain with adequate doses of acetaminophen.

> *"Toxicity is the major reason for not recommending the use of NSAIDs as first-line therapy for patients with OA of the hip. Data from epidemiologic studies demonstrate that among persons ages 65 and older, 20-30% of all hospitalizations and deaths due to peptic ulcer disease were attributable to NSAID therapy."*[2]

The importance of this recommendation is highlighted by the incidence of major complications and death from gastrointestinal bleeds due to non-selective COX inhibitors (NSAIDs). This represents a public health problem for patients requiring the management of chronic pain. Hospital admissions arise in 0.25 - 1.58% of users per year and deaths occur in 7,000 US patients annually. [1] In many cases of major GI bleed due to NSAIDs there is no prior warning.

Table 3. Pharmacologic therapy for patients with osteoarthritis*
(Taken from ACR OA Hip & Knee Guideline)

Oral
Acetaminophen
COX-2-specific inhibitor
*Nonselective NSAID plus misoprostol or a proton pump inhibitor***
Nonacetylated salicylate
Other pure analgesics Tramadol

Opioids Intraarticular
Glucocorticoids
Hyaluronan
Topical
Capsaicin
Methylsalicylate

- *The choice of agent(s) should be individualized for each patient as noted in the text. COX-2 = cyclooxygenase 2; NSAID = nonsteroidal antiinflammatory drug.*

***Misoprostol and proton pump inhibitors are recommended in patients who are at increased risk for upper gastrointestinal adverse events.* [1]

Subsequent to the writing of the guidelines noted above, several large outcome studies have been published confirming that COX-2 selective inhibitors can reduce GI morbidity 50% to 80% vs. non-selective NSAIDs. The VIGOR study [5] showed a 50% reduction in GI risk for patients taking rofecoxib versus an NSAID. The TARGET study shows an even greater reduction of approximately 80% for lumaricoxib. [6] Short-term endoscopy studies for all available COX-2 drugs show substantial risk reductions for endoscopic ulcers. [7]

The American Pain Society (APS) recently released a clinical guideline on the treatment of acute and chronic pain associated with arthritis. This multidisciplinary, evidence-based guideline was developed by a panel of experts in arthritis pain management confirms the use of COX-2 specific inhibitors prior to the use of the non-specific NSAIDs.

> *"For persons with moderate to severe pain from osteoarthritis and rheumatoid arthritis, COX-2 nonsteroidal anti-inflammatory drugs (NSAIDs) are the best choice for their pain-relieving potency and lower incidence of gastrointestinal (GI) side effects. Use of nonselective NSAIDs should be considered only if the patient does not respond to acetaminophen and COX-2 drugs, and is not at risk for NSAID-induced GI side effects. Because of the high cost of COX-2 agents, some patients may benefit from nonspecific NSAID therapy combined with a medication to moderate GI distress."* [6]

Early concerns that rofecoxib-specific increases in cardiovascular risk may represent a class effect have been negated by the benign CV profile shown in the TARGET study. [9]

The American College of Rheumatology guidelines for the management of rheumatoid arthritis points out that patients with RA are twice as likely as OA patient to have a serious complication from non-specific NSAID therapy. Strategies to avoid the GI toxic effects of nonspecific NSAIDs, include the use of a highly selective COX-2 inhibitor.[10]

These data, taken together, shows that the COX-2 drugs are sufficiently different in their safety profile from ns-NSAIDS as to represent a distinct class of medications, offering patients a distinct benefit over ns-NSAIDs. These drugs should be considered as separate therapeutic

options for patients at risk of serious GI bleeding (advanced age, chronic use and other risk factors).

For these reasons, GSK recommends that the Anti-inflammatory Therapeutic Category be revised as follows.

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	*Recommended Subdivisions*
Anti-inflammatory	Corticosteroids (see Hormones)	
	COX-2 Inhibitors	
	Salicylates	
	Nonsteroidals, Other	

References:

1. Altman RD, Hochberg MC, Moskowitz RW, Schnitzer TJ. Recommendations for the Medical Management of Osteoarthrits of the Hip and Knee. American College of Rheumatology Subcommittee on Osteoarthritis Guidelines. *Arthritis & Rheumatism*. 2000; 43;1905-1915.

2. Hocberg MC, Altman RD, Brandt KD, Clark BM, Dieppe PA, et al. Special Article Guidelines for the Medical Management of Osteoarthritis Part I. Osteoarthritis of the Hip. *Arthritis & Rheumatism*. 1995;38; 1535-1540.

3. Ombardier CB, et al. COMPARISON OF UPPER GASTROINTESTINAL TOXICITY OF ROFECOXIB AND NAPROXEN IN PATIENTS WITH RHEUMATOID ARTHRITIS CLAIRE B OMBARDIER. *New England Journal of Medicine*. 2000;1520 – 1528.

4. Schnitzer TJ, Bumester GR, Mysler E, Hochber MC, Doherty M, et al. Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), reduction in ulcer complications: randomised controlled trial. *Lancet.* 2004; 364; 665–74.

5. US package inserts, BEXTRA, CELECOXIB, VIOXX

6. Schnitzer TJ, Burmester GR, Mysler E, Hocberg MC, Doherty M, et al. Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), reduction in ulcer complications: randomised controlled trial. Lancet 2004; 364: 665–74

7. Farkouh ME, Kirshner H, Harrington RA, Ruland S, Freek WA, et al. Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), cardiovascular outcomes: randomized controlled trial. *Lancet* 2004; 364: 675–84

8. Newsome G. American College of Rheumatology. Guidelines for the Management of Rheumatoid Arthritis. 2002 Update. American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Arthritis and Rheumatism. 2002; 46; 328-346.

I. Antineoplastics Therapeutic Category, All Pharmacologic Classes

Current cancer treatment practice creates a unique situation that clearly does not fit well within the proposed draft USP formulary categories and the potential minimum requirement of two drugs per category.

Cancer is not one disease but rather a wide range of diseases, with products from multiple pharmacological classes used based on tumor type, stage of disease, available biomarkers, proven combination regimens and patient tolerability. Included in the pharmacological classes used in the treatment of cancer are antineoplastics, hormone suppressants, immune suppressants and other immunological agents. Current treatment guidelines, such as the NCCN Guidelines in Oncology, often offer a range of options for management based not purely on labeled indications but also on available scientific evidence for all of the product categories outlined above.[1] Therefore, many cancer treatments are used by physicians off label.

As written, many of the proposed categories in the draft USP formulary guide do not contain any self-administered products. As an example, many future self-administered products are likely to fall within the proposed "Targeted Molecular Therapies" section. This section could therefore potentially cover several very distinct classes of targeted molecular therapies, which have very discreet targets, indications, lines of therapy, tumor types, potential combination uses and biomarker requirements for use.

Cancer products that have similar mechanisms of action frequently have very different indications not only by tumor type but also by stage of disease and recommended combination regimens. Unlike many other therapy areas, Oncology is often characterized by initial approvals often being gained as accelerated indications for niche or highly refractory patient groups. Subsequent development then often leads to an expansion to earlier lines of therapy, alternative combination protocols and different tumor types. There are often significant time gaps between this evidence being published and its incorporation into product labeling, compendia and practice and treatment guidelines.

Based on the points above, GSK has significant concerns that, with the currently proposed formulary and the proposed requirement that only two drugs of any one category need be covered by the PDPs, many Medicare beneficiaries who may benefit from cancer therapies will be discriminated against by being denied appropriate treatment options for the management of their Cancer.

GSK therefore recommends that the USP grant an exception for anti-cancer therapies including antineoplastics, hormones suppressants, immune suppressants and other immunological agents and permit an open formulary for all Cancer treatment options.

Reference:

1. NCCN/ACS Treatment Guidelines for Patients. National Comprehensive Cancer Network. 2004. http://www.nccn.org/professionals/physician_gls/f_guidelines.asp#site

J. Antiparkinson Agents – Therapeutic Category (No. 47)

GSK recommends expanding the Therapeutic Category defined as "Antiparkinson Agents" to "Antiparkinson and Movement Disorder Agents."

Movement disorders are neurological motor disturbances characterized by either abnormally increased motor activity or by abnormally decreased motor function or mobility. It is believed that Movement Disorders develop from an abnormally functioning basal ganglia, the portion of the brain deep in the cerebral hemispheres most responsible for the body's motor control.[1]

In the current USP draft guidelines, treatments for Parkinson's disease do not fully address Movement Disorders. Movement Disorders include but are not limited to Parkinson's Disease, Dystonia, Restless Legs Syndrome, Essential Tremor, Multiple System Atrophy (MSA), Progressive Supranuclear Palsy (PSP), Huntington's Disease, Tourette Syndrome, Ataxia, Tics, Rett Syndrome, Spasticity and Wilson Disease. This is consistent with Parkinson's Disease & Movement Disorders, Fourth Edition, Editors, Joseph J. Jankovich, M.D., and Eduardo Tolosa, M.D., Lippincott Williams & Wilkins, New York, 2002.

Clinicians who care for those afflicted with Parkinson's disease and other movement disorders need a broad array of pharmacologic agents to address the complexities of these conditions. If this category is not expanded to address movement disorders, Medicare beneficiaries will be disadvantaged from receiving the appropriate medications to treat these conditions.

Therefore, we recommend that USP expand the Antiparkinson Agents Therapeutic Category to "Antiparkinson and Movement Disorder Agents."

<u>Reference</u>:

1. Department of Neurology, Baylor College of Medicine, www.bcm.edu/neurol/struct/park/park/.html.

K. <u>Therapeutic Category: Antivirals, Pharmacologic Classes (Nos. 58-69):</u>

The proposed HIV pharmacologic classes should be removed from the antivirals therapeutic category. Limiting coverage and restricting access to HIV treatments jeopardizes the lives of HIV patients. This special population should be treated as such under Medicare Part D.

The standard of care in HIV is a minimum of three HIV drugs at any one time. Those three drugs are usually from only one or two pharmacologic classes at a given time[1]. Two drugs each from the proposed pharmacologic classes is contrary to the DHHS guidelines for HIV. In fact, specifying any limited number of agents in these classes is contrary to national treatment guidelines. For example, the vast majority of people on treatment for HIV are taking a "backbone" of two drugs from the nucleoside/nucleotide reverse transcriptase inhibitor category. Even though the drugs are in the same pharmaceutical class and have the same general mechanism of action, a specific mutation in the HIV virus may render some drugs in this class unusable, while others are highly effective. There are several of these specific mutations (or patterns of mutations) so it is not possible to single out two drugs that would be effective in all patients.[2]

Research and practice have shown that adherence to medication regimens is essential in HIV treatment [3]. In order to enable patient adherence to medication, HIV therapy must be individualized for the patient based on a number of issues, including:

- pill burden
- dosing frequency
- toxicities
- drug-drug interactions
- pregnancy
- co-morbid conditions
- level of HIV in the blood[4]

Creating HIV pharmacologic classifications in an effort to reduce costs will have the opposite effect, increasing adverse events for patients and costs for CMS. Reducing the number of classifications further increases CMS cost and put HIV beneficiaries' lives in danger.

Therefore, based on these reasons, GSK proposes that the proposed HIV pharmacologic classes should be removed from the antivirals therapeutic category.

References

1. US .Department of Health and Human Services Guidelines for HIV. 2004. http://www.dhhs.gov/diseases/index.shtml. Accessed on September 16, 2004 Page 13.

2. US .Department of Health and Human Services Guidelines for HIV. 2004. Page 13 http://www.dhhs.gov/diseases/index.shtml. Accessed on September 16, 2004. page 19.

3. Mylonakis, E, Paliou, M, Rich, JD. Plasma viral load testing in the management of HIV infection. American Family Physician , February 1, 2001. Available at http://www. aafp.org.afp/20010201/483.html. Accessed on September 16, 2004.

4. US .Department of Health and Human Services Guidelines for HIV. 2004. Page 13 http://www.dhhs.gov/diseases/index.shtml. Accessed on September 16, 2004. page 53 .

L. Bipolar Agents Therapeutic Category (No. 76)

GSK recommends adding two (2) pharmacologic class listings titled "Mania or Mixed Episodes" and "Bipolar Depression" to the therapeutic category titled "Bipolar Agents". Although not pharmacologic classes per se, the pharmacologic class listings recommended mirror the treatment categories used in the American Psychiatric Association (APA) Practice Guideline for the Treatment of Patients with Bipolar Disorder (April 2002 Revision).[1]

The current Draft Model Guidelines fail to recognize the distinct episodes of bipolar disorder, which include mania, depression and mixed episodes, as well as distinctions between acute and maintenance treatment. As written, the two agents that could be selected by a PDP may or may not provide adequate treatment for all types of bipolar episodes. For instance, the two selected agents may only treat acute mania and not adequately prevent recurrence of bipolar depression. This is recognized in the APA Practice Guideline which makes separate treatment recommendation for the different episodes of bipolar disorder. Accordingly, practitioners require access to a minimum of four therapeutic categories: antipsychotics, anticonvulsants, antidepressants and mood stabilizers (e.g., lithium) to adequately manage both the acute and long-term treatment of bipolar disorder, as well as the types of episodes.

The goal of short term treatment for bipolar disorder is to control acute symptoms and help a patient return to normal function. However, the goal of long term treatment is help prevent future relapse, reduce symptoms, including risk of suicide and improve a patient's general functioning. [2] Furthermore, as bipolar disorder is usually a long term illness, maintenance treatment presents a unique challenge. Agents used in the short term treatment of bipolar disorder are often used long term, despite limited evidence to support their use. Therefore, agents that have demonstrated safety and efficacy in long term treatment are of importance in the overall therapy of a patient with bipolar disorder.

The devastating consequences of bipolar disorder and the failure of a single agent to effectively treat all bipolar episodes require broad access to multiple medications. The current Model Guideline places Medicare part D patients at enormous risk for inadequate access to critical bipolar disorder medications. Furthermore, inappropriate drug selection can contribute to rapid cycling, a difficult to treat condition where patients experience four or more mood disturbances within a single year. In particular, there are suggestions that use of antidepressants in patients with bipolar disorder may contribute to rapid cycling.[1] Therefore, a clear distinction between bipolar depression and unipolar depression, for the purposes of treatment, is required.
[1]

In addition, a recent survey revealed that 69% of patients with bipolar disorder were misdiagnosed with major depression (60%), anxiety disorder (26%), schizophrenia (18%) and borderline personality disorder (17%). [3] The high rate of misdiagnoses, in addition to the reasons noted above, underscores the need to have bipolar agents as a therapeutic category.

Proposed Classification – Bipolar Agents

Reference Line	Therapeutic Category	Pharmacologic Class	Recommended Subdivisions
76	**Bipolar Agents**	**Mania or Mixed Episodes**	
77		**Bipolar Depression**	

Bipolar References
1.American Psychiatric Association. Practice guideline for the treatment of patients with bipolar disorder (revision). *Am J Psychiatry*. 2002;159(4 suppl):1-50.

2. American Psychiatric Association. Practice guideline for the treatment of patients with bipolar disorder (revision). *Am J Psychiatry*. 2002;159(4 suppl):30.

3. Hirshfeld RMA, Lewis L, Vornik LA. Perceptions and impact of bipolar disorder: how far have we really come? Results of the National Depressive and Manic-Depressive Association 2000 survey of individuals with bipolar disorder. *J Clin Psychiatry*. 2003;64:161-174.

M. Blood Glucose Regulating Agents Therapeutic Category:, Insulins Pharmacologic Class (No. 77) and Hypoglycemic Agents, Oral Pharmacologic Class (No.78)

The proposed pharmacologic classification "Hypoglycemic Agents, Oral" is inconsistent with appropriate treatment of diabetes recognized in peer-reviewed scientific literature and standard medical practice. Further, compliant formularies would allow discrimination against sicker Medicare beneficiaries. To resolve these problems with the proposed classifications, we strongly support redefining "recommended subdivisions" as "pharmacologic classes", thereby requiring formulary coverage for each class and assuring coverage for appropriate multiple medication use.

Type 2 Diabetes (T2D) is a progressive disease where glycemic control is lost over time regardless of the treatment used (e.g. diet, sulfonylureas, metformin or insulin). Recent studies have shown that approximately 64% of patients with Type 2 Diabetes are not at the American Diabetes Association (ADA) A1C goal of 7% or lower, therefore demonstrating the need for more intensive treatment strategies and broad access to available treatment options.[1] During the course of T2D treatment, physicians typically add therapies without dropping current therapies to meet escalating patient needs (from monotherapy to increasing use of oral polytherapy to oral polytherapy plus insulin).

This standard of practice is supported in the literature as demonstrated in the classic Turner paper from the landmark UK Prospective Diabetes Study (UKPDS), which observed outcomes for more than 4000 patients randomized to 'conventional' versus 'intensive' therapy over a ten year period. The study demonstrated that there is a progressive need for multiple therapies to control hyperglycemia (by 3 years approximately 50% of patients will need more than one agent, and by 9 years 75% of patients will need multiple agents to achieve A1C goals).[2] The amassing of compelling evidence such as this is increasingly challenging the previous slow addition of further hypoglycemic agents in favor of a more intensive stepwise treatment approach involving combination therapy.[3,4] The pathophysiology of T2D reveals complex metabolic defects that cause the disease which may explain the need for multiple medications. The importance of using multiple medications that target these defects (insulin resistance, defective pancreatic insulin secretion, hepatic glucose production etc) is also described by Inzucchi in JAMA.[5] The right combination must be driven by patient-specific criteria such as tolerability, contraindications etc. However, physicians have relatively few treatment options to treat type 2 diabetes, particularly since several therapies are poorly tolerated.[6,7]

Therefore, the proposed oral hypoglycemic classification, within the Draft Model Guidelines does not assure that the necessary variety of medications needed to target the multiple defects would be covered. Participating PDPs limiting the number of

therapies to two could thus discriminate against beneficiaries requiring polytherapy (particularly those unable to tolerate one or more of the covered agents).

This creates significant concerns, not only regarding access to quality care for those who need it most but also regarding potential escalation of costs. Diabetes cost the US an estimated $132 billion in medical expenditures and lost productivity.[8] The significant direct medical costs are driven by the costs of complications of the disease.[9] As demonstrated in two papers from Diabetes Care and JAMA, improved glycemic control is associated with significant cost savings.[10,11] Because the use of appropriate medications can reduce direct costs, limiting medication coverage for diabetes is likely to have a negative impact on total CMS expenditures. The ADA recognizes the staggering costs of direct medical care for diabetes (e.g., hospitalizations for complications) versus the much lower costs of medications (broken out by outpatient meds, insulins/injectables, oral antidiabetics) which could reduce those complications.[8]

Therefore, GSK recommends the following changes to the Model Guidelines.

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	*Recommended Subdivisions*
Blood Glucose Regulating Agents	Insulin: Rapid	
	Insulin: Short	
	Insulin: Intermediate	
	Insulin: Long	
	Alpha Glucosidase Inhibitors	
	Meglitinides	
	Biguanides	
	Sulphonylureas	
	Thiazolidinediones	

We will also be proposing to CMS that diabetes be considered a special population under Medicare Part D regulations.

References:

1. Koro, CE, Bowlin, SJ, Bourgeois, N, et al. Glycemic control from 1988-2000 among U.S. adults diagnosed with type 2 diabetes. *Diabetes Care*. 2004; 27:17-20.
2. Turner, RC, Cull, CA, Frighi, V, et al. Glycemic control with diet, sulfonylurea, metformin, or insulin in patients with type 2 diabetes mellitus. *JAMA*. 1999; 1:2005-2012.
3. Gerich, EJ. Redefining the clinical management of type 2 diabetes: matching therapy to pathophysiology. *Eur J Clin Invest*. 2002 Jun; 32 Suppl 3:46-53.
4. Nathan, DM. Clinical practice. Initial management of glycemia in type 2 diabetes mellitus. *N Engl J Med*. 2002 Oct 24; 347(17):1342-9.
5. Inzzucchi, SE. Oral antihyperglycemic therapy for type 2 diabetes. *JAMA*.2002; 287; 360-372.
6. Harrower, AD. Comparative tolerability of sulphonylureas in diabetes mellitus. *Drug Safety*. 2000, 22; 313-320.
7. Kirpichnikov D, McFarlane, SI, Soweres, JR. Metformin: an update. *Annals of Internal Medicine*.2002; 137; 25-33.
8. HoganP, Dall T, Nikolov P et al. Economic Costs of Diabetes in the US in 2002. *Diabetes Care*. 2003;26: 917-932.
9. Gilmer, TP, O'Connor, PJ, Manning, WG, Rush, WA. The cost to health plans of poor glycemic control. *Diabetes Care*. 1997; 20; 1847-1853.
10. Wagner, EH, Sandhu, N, Newton, KM, et al. Effect of improved glycemic control on health care costs and utilization. *JAMA*. 2001; 285;182-189.
11. Menzen, J, Langley-Hawthorne, C, Friedman, M, et al. Potential short-term economic benefits of improved glycemic control. *Diabetes Care*. 2001; 24; 51-55.

N. Therapeutic Category: Blood Products/Modifiers/Volume Expanders

Pharmacologic Classes: Blood formation and Anitcoagulants (80-84)

GSK recommends adding three (3) pharmacologic class listings titled "Agent for Anemia", "Agent for Neutropenia", "Agent for Thrombocytopenia and Other" to the Therapeutic Category titled "Blood Products/Modifiers/ Volume Expanders". The current category of Colony Stimulating Factors is too broad and excludes several current products by definition.

In addition, GSK recommends the pharmacologic class of Anticoagulants should be updated to be consistent with The Seventh 2003 ACCP (American College of Chest Physicians) Guidelines on Antithrombotic Therapy and Thrombolytic Therapy scheduled for release on September 24, 2004. At least one covered drug from the six subdivisions of anticoagulants must be included as they cover distinct mechanisms of action.

Proposed Classification

Reference Line	**Therapeutic Category**	**Pharmacologic Class**	**Recommended Subdivisions**
81	Blood Products/Modifiers/ Volume Expanders	Agent for Anemia	
		Agent for Neutropenia	
		Agent for Thrombocytopenia and Other	
Reference Line	**Therapeutic Category**	**Pharmacologic Class**	**Recommended Subdivisions**
82	Blood Products/Modifiers/ Volume Expanders	Anticoagulants	Heparin, Unfractionated
			Heparin, Low Molecular Weight
			Direct Thrombin Inhibitors
			Factor Xa Inhibitors
			Vitamin K Antagonists

			Thrombolytic Agents

O. Cardiovascular Medicines Therapeutic Category, Beta-Blockers/Related Pharmacologic Class with Recommended Subdivisions of Nonselective, Cardioselective, and Alpha-beta Blockers.

Because of the unique properties and clinical benefits of the classes listed in the Beta-blocker "recommended subdivisions," we recommend that the USP Model Guidelines Pharmacologic Classification for Beta-Blockers/Related be changed to list Nonselective, Cardioselective, and Alpha-beta Blockers as unique pharmacologic classifications.

Beta-blockers are currently used for a broad spectrum of cardiovascular diseases (i.e. hypertension, angina pectoris, antiarrhythmics, hypertropic subaortic stenosis, left ventricular dysfunction following myocardial infarction, and mild to severe heart failure of ischemic or cardiomypatic origin, plus other non-cardiovascular applications). The current proposed classification suggests there is no significant difference among the three subdivisions and that there is, in essence, a class effect for all agents for all applications. The UCLA Heart Failure Clinical Practice Guidelines, however, recognize the differences among these classes, as evidenced in the following quote:

> "The ACC/AHA guidelines recommend using only those beta-blockers and those doses that have been proven to reduce mortality (i.e., mortality reduction is not a class effect)." [1]

Not all beta-blockers have been proven to reduce mortality in patients with Class I-IV heart failure, and not all of those have been proven to work across the entire spectrum of disease.

Similar arguments can also be made for use of beta blockers in diabetics. In diabetics, heart disease is a frequent complication with significant mortality and morbidity. Because of the impact on glycemic control, those beta-blockers that have a neutral effect on glycemic control should be explicitly covered. Older beta generation beta blockers, i.e., the non-selective, may have an adverse detrimental effect on glycemic control. The American Diabetes Association (ADA) 2004 Clinical Practice Recommendations reinforces the differences in beta blockers as exemplified in the following :

> "Utilization of β-blockade, ACE inhibitors, or possibly angiotensin receptor blockers is essential in preventing remodeling with its associated decline in ventricular function. Beta-Blockers not only prevent, but may also reverse, cardiac remodeling. Glycemic control may also play an important role in the

> therapy of diabetic HF. The adverse metabolic side effects that have been associated with β-adrenergic inhibitors in the diabetic patient may be circumvented by use of a third-generation β-Blocker. Prophylactic utilization of ACE inhibitors and β-Blockers to avoid rather than await, the need to treat high-risk diabetic patients."[2]

The alpha-beta-blocker subdivision is recognized as a third-generation beta blocker.

Because of the unique properties that alpha-beta-blockers have beyond just beta blocker effect, alpha-beta blockers do not belong in the beta blocker class as a subdivision. The addition of alpha-blockade to beta-blockade creates more complete adrenergic effects and additional ancillary pharmacologic properties which may include antioxidant, antiapoptotic, antiproliferative, electrophysiologic and metabolic effects. These unique effects differentiates alpha-beta-blockers from traditional beta blocker, warranting a separate pharmacologic classification. Although an argument could be made to simply put the alpha-beta blockers in a distinct class without placing the beta blockers in separate classes, we recommend that all three be listed as separate due their uniqueness and the lack of class effect

Therapeutic Category	**Pharmacologic Class**	**Recommended Subdivisions**
Cardiovascular	Nonselective Beta Blocker	
	Cardioselective Beta Blocker	
	Alpha-beta Blockers	

References:

1. UCLA Heart Failure Clinical Practice Guidelines-2003

2. Reference in support of the ADA 2004 Clinical Practice Recommendations: Diabetes Care 26:2433-2441, 2003; "Heart Failure – The frequent, forgotten, and often fatal complication of diabetes"; ADA

P. Gastrointestinal Medications Therapeutic Category, New Pharmacologic Class

The term "opioid antagonist" in the current subdivision of antidotes has become outdated and should be changed to specify "centrally acting opioid antagonists." A new opioid antagonist pharmacologic classification "peripherally acting opioid agonist" should be added to the Gastrointestinal Medications section for differentiation.

The new class of agent is peri registration for the treatment of Post Operative Ileus and under development for other Gastrointestinal conditions. The two distinct mechanisms of action and clearly different potential indications should be differentiated in the USP model guidelines.

Therefore, GSK recommends the following addition to the Draft Model Guidelines.

Therapeutic Category	Pharmacologic Classification	Recommended Subdivisions
Gastrointestinal Medications	Peripherally Acting Opioid Antagonist	

Q. Genitourinary Medicines Therapeutic Category; Benign Prostatic Hyperplasia (BPH) Agents Pharmacologic Class (No. 114)

The proposed BPH Pharmacologic Class is inconsistent with nationally recognized BPH treatment guidelines. The AUA guidelines specify two types of medications with distinct mechanisms of action and recommend using both types of agents for some patients. The proposed classifications do not assure access to appropriate medications for men with BPH because plans could choose any two medications and not at least one from each class.

To be consistent with recognized practice guidelines, GSK recommends changes to the BPH pharmacologic class which include a subdivision for alpha-blockers and a subdivision for 5ARIs. Because the recommended treatment for BPH includes both treatment of the underlying disease along with reduction in urinary retention and BPH related surgery, both of these subdivisions should have at least one covered drug.

Benign prostatic hyperplasia (BPH) is a progressive disease where the prostate continues to enlarge over time. The prevalence is age dependent, beginning usually after age 40; by age 60, prevalence is greater than 50%, and by age 85, as high as 90%[1]. Treatment is based on severity of symptoms and is directed to reduce prostate size through specific drug therapy or surgery (TURP or prostatectomy). The current pharmacological treatment options for lower urinary tract symptoms (LUTS) secondary to BPH include α-blockers and 5α-reductase inhibitors or 5ARIs. Alpha-blockers are recognized as appropriate therapy for prostatic enlargement and are used for relief of symptoms as well as prevention of disease progression. 5ARIs are effective for symptoms associated with prostatic enlargement, prevent disease progression and reduce the risk of acute urinary retention and the need for BPH-related surgery. Combination therapy, utilizing both 5ARIs with an alpha-blocker, appears to be more effective than alpha-blocker monotherapy in reducing the likelihood of acute urinary retention and surgery.[1,2,3,4] The European Urological Association (EUA) 2004 guidelines are consistent with the AUA guidelines[2].

With a higher prevalence of BPH in men over 65, it is especially important to assure access to appropriate medications. Left untreated, 1 in 6 patients with an enlarged prostate and symptoms may experience acute urinary retention or BPH related surgery over a 4-year time period[5].

For these reasons GSK recommends the following changes to the Model Guidelines.

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	Recommended Subdivisions
Genitourinary Medications	BPH Agents	*Alpha-blockers*
		5α-Reductase Inhibitors

References:

1. American Urological Association (AUA) Guideline on management of benign prostatic hyperplasia. 2003. Chapter 1: Diagnosis and treatment recommendations. The Journal of Urology, 170; 530-547.

2. European Urological Association (EUA) Guidelines on benign prostatic hyperplasia (Update 2004). Available at http://www.uroweb.nl/files/uploaded_files/guidelines/BPH_August_2004.pdf. Accessed September 15, 2004.

3. Barkin, J, Guimaraes, B, Jacobi, G, et al. 2003. Alpha-blocker therapy can be withdrawn in the majority of men following initial combination therapy with the dual 5ά-reductase inhibitor dutasteride. European Urology, 44; 461-466.

4. McConnell, JD, Roehrborn, CG, Bautista, OM. 2003. The long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. N Engl J Med, 2003;349; 2387-2398.

5. Debruyne, F Barkin, J, van Erps, P, et al. 2004. Efficacy and safety of long-term treatment with the dual 5ά-reductase inhibitor dutasteride in men with symptomatic benign prostatic hyperplasia. European Urology, 46:488-495.

R. Immunological Agents Therapeutic Category (No. 125)

The proposed Model Guidelines consider vaccines to be a recommended subdivision of the Immune Stimulants Pharmacologic Class, Immunological Agents Therapeutic Category.

While a plan may choose not to provide immunization to Medicare beneficiaries, it is in the interest of public health and the health of individuals to facilitate the ability of PDPs and MA-PDs to choose to provide immunizations. This would be consistent not only with the health of individuals but also consistent with overall public health objectives.

For this reason, GSK recommends that the USP establish Vaccines as a Therapeutic Category (stating that this category may not need to be populated as part of the Part D "safe harbor" standard) and establish a number of Pharmacological Classes, each with a disease that can be prevented by vaccines. Each disease has a specific vaccine, and these vaccines are not interchangeable in the same way as may be the case with other products with similar mechanisms of action.

Some adult immunizations are already provided under Medicare Part B (e.g., influenza, pneumococcal, hepatitis B to select populations). However, senior adults may need immunizations that are not currently covered by Part B. For example, Healthy People 2010 includes an objective of reducing levels of hepatitis A from the 1997 baseline of 11.3 new cases per 100,000 people to 4.5 new cases per 100,000 by 2010.[1] One of the strategies is to target high risk adults over age 40. The availability of hepatitis A vaccine from a plan offering a Part D benefit would make it easier to meet that objective. In addition, Healthy People 2010 contains an objective to reduce cases of Hepatitis B from the 1997 baseline of 15.0 cases per 100,000 to 3.8 cases per 100,000 by 2010.[1] Universal immunization of children will go a long way to reaching that objective, but there are many seniors outside of the traditional high risk groups currently eligible for Medicare covered hepatitis B immunization who have never been immunized. This additional population may still be at risk because hepatitis B is a blood-borne pathogen that may be contracted in a variety of circumstances. In fact, hepatitis B is easier to contract than HIV. Another category of beneficiaries who should be vaccinated, according to the CDC, are travelers to selected countries.

For these reasons, GSK requests that the following Pharmacologic Classes be considered for inclusion in the Immunological Agents Therapeutic Category:

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	*Recommended Subdivisions*
Immunological Agents	Tetanus-Diphtheria Vaccine	
	Influenza (Flu) Vaccine	
	Pneumococcal Vaccine	
	Hepatitis B Vaccine	
	Hepatitis A Vaccine	
	Hepatitis A and B Vaccine	
	Measles-Mumps-Rubella (MMR) Vaccine	
	Varicella (chickenpox) Vaccine	
	Polio Vaccine	
	Yellow Fever Vaccine	
	Typhoid Vaccine	

Reference:

1. Healthy People 2010. 14 Immunization and Infectious Diseases. Available at www.healthypeople.gov/Document/HTML/Volume1/14Immunization.htm

S. Hormones, Stimulant/Replacement – Therapeutic Category (No. 117)

GSK recommends adding one (1) new therapeutic category entitled "Bone Affecting Agents, Bone Resorption Inhibitors/Bone Formation Agents. Such a therapeutic category is consistent with how bisphosphonates are categorized in two of the official pharmaceutical compendia, the USPDI and the American Hospital Formulary Service (AHFS).

In the current draft guidelines, treatments for osteoporosis are lumped into an overly broad category of "Hormones, Stimulants/Replacements" that includes treatments for thyroid disorders, sexual dysfunction, menopausal symptoms, pituitary and other disorders. This therapeutic category is inappropriate for bisphosphonates used for the treatment and prevention of osteoporosis, as bisphosphonates are neither hormone stimulants nor hormone replacements.

Osteoporosis, which means "porous bones," is a condition of excessive skeletal fragility resulting in bones that break easily. According to the National Osteoporosis Foundation (NOF), osteoporosis and osteopenia (low bone mass) affect an estimated 44 million American women and men age 50 and over. This number is expected to rise to more than 52 million by 2010.

Osteoporosis is the primary cause of hip fracture, which can lead to permanent disability, loss of independence and sometimes even death. Collapsing spinal vertebrae can produce stooped posture and a "dowager's hump," resulting in loss of height and severe back pain. Osteoporosis leads to 1.5 million fractures per year, mostly in the hip, spine and wrist. According to the National Institutes of Health (NIH), one in two women and one in four men older than 50 will suffer a vertebral fracture, and the annual cost of treatment is estimated at $17 billion and rising. These numbers are only expected to rise as the U.S. population ages.

Osteoporosis, if not prevented or appropriately treated, is costly to the Medicare program. According to one estimate, Medicare pays for about 75% of hospital costs associated with osteoporosis-related admissions among adults age 45 and older. [1]

Although some bone loss is expected as people age, osteoporosis is no longer viewed as inevitable. Diagnosis and treatment may begin before bones break, delaying the disease's onset and diminishing its severity. Most important, early intervention can prevent devastating fractures.

Given the importance of this disease to the Medicare population, and the need for flexibility in addressing the needs of both the healthy and frail elderly in terms of co-morbidities, drug-drug interactions and other parameters of patient care, we recommend that USP create a separate therapeutic category for these agents

designated as "Bone Affecting Agents, Bone Resorption Inhibitors/Bone Formation Agents."

Such a therapeutic category is consistent with how bisphosphonates are categorized in two of the official pharmaceutical compendia, the USPDI and the American Hospital Formulary Service (AHFS). The USPDI lists bisphosphonates (and raloxifene) as "category: bone resorption inhibitors." Additionally, the AHFS includes bisphosphonates under section 92:00, Unclassified Therapeutic Agents, recognizing that an appropriate pharmacologic-therapeutic category does not exist in their classification system. AHFS *does* have a category for hormones (68:00 Hormones and Synthetic Substitutes, which, like the USP draft guidelines, includes the subcategories of adrenals, pituitary, thyroid, estrogens, and others), but does not include bisphosphonates in the same category.

We further recommend that the pharmacologic classes within the new therapeutic category be designated as follows: Bone Resorption Inhibitors - Bisphosphonates, Bone Resorption Inhibitors – Hormone/Hormone-like, Bone Resorption Agents – Other, Bone Formation Agents – Parathyroid Hormones.

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	Recommended Subdivisions
Bone Affecting Agents, Bone Resorption Inhibitors/Bone Formation Agents	Bone Resorption Inhibitors - Bisphosphonates	
	Bone Resorption Inhibitors – Hormone/Hormone-like	
	Bone Resorption Agents – Other	
	Bone Formation Agents – Parathyroid Hormones	

If USP does not wish to place osteoporosis drugs in their own category, we recommend at a minimum that the category 118 be expanded and renamed "Hormone/Hormone Antagonist/Hormone Substitutes/ Bone Affecting Agents/Bone Resorption Inhibitors/Bone Formation Agents" to account for the broad range of treatments covered in this category and to appropriately characterize the osteoporosis agents as pharmacologic classes within the category. (We note that as a general matter, the term "Hormone, Hormone Antagonist and Hormone Substitutes" is more consistent

with the standard nomenclature used in Medical Subject Headings.) We further recommend that the pharmacologic classes named above be included in such category.

Reference:

1. Testimony before the USP of the National Osteoporosis Foundation, the American Society for Bone and Mineral Research and the International Society for clinical Densitometry, August 27, 2004, citing Max W, Sinnot P, Kao C, Sung HY, Ride DP. The burden of osteoporosis in California, 1998. Osteoporos Int. 2002; 13(6): 493-500.

T. Respiratory Tract Medications Therapeutic Category Pharmacologic Classes: Antiasthma/Antileucotrienes (No. 136) Antiasthma/Bronchodilators (No. 137), Antiasthma Agents, other (No. 138), Mast Cell Stabilizers (No. 139), Mucolytics (No. 140) and Respiratory Tract Medications, Other (No. 141)

As currently constructed, the pharmacologic classes and subdivisions of the Respiratory Tract Medications Category proposed by USP present the available pharmacologic agents in a manner that is inconsistent with their mechanism of action, inconsistent with recommendations of evidence-based, nationally accepted practice guidelines [1,2,3] and inconsistent with accepted clinical practice for treating asthma and COPD.

GSK recommends that the proposed Respiratory Tract Medications Category pharmacologic classifications and subdivisions be replaced with the following classes (no subdivisions; alphabetic order):

- **Anticholinergics**
- **Beta-agonists – long acting**
- **Beta-agonists – short acting**
- **Inhaled Corticosteroids**
- **Leukotriene Modifiers**
- **Mucolytics**
- **Respiratory Tract Medication – other**

The proposed USP classification for Respiratory Tract Medications compresses three different classes of medications, the short acting beta-agonist (SABA), inhaled corticosteroids (ICS) and long-acting beta-agonists (LABA) into a single artificial grouping that doesn't reflect their differing mechanisms of action, guideline recommendations or standard clinical practice. Accordingly, the proposed structure creates potential for therapy for Medicare patients that is both inconsistent with national guidelines and inadequate to control disease.

Note: Because Mast Cell Stabilizers are rarely used in practice, USP should consider dropping them as pharmacologic classifications or consider them part of the "other" classification.

GSK is also concerned that the proposed Respiratory Tract Category and associated pharmacologic classes emphasize "anti-asthma" therapies and do not adequately address the different treatment options necessary for Medicare beneficiaries with COPD.

Revising the Respiratory Tract pharmacologic classes as outlined above creates a close alignment with long-standing treatment guidelines and clinical practice standards and should thus help ensure access to appropriate treatment options for Medicare patients with asthma and COPD.

Regarding asthma, the NIH/NHLBI guidelines indicate that patients with persistent asthma require at least two types of medication. Specifically, the guidelines state:

> "All patients need to have a short acting-inhaled beta2-agonist (SABA) to take as needed for symptoms. Patients with mild, moderate or severe persistent asthma require daily long-term-control medication to control their asthma (page 9)." Further, patients with moderate persistent asthma may need and patients with severe persistent asthma should have a long acting inhaled beta2-agonist in addition to the short acting beta2-agonist and a controller medication (page 11). [4]

Current clinical practice for asthma reflects the guidelines in that most treated asthma patients are managed with multiple medications. Market databases show that while a small portion of asthma patients (~20%) are managed with SABA alone, the vast majority of patients with asthma (~80%) require multiple medications to control their disease. [5]

COPD is a distinct, complex, multi-component disease characterized by airflow limitation that is not fully reversible. There are specific ICD-9 codes, nationally and internationally recognized guidelines [2,3] and treatment recommendations specifically for COPD.

The guidelines indicate that appropriate treatment for COPD often includes simultaneous use of multiple medications. Specifically, Celli B, MacNee W, et al. in *Standards for the Diagnosis and Treatment of Patients with COPD: a Summary of the ATS/ERS Position Paper* [3] state that:

- Combining different therapeutic agents produces a greater change in lung function and symptoms than single agents alone.
- Data from trials combining long-acting inhaled beta-agonists and inhaled corticosteroids show a significant additional effect on pulmonary function and a reduction in symptoms in those receiving combination therapy compared with its components.
- The largest effects in terms of exacerbations and health status are seen in patients with an FEV1<50% predicted, where combining treatment is clearly better than either component alone.

Again, as with asthma, the norm for treatment of COPD in clinical practice includes the use of multiple medications. Market databases show that nearly 90% of patients currently being treated for COPD receive more than one class of medication.

GSK proposes the following changes to the Model Guidelines:

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	*Recommended Subdivisions*
Respiratory Tract Medications	Anticholinergics	none
	Beta-agonists – long acting	
	Beta-agonists – short acting	
	Inhaled Corticosteroids	
	Leukotriene Modifiers	
	Mucolytics	
	Respiratory Tract Medication – other	

References:

1. National Institutes of Health National Heart Lung and Blood Institute. National Asthma Education and Prevention Program. Executive summary of the NAEPP expert panel report. Guidelines for the diagnosis and management of asthma- update on selected topics 2002. NIH Publication No. 02-5075. June 2002.

2. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: Executive Summary—Updated 2003. Bethesda, Md: NIH, NHLBI; 2003.

3. Celli B, MacNee W, et al. Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. Eur Respir J 2004;23:932-946

4. National Institutes of Health National Heart Lung and Blood Institute. National Asthma Education and Prevention Program. Executive summary of the NAEPP expert panel report. Guidelines for the diagnosis and management of asthma- update on selected topics 2002. NIH Publication No. 02-5075. June 2002.

5. Surveillance Data, Incorporated (SDI), June 2004.

III. Need for New Categories or Classes

In addition to the above revisions to the groupings in the Draft Guidelines, we believe that a number of products were missed in USP's creation of these groupings. Below we identify these omissions and provide suggested categories or classes for each.

A. Obesity Therapeutic Category

Obesity is associated with diabetes, coronary heart disease and hypertension. Because of the impact of these diseases for the elderly population especially, obesity treatments should be included as a therapeutic class in the Model Guidelines.

Obesity has been shown to increase the risk of developing diabetes, and conversely, interventional data has shown that weight management medications can effectively prevent diabetes.[1] Also, the American Heart Association (AHA) has classified obesity as a modifiable risk factor for coronary heart disease. Risk estimates from population studies suggest that >=75% of hypertension can be directly attributed to obesity. Obesity has a strong effect on lipoprotein metabolism, regardless of ethnic group. Increased weight is a determinant of higher levels of triglycerides, elevated LDL-C and low HDL-C. Conversely, weight loss is associated with a healthier lipoprotein profile in both men and women: triglycerides decrease, HDL-C increases and LDL-C decreases. [2,3,4,5,6]

Therefore, GSK requests that the following changes be made to the Model Guidelines:

THERAPEUTIC CATEGORY	**PHARMACOLOGIC CLASS**	***Recommended Subdivisions***
Obesity	**Centrally Acting**	*Sympathomametic*
		Non –sympathomametic
	Peripherally Acting	*Digestive Inhibitors*
	Hormonal Manipulation	

These proposed classes are drawn from the categories identified for the pharmacotherapy treatment of obesity by the National Institutes of Health (The Practical Guide. Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. Available at http://www.nhlbi.nih.gov/guidelines/obesity/prctgd_b.pdf . Accessed September 15, 2004.) and the American Academy of Family Physicians (Drug Therapy for Obesity. http://www.aafp.org/afp/20000401/2131.html. Accessed September 15, 2004.)

References:

1. The XENDOS trial (Diabetes Care 27:155-161, 2004).

2. American Heart Association conference entitled "Obesity: Impact on Cardiovascular Disease" was held May 22-24, 1998, http://www.americanheart.org/presenter.jhtml?identifier=1818

3. Risk Stratification of Obesity as a Coronary Risk Factor. American Journal of Cardiology 2002;90:697-701

4. Risk Stratification of Obesity as a Coronary Risk Factor. American Journal of Cardiology 2002;90:697-701

5. Obesity Is Independently Associated With Coronary Endothelial Dysfunction in Patients with Normal or Mildly Diseased Coronary Arteries. J Amer Coll Cardiol 2001;37:1523-8

6. The Relationship of Obesity and the Development of Coronary Heart Disease to Longitudinal Changes in Systolic Blood Pressure. Coll. Antropol 1998;22(2):333-344.

A. **Addition of Future New Therapeutic Categories and Pharmacologic Classes**

Critical to these processes is that the USP remain aware of newly approved drugs, new indications and other clinical developments that would warrant prompt revision to categories and classes in the Model Guidelines, and that all pertinent information is obtained by USP. The Statute assigns USP the function of adding new categories and classes to the Model Guidelines. The preamble to the Part D rules states that "the USP will revise its classification system periodically to reflect changes in therapeutic uses of covered Part D drugs and any additions of new covered Part D drugs." 69 Fed Reg 46660. According to the USP Web site, the Cooperative Agreement provides that the Guidelines will need to be revised over time, based on new information (such as therapeutic uses) about existing drugs and FDA approval of new drugs. In addition to establishing a mechanism for its own review of the Model Guidelines, we also recommend that USP establish a mechanism by which any interested member of the public (*e.g.*, patient groups, physicians, and manufacturers) can submit information to USP to identify a potential need for revision to the Model Guidelines. This mechanism should ensure that information related to newly approved drugs is easily identified so that the expedited process for such requests discussed above can commence immediately. Moreover, consistent with the USP's commitment to an open and public process, we believe that as issues are raised for consideration, the USP should use its Web site to publicize the consideration of such issues so that the public can submit information that it believes relevant to any such issues. In GSK's view, these processes and the involvement of the public will help ensure that the Model Guidelines remain current and thus continue to ensure that beneficiaries have access to a meaningful range of therapies.

CONCLUSION

GSK appreciates the opportunity to comment on the Draft Guidelines, and we recognize the extensive efforts of the USP in the development of the Model Guidelines. Yet, we believe considerable work remains in finalizing the guidelines so that they serve their intended purpose – the identification of categories and classes that, if followed by a PDP plan, will ensure that beneficiaries can enroll in the plan and have access to the drugs they need. While making all of the subdivisions in the Draft Guidelines categories or classes would be a positive step towards reaching this goal, as described above, certain changes also must be made to the categories, classes and subdivisions. Moreover, additional categories or classes must be developed to address products that seemingly were overlooked in the development of the Draft Guidelines. Please feel free to contact Debbie Fritz, PhD., at (919) 483-2191 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Dean Hakanson, MD
Vice-President
GlaxoSmithKline

CMS-4068-P-1219

Submitter : Miss. Binita Patel **Date & Time:** 10/04/2004 08:10:44

Organization : UNC- Chapel Hill

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I am currently a 3rd year PharmD student at the University of North Carolina at Chapel Hill. I am concerned about the proposed regulation that allows plans to establish preferred and non-preferred pharmacies. If this occurs, my role as a pharmacist will not be what I have spent the past three years working towards. I joined this profession because its core value of being able to help patients. If patients are forced to go to other places to receive their medications, I will not be about to fulfill my duties as a pharmacist. At UNC, our academic focus has been on the patient. If you decide to implement this law, then we will not be able to practice.

Also, patients with two more chronic diseases and two or more drugs should qualify for medication therapy management services. A pharmacist can offer so much knowledge to patients in regards to medication management. Everyday, patients use their medications incorrectly causing harm to them. If pharmacists were there to intervene, we could eliminate such problems. Certain disease states can be very well managed if there was adequate knowledge by the patient.

Thank you for considering my view.

Binita Patel

CMS-4068-P-1220

Submitter : Dr. Clifford Wong **Date & Time:** 10/04/2004 08:10:00

Organization : MedImpact Healthcare Systems, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Part III: Collection of Information Requirements
Recommendations in the area are:
* Where ever possible, use the standards developed and adopted by HIPAA or other regulating entities. Examples are: NCPDP 5.1 transmission, X12 standards (270/271, 834, 835, etc.).
* If the standard record formats do not meet Part D requirements, then the recommendation is to interface with the appropriate sub-groups to begin modifications once data requirements are known.
* Utilize the current Drug Discount Card standards if possible, since many systems have been programmed for these record formats. This includes enrollment application information, Request/Response records to CMS for eligibility verificiation, disenrollment, etc.

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

See attachment for comments

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

See attachment for comments

Issues 11-20

FALLBACK PLANS

See attachment for comments

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

See attachment for comments.

CMS-4068-P-1220-Attach-4.doc

CMS-4068-P-1220-Attach-3.doc

CMS-4068-P-1220-Attach-2.doc

CMS-4068-P-1220-Attach-1.doc

CMS-4068-P-1220-Attach-1.doc

CMS-4068-P-1220-Attach-2.doc

CMS-4068-P-1220-Attach-4.doc

CMS-4068-P-1220-Attach-3.doc

CMS-4068-P-1220-Attach-4.doc

CMS-4068-P-1220-Attach-3.doc

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CMS-4068-P-1220-Attach-4.doc

CMS-4068-P-1220-Attach-2.doc

CMS-4068-P-1220-Attach-1.doc

CMS-4068-P-1220-Attach-3.doc

MedImpact Healthcare Systems Inc, Comments for
Medicare Prescription Drug Benefit Proposed Rules Review: File Code CMS-4068 P

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

Summary: We are required to implement population based drug utilization management and quality assurance programs as well as targeted medication therapy management programs for individual patients. We may already have some of these programs in place, but will need to develop new programs and processes to meet this requirement. We will be required to submit data to an independent Quality Improvement Organization for the purpose of monitoring. Sponsors are encouraged to use electronic prescribing and physician incentives are included. We are required to be accredited as a PDP sponsor.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans		
FR Page #	***Excerpt***	***Comment/Question***
46667 D.2.	*"Cost & Utilization Management, QA, MTM, Programs to control fraud, abuse, and waste.* "…drug utilization management and quality assurance systems are generally considered to be population based while medication therapy management involves targeted, direct patient care.	

MedImpact Healthcare Systems Inc, Comments for
Medicare Prescription Drug Benefit Proposed Rules Review: File Code CMS-4068 P

46667	*P&T Committee oversight of cost-effective drug utilization management programs* "We believe that a cost-effective drug utilization management program could also employ the use of prior authorization, step therapy, tiered cost-sharing, and other tools to manage utilization" "Although we have not included proposed regulations, we are considering in the final rule a requirement that these tools should be under the direction and oversight of a Pharmacy and Therapeutics Committee to ensure an appropriate balance between clinical efficacy and cost effectiveness."	1. MedImpact's comment speaks to optimizing the use of the noted tools provided by PBMs to supporting MA PD or PDPs in their efforts to provide a quality, affordable, and accessible drug benefit. CMS rules must allow PBMs to exercise and use all available tools at their disposal to help manage the quality and cost of providing drug benefits to large populations. Benefit design strategies allowing actuarially equivalent products need to be considered and modeled with a creative intent based upon a societal mission to serve our elderly population. P & T committees provide quality oversight in the arena of drug therapeutics and selection based upon scientific evidence. It is our belief that P & T selects the best available clinical products and then supports the efforts of the PBM team to effectively design the benefit structures to administer affordability and accessibility. The fundamental guiding principle in the regulation is to provide actuarial equivalence to assure equivalent financial value to the beneficiary. The primary role of P & T remains to assure QUALITY while the AFFORDABILITY and ACCESSIBILITY of the drug benefit is achieved by a team consisting of pharmacists, actuaries, benefits experts, I.T. designers, and many others. We do not believe that there is a need for language requiring P & T oversight over the broad operations of a PBM. The Chief Medical Officer exercises that critical oversight role in assuring that corporate philosophy balances clinical quality with fiscal responsibility. 2. We would further note that "quality" includes the principles of safety and efficacy. Thus P & T has an expansive role and responsibility in this stead whereas benefits design and systems management to administer a benefits design is clearly in a different arena requiring support from actuaries, I.T. analysts, finance experts, actuaries, and of course pharmacists. We do not see where the limited time resources of a physician led team needs to provide direct oversight in the operations and technology arena.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans		
FR Page #	***Excerpt***	***Comment/Question***
	P&T Committee oversight of cost-effective drug utilization management programs *(Continued)*	I would recommend that we emphasis that the P&T Committee focus not only on Quality, but the evaluation of the Safety and Efficacy of the drug products available under a defined program. The benefit strategies are uniquely different from P&T activities of product review and recommendations and your point carries this message out. If this is helpful, attached are some excerpts from the current P&T charter: Committee description: A committee shall exist at MedImpact Healthcare Systems that will be the policy recommending body to MedImpact administration and the Health Services staff and the administration, pharmacy and related benefit administration departments of client health care organizations and plans on matters related to the therapeutic use of drugs. This committee shall be called the Pharmacy & Therapeutics Committee ("Committee"). To serve in an advisory capacity to MedImpact administration and to the medical, health care and related benefit professionals of MedImpact clients on matters pertaining to the use of drugs, including recommendations on the coverage for specific drug therapies.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans		
FR Page #	***Excerpt***	***Comment/Question***
	P&T Committee oversight of cost-effective drug utilization management programs *(Continued)*	Committee scope: • To recommend therapeutic designations and appropriate prescribing guidelines to assist with the placement of products on Drug Formulary(ies) acceptable for use in the ambulatory care setting and provide for ongoing constant revision. • To initiate or direct recommended Drug Use Review (DUR) and Drug Use Evaluation (DUE) programs. • To advise MedImpact Healthcare Systems on suitable educational programs and make recommendations in the implementation of effective drug control procedures. • To document such formulary or drug use functions that are used by MedImpact or delegated to it by clients.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans		
FR Page #	***Excerpt***	***Comment/Question***
46667	*Notice to members about cost-effective drug utilization management programs* "In addition, appropriate drug utilization management programs would have policies and systems in place to assist in preventing overutilization and underutilization of prescribed medications. PDP sponsors and MA Organizations offering MA-PD plans must inform enrollees of program requirements and procedures in order to prevent unintended interruptions in drug therapy. For example, enrollees would be made aware of how to proceed if special circumstances require their prescriptions be refilled before the targeted refill date."	1. PBM systems can detect and prevent early refills based upon protocols established by MCO, MA plans. We are not clear as to what special circumstance would require prescriptions to be filled BEFORE the targeted refill date. Patients have access to a vast network of over 50,000 pharmacies and can have refills completed on virtually any given day. Our sophisticated systems in combination with that of the chain retail pharmacies provide virtual access. Patients on specialty or unique prescription items definitely have to plan their prescription needs more carefully. We believe that enrollees and their care givers have accountability to manage their care and to plan accordingly .
46667 D.2.b	*Quality assurance requirements and the Omnibus Reconciliation Act of 1990* "We are proposing the quality assurance programs include requirements for drug utilization review, patient counseling, and patient information record keeping. We believe that these requirements would generally need to comply with section 4401 of the Omnibus Reconciliation Act of 1990 as codified in 42 CFR 456.705 and section 1927(g)(2)(A) of the At, and we are considering such specific requirements for the final rule…….We solicit comments on whether the Medicaid standards are in fact industry standards, whether they are appropriate standards for part D, and if they are, how they should be adapted for use in part D."	1. DUR review and patient information record keeping are done in compliance with OBRA 90 at the MCO, MA and contracted provider levels. Patient counseling at the pharmacy point of service is mandated by State law and is a cornerstone of retail pharmacy practice. Pharmacy consultation is provided to all patients, not just Medicaid. Quality Assurance in an integrated health care delivery system has advantages which are not as readily achieved in a network provider model. Within integrated deliver systems, electronic medical records and electronic prescribing to staff type pharmacies is emerging. Access to powerful information systems such as this is not yet available to the network models utilizing contracted providers in medicine and pharmacy. Thus, record keeping and quality assurance program regulation evolution needs to be mindful of this reality. .

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans		
FR Page #	***Excerpt***	***Comment/Question***
46667	*Elements of a quality assurance program* "The elements that are currently viewed as desirable for quality assurance programs are – (1) electronic prescribing (which will become a requirement in the future as discussed later in this preamble); (2) clinical decision support systems; (3) educational interventions, which could be provided by QIO or could rely on other mechanisms; (4) bar codes; (5) adverse event reporting systems; and (6) provider and patient education. We do not expect PDPs and MA-PD plans to adopt all of these elements. However, we expect substantial innovation and rapid development of improved quality assurance systems in the new competitive and transparent market being created by the new Part D benefit.	1. Unclear about what type of policies and systems CMS refers to in this section. The implementation of HealthConnect over the next several years should enhance current quality assurance programs. 2. Electronic prescribing: MedImpact supports the evolution of this technology and will engage in furthering its development as required with MA, PDP clients. While this technology appears readily available, there are many challenges to be overcome to assure physician adoption and broad industry utilization. 3. Bar code technology for prescription dispensing is a standard of practice within the mail fulfillment industry and is just beginning to emerge in progressive retail pharmacy outlets using varying levels of automated dispensing technology. Retail stores with high prescription volume and pharmacist staffing shortages are beginning to invest in this technology. It will be many years before this technology will be implemented across all retail practice settings.
46667	*Definition of medication error* "…the Food and Drug Administration adopted the following definition of a medication error: > Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use (see 687 FR 12500 (March 14, 2003)). …We are citing this definition in this preamble as one that we would use initially in interpretive guidance."	1. This definition is broad and MA-PD plans may interpret reporting requirements differently, thus leading to different reporting rates. 2. "Medication error" reduction and management is a risk management process which is the accountability of the participating network pharmacy. PBMs are not engaged in the risk management process dealing with prescription dispensing errors at the retail pharmacy POS. The data within the PBM database is utilized for adjudication purposes and population management processes. The data within the participating network pharmacy system is utilized for direct patient care and prescription fulfillment. Any rules promulgated for QA involving medication error management needs to consider how separate and distinct information systems and organizations can work together to integrate and support broad QA mandates.

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FR Page #	***Excerpt***	***Comment/Question***
	Evaluation of quality assurance programs " Therefore, we particularly invite comments on how we could evaluate PDPs and MA-PDs based on the types of quality assurance measures and systems they have in place, how error rates can be used to compare and evaluate plans, and how this information could be best provided to beneficiaries to assist them in making their choices among plans"	1. CMS needs to be aware that integrated systems may effectively document and track errors or occurrences within a uniform overarching infrastructure. Network systems lacking such an overarching framework will be following separate guidelines and processes without a singular reporting point. It is reasonable to assume that data capture and reporting rates may be less within the network process and is not necessarily an accurate reflection of quality. A fair and scientific comparison would be based upon uniformly accepted standards. 2. MA PDs and PDPs are different organizational structures newly established to provide access to the new MMA with Medicare Part D. There are no current standards of comparison for this new entity. MAs may possibly be compared via current NCQA or HEDIS benchmarks for how they served their commercial populations. The contracted hospitals may be compared via their JCAHO ratings. State regulatory agencies will have incidents of complaints or citations. There are other not for profit organizations providing quality and service ratings which may be used, but none are focused specifically on the management of the pharmacy benefit. Comparison of pharmacy chains have been provided by various consumer based organizations. We would note that MMA is a broad modernization act which goes beyond just Part D. PBMs which may be PDPs or PDs for MA-PDs have been compared on service issues. This is a very complex issue and there are no simple and accurate ratings or processes which would serve consumers best. Consumers are focused on the cost of the premium and the value of the corresponding drug benefit which is provided via a network pharmacy. The fact that a chain pharmacy will probably serve MULTIPLE PDPs or MA-PDs will complicate targeted comparison even further. Are you comparing the retail POS outlet or the MA-PD or PDP plan? The benefit is defined by law and all variations are required to be actuarial equivalents. Comparison processes will need to wait until there is adequate experience and industry consensus as to what will be appropriate and fair quality benchmarks.

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FR Page #	***Excerpt***	***Comment/Question***
46668 - 69	*Medication therapy management services reimbursable* "Medication management services would be reimbursable when adopted by a plan only when provided to targeted beneficiaries as defined in §423.153(2) of our proposed rule and later in this preamble." "…services could include, but not be limited to, performing patient health status assessments, formulating prescription drug treatment plans, managing high cost "specialty" medications, evaluating and monitoring patient response to drug therapy, providing education and training , coordinating medication therapy with other care management services, and participating in State-approved collaborative drug therapy management." "We will ask a PDP sponsor or MA organization to disclose the fees it pays to pharmacists or others, including an explanation of those fees attributable to MTMP services."	1. We are not clear yet as to how MTMP services will be reimbursed and how that reimbursement will be provided to pharmacies at the POS. If such service is to be provided at the pharmacy POS, contractual negotiations will need to be undertaken to establish an appropriate fee schedule. Credentialing or evidence of competency in selected disease states will need to be provided. The shortage of pharmacists at the POS in the retail sector needs to be considered. Likewise, retail pharmacies in general do NOT have truly confidential areas for detailed consultations envisioned for MTMPs. Such services are most effectively provided in clinical environments such as integrated delivery systems, clinic offices, or by appointment in certain retail pharmacy facilities with adequate consultation facilities. 2. MA-PDs and PDPs will need to develop estimates of costs to submit with their solicitations under what we assume will be administrative costs incident to appropriate drug therapy. Enrollees will not pay for these services, thus the cost with appropriate margin must be built into the premiums for an adjusted or separate administrative costs line. There are no established models for this service and we will be evolving reasonable business assumptions and modeling to support a proposal. 3. Targeted enrollees who may benefit from this service are described as "taking multiple Part D covered drugs, and are likely to incur annual costs that exceed a certain level that we can determine." We believe that this may require forecasts to be done for 2006 but will require CMS to allow accrual of costs to be reconciled in the following year based on lack of present data. PDPs of MA PDs must develop forecasts by early 2005 to submit with their solicitation or to adjust their proposed cost structures to CMS at subsequent quarters. CMS must allow flexibility in this regard prior to formulation of firm and fast rules.

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FR Page #	***Excerpt***	***Comment/Question***
46668 – 69	*Medication therapy management services targeted individuals* "Second, section 1860D4(c)(2)(A)(ii) of the Act requires that MTMP services be provided only for targeted individuals. In other words, not all members of a plan would be entitled to receive these services. As provided under §423.153(d)(2), "targeted beneficiaries" would be plan enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs that exceed a certain level that we determine. We would invite comments on how we should provide comments to drug plans in defining "multiple chronic diseases" and "multiple covered Part D drugs" for the purposes of determining which Part D enrollees would qualify for MTMP services, or whether such determinations are left to the plans as part of their benefit design." "In addition, we are concerned about the method that plans should use to determine that plans should use to determine the costs that enrollees are "likely to incur" to ascertain whether they qualify as targeted beneficiaries." "Active beneficiary participation and consistent delivery of quality MTMP services will require developing and maintaining on-going beneficiary-provider relationships."	1. Existing Disease Management programs manages patients with diabetes, asthma, CAD, CKD, CVD, CHF, hypertension, osteoporosis and depression. These would most likely be the type of disease states that CMS will be targeting. We will be dependent on ICD-9 coding and inferential data (e.g. prescription data, hospital discharge diagnosis, Encounter Coding System) to identify patients with these disease states. This methodology employed by the Disease Management programs results in a positive predictive value of 85-95% (=5%-15% false positives). We will need to determine how to identify patients with specific chronic diseases. 2. If eligibility for MTMP participation depends upon incurred costs, what are the criteria for ineligibility? Will patients transition in and out of MTMP? For example, suppose a member qualifies in year 1 based upon achieving a certain threshold for drug costs. Assume the program is successful and the member reduces their drug costs in year 2. Would the member still be eligible to enroll for year 3 or would they be disqualified? Such inconsistency may be confusing for members and may result in dissatisfaction with their health care.

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FR Page #	***Excerpt***	***Comment/Question***
46669	*Pharmacists as MTMP providers* "Section 1860D-4(c)(2)(A)(i) of the Act specifically states that a pharmacist may furnish MTMP services. While we believe that pharmacists will be the primary providers of these services, MTMPs could also include other qualified health care professionals as providers of services."	1. How will we separate and bill non-pharmacists services in order to receive reimbursement? 2. Our comments above touch upon pharmacists in the retail network environment as providers of this service. We again reiterate the concern regarding the national shortage of pharmacists. Without a doubt, segments of the retail pharmacist industry lobbied successfully for this language. However, to effectively serve large populations, a supportive clinical, financial and operations infrastructure will be critical to the success of the program. We believe that the oversight for this process begins with the physician referring and guiding patients to MTMP based upon established protocols. MA-PDs, PDPs, PPOs will need to develop such protocols and guidelines with corresponding assumptions leading to cost forecast for premium adjustments. It would be difficult for self directed enrollment unless the patient is identified as a targeted individual enrollee. Some MA-PDs, PDPs may wish to contract with a subcontractor to provide such services. Pharmaceutical companies may wish to provide, support, or sponsor programs which could be of great value to enrollees utilizing their products. No doubt, the pharmacists will play a key role, but the scope and nature of intended MTMP is much more expansive and requires coordinated efforts which engage physicians, patient educators, laboratory data, medical records, and a long term care treatment plan for patients who have a variety of clinical conditions which broadly impact appropriate therapy beyond the prescription. While the notion of call centers seems impersonal, a pharmacist at a call center with the required medical data may be THE most effective facilitator and coordinator of the MTMP. 3. Cost effectiveness for such programs will require long term research involving all aspects of the continuum of care. We would suggest that models for implementation be provided research grant funding as well as operations funding to evolve the optimal models going forward. It would be a good investment to bring together an expert panel to envision various models and to solicit participants willing to commit to execution with a defined statistically significant population. In this way, we may evolve the best practice courses to optimize the use of Medicare and thus taxpayer dollars.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

FR Page #	*Excerpt*	*Comment/Question*
46670 D.2.d.	*Additional fraud, abuse, and waste standards* "We would also like comments on the value added from requiring plans to develop comprehensive performance standards for use in evaluating internal processes that would appropriately and efficiency research, identify, monitor, and take immediate action to mitigate fraud, abuse, and waste" "For instance, PDPs and MA-PDs need to determine whether or not physicians are illegally prescribing narcotics. In addition to available appropriate data that might be supplied by us, the plans could develop and utilize methods such as data analysis , record audit of PBMSs, pharmacies, physicians, and other providers, DUR….."	1. Will CMS develop uniform standards for all MA-PD plans or will each MA-PD plan develop their own criteria? Will this data be used to compare against other MA-PD plans? How will CMS account for differences in internal processes? 2. CMS has demonstrated a strong interest in identifying physicians who are illegally prescribing narcotics. This was clear in the DDC rules as well. This type of reporting and tracking is not something PBMs have done as routine reporting to health plans or to law enforcement agencies. We would suggest that CMS keep this type of fraud and abuse detection separate from the clinical, financial, and business requirements needed to effectively administer the MMA Part D drug benefit. If such tracking is desirable to obtain prosecutorial evidence, CMS may wish to develop a proposal soliciting bids from PBMs or other claims processing firms to undertake this as a separate project in conjunction with appropriate state and federal law enforcement agencies. Compensation to the successful bidder would be provided to cover administrative as well as operations costs, materials, and start up investment. Successful identification of such illicit prescribing will require coordination with the dispensing pharmacies, federal and state law enforcement, and the appropriate medical and pharmacy licensing agencies. Generation of reports of possible illicit prescribing serves no value unless there is an action plan and infrastructure established to act upon the data. Data from the PBM will need to be reinforced with actual copies of prescriptions and identification of patients. Prosecutorial success requires significant investment in the data analysis at all levels of the fulfillment system. These are law enforcement processes which seem distinct from our clinical and drug benefit management core competencies. Should MA-PD and PDPs forecast costs for such endeavors in their solicitations? Who will pay for these services?

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46670	*Monitoring fraud, abuse, and waste* "One area of concern is inappropriate switching of prescriptions by a PDP or MA-PD plan without consulting a prescribing physician."	1. Pharmacists have been identified by national polls as one of the most trusted professionals in America. Also, the practice of pharmacy is highly regulated and pharmacists are trained and ingrained to practice within the scope of the law. Pharmacists will not put their licenses on the line to switch prescriptions illegally without consulting with and getting physician approval. Pharmacists licensed and registered in the state of practice should ALWAYS have responsibility and accountability for any switching programs instituted by that organization. CMS may wish to focus on developing rules that state as such. In no instance, should non-pharmacist managers supervise or over see such programs. Development of policies and procedures governing a switching program need to be reviewed and approved by the responsible pharmacy executive and manager who should assume accountability for compliance to governing federal and state laws. The practice of pharmacy by a pharmacist is regulated by the governing State Board of Pharmacy.

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46670	*Testing integrity analytical tools for effectiveness* "We also seek comments on the appropriateness, value and need for requiring the plans to test program integrity analytic tools for effectiveness, efficiency, and adaptability to the Medicare Benefit environment. For example, one approach could require the plans to provide any of the following in periodic reports; (1) Summary of data analysis activities, (2) resources, (3) tools, or (4) trend analysis. Alternatively, the plans could be required to develop their strategy and propose what each plan determines to be the best approach for detecting and deterring fraud and abuse. Furthermore, the plans could be asked to demonstrate that the agreed upon activities and outcomes that the plans achieve are in relation to the priorities established by us."	1. What would be the purpose of providing the noted periodic reports? PBMs consistently monitor drug trends to allow clients to make key decisions on how to manage their population of beneficiaries. In the competitive Medicare market place where margins are narrow and pricing is on a cost plus basis, what is the value of providing reports for which there is no defined actionable outcome? Rest assured that the MA-PD and PDP will be doing everything reasonable to manage drug spend as required by CMS and to achieve a reasonable profit within the allowable risk corridors. Development of additional reports requires IT investments and analyst support which adds to costs. We would rather invest all available dollars for appropriate drug spend. 2. The continuing note "Alternatively, the plans could be required to develop their strategy and propose what each plan determines to be the best approach for detecting and deterring fraud and abuse. Furthermore, the plans could be asked to demonstrate that the agreed upon activities …are in relation to priorities established by us." We believe that the drug benefit is one of the areas most easily monitored and analyzed due to the sophistication of the systems and establishment of NCPDP standard data formats. The pharmacy system is such that every transaction may be tracked back to a patient, a prescriber, a pharmacy and ultimately the prescription and the inventory of the dispensing pharmacy. If there is collusion between a local physician and a pharmacist, that may be detected most effectively at the local level and not by a population focused data base. Criminal fraud surely exists, but relative to prescription fraud and abuse in the Medicare population in particular with Controlled Substances, we are not knowing of the data which supports that assumption. We are confident that reports may be generated to identify prescribing outliers. We refer to our prior comments: Who wants this data and for what purpose? Who is willing to pay for such data gathering and analysis? And, should such costs be forecasted into any solicitation proposal to be a PDP or MA-PD?

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FR Page #	***Excerpt***	***Comment/Question***
46670	*Consumer satisfaction surveys* Under §423.156 we would conduct consumer satisfaction surveys among enrollees of PDPs and MA Organizations offering MA-PD plans in order to provide comparative information about qualified prescription drug coverage to enrollees as part of our information dissemination efforts."	1. We would suggest that CMS and CAHPS provide straw man models of survey instruments to the MA-PDs and PDPs for input prior to final draft and distribution. 2. How will CAHPS/AHRQ differentiate satisfaction with the benefit versus the service provided by the network pharmacy? 3. If all plans are actuarially equivalent as approved by CMS, how will CMS differentiate consumer satisfaction?

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46670 D.4.	*Electronic prescribing program* "Section 1860D-4(e) of the Act contains provisions for electronic prescription programs. The statute contains specific provisions on when voluntary initial standards may be adopted (not later than September 1, 2005) and when final standards should be published (not later than April 1, 2008) and then effective (not later than 1 year after the date of promulgation of the final standards)."	1. 423.159(a) would require that PDP sponsors and MA PD PLANS must have the capacity to support e-prescribing programs. We would await the development of the final standards to ascertain how we could support such. 2. The statutory language is specific in that e-prescribing will also transmit data to the pharmacy such as: prescription, formulary information, medical history, possibility of any ADR, availability of lower priced alternative. Please note that "medical history" needs to be defined such that it may be transmitted in a NCPDP field. All the information to be provided to the pharmacy needs to fit a NCPDP approved field. This statute may require significant investment by all stakeholders in IT SYSTEMS. The discussion suggests that only the MA-PD and PDPs have the capability and capacity to undertake compliance to serve the pharmacies. We are supportive of e-Prescribing, but recognize that there will be significant investments required. Pharmacies will benefit by having a clean and almost pristine prescription readily adjudicated and easily entered into their internal pharmacy system. There may be costs associated with the provision of such data elements which will need to be shared across the entire provider continuum.

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	Electronic prescribing program (Continued)	3. There is NO REQUIREMENT THAT PHYSICIANS WRITE PRSCRIPTIOINS ELECTRONICALLY. This is the limiting adoption factor. The language allows differential payment to physicians who elect use e-Prescribing and comply with the forthcoming standards. MA PDs and MCOs will require time to revise their contracts with physicians within their network. Incentives will need to be designed and in place in the contract period prior to CMS implementation of the standard. Physicians will need to invest in the I.T. systems within their practice management systems to comply. Many physicians are appropriately concerned about the investment costs and the impact upon their office efficiency. There is not uniform agreement among physicians and other prescribers that the quality gains offset the lost efficiency and cost investments. The Medicare population is probably about 10-20% of any given physicians practice. Adoption of e-Prescribing will require a process that covers at least 66 to 75% of the physician's panel. The system will need to be able to serve almost his/her entire patient commercial panel as well. Physicians need ONE system that covers all. If the e-Prescribing is geared only for Medicare, adoption will be minimal as the investment ROI will be questioned.

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46671-72	*Physician incentives to use electronic prescribing* "We have added regulations at §423.159(b) of this proposed rule that would allow an MA-PD plan to provide a separate or differential payment to a participating physician who prescribed covered part D drugs in accordance with electronic prescription standards (Note that this provision only applies to MA-PD plans and not to PDPs). "Differential payments, at the MA organization's discretion, could take into consideration the cost to the physician in implementing the program and could be increased for participating physicians who use e-prescribing to significantly increase – (1) Formulary compliance where medically appropriate; (2) Use of lower cost, therapeutically equivalent alternatives; (3) Reductions in adverse drug interactions as evidenced by appropriate use of drug interaction checking functions in electronic prescribing; and (4) Efficiencies in filling and refilling prescriptions through reduced administrative costs." "We note that any payment must be in compliance with other Federal and State laws…"	1. Would we still be in compliance with California's Knox-Keene Health Care Service Plan Act? Would it apply in this situation since it involves Medicare patients only? **§ 1348.6. Contracts between health care service plans and licensed health care practitioners; prohibition on certain incentive plans** (a) No contract between a health care service plan and a physician, physician group, or other licensed health care practitioner shall contain any incentive plan that includes specific payment made directly, in any type or form, to a physician, physician group, or other licensed health care practitioner as an inducement to deny, reduce, limit, or delay specific, medically necessary, and appropriate services provided with respect to a specific enrollee or groups of enrollees with similar medical conditions. 2. Incentives for physician adoption need to take into account applicable state and other governing regulations. We would reiterate that adoption rate will be higher if the e-prescribing is applicable to at least 67-75% of the physicians entire panel. Unless the physician's office and treatment rooms are set up with the needed equipment (desk top or hand held) to assure optimal efficiency in serving patients, the actual e-prescribing may be done by a clerk or medical assistant on behalf of the physician. The pharmacy receives only what is inputted from the providers office whether it comes from the provider or his staff.

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46672	*Quality Improvement Organizations data requirements* "To fulfill this responsibility, QIOs would need access to data from the transactions between pharmacies and PDPs and MA-PD plans providing the Part D benefit" "The data would include payment related information (that is, plan identification, beneficiary HIC, date prescription filled, NDC, quantity dispensed, ingredient cost, dispensing fee, and pharmacy zip code) and additional items such as prescriber identifiers, dose, days supply, and other dispensing information. Potentially, the information gathered would be aggregated in our data warehouse, and then distributed to QIOs to fulfill their requirements for quality improvement as specified in their contracts and in response to requests."	1. Please provide data and examples as to the type of assistance that QIOs may provide to MA-PDs, PDPs. 2. QIOs are required to offer providers, practioners, MA organizations, and PDP sponsors QI assistance pertaining to health care services, including those related to prescriptions. Please provide list of some of the current QIO vendors approved by CMS. 3. Are the QIO costs to be included in the solicitation we submit, or are these costs already within the CMS forecast and resources are made available to the stakeholders? 4. How are QIOs assigned to stakeholders or do we solicit and hire our own?
46673 D.6	*Accreditation* "Section 1860D-4(j) of the Act requires that the provisions of section 1852(e)(4) of the Act relating to the treatment of accreditation will apply to PDP sponsors with respect to – (1) access to covered Part D drugs including the pharmacy access requirements and the use of standardized technology and formulary requirements; (2) quality assurance, drug utilization review, medication therapy management, and a program to control fraud, abuse, and waste; and (3) confidentiality and accuracy of enrollee records." "A PDP sponsor may be demed to meet the requirements that relate to access….quality assurance…DUR, MTM, and a program to control fraud, waste, and abuse……if it is accredited and periodically reaccredited by a private national accrediting organization under a process that we have determined meets a process and standards that are no less stringent than our applicable requirements. National accreditation organizations are those entities that offer accreditation services that are available in every State to every organization wishing to obtain accreditation status."	1. Please cite specific examples of accrediting organizations that would meet your standards. 2. PBMs are not usually accredited by JCAHO, NCQA-HEDIS. Would affiliation with a disease management organization who has met those accreditation standards for QA, DUR, suffice? 3. Would having disease state management programs within a PBM accredited by national accrediting agencies meet the CMS pending requirement?

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Part J: Coordination Under Part D Plans with Other Prescription Drug Coverage

Summary: CMS intends to implement section 1860D-11(J) OF THE Act at 423.464(a) of the proposed rule and require sponsors of Part D plans to coordinate with State Pharmaceutical Assistance Programs and other drug plans. In this section, CMS specifies the other plans with which Part D plans must coordinate benefits

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46696 J. 1.	"Whenever we mention or reference Part D Plans, we mean any or all of MA-PD plans, PDPs, and fallback prescription plans. Likewise th term Part D plan sponsor refers to MA organizations offering MA-PD plan, PDP sponsors, and eligble fall back entities offering fallback plans. "We propose to implement sections…of the act….of proposed rule and REQUIRE sponsors of Part D plans to coordinate with State pharmaceutical assistance programs and other prescription drug plans…..we specify the other plans with which Part D plans must coordinate benefits in accordance with section 1860D-24(b) of the Act and define SPAP in accordance with….	Coordination of Benefits will pose a unique challenge to PBMs functioning as contractors or subcontractors at risk or with MA-PDs. The scope of the proposed COB providers contributions to the TrOOP is daunting and will require significant IT investments by CMS or its contractor to support the process. We strongly recommend that CMS pursue Option 2 to provide a single point of contact option and requiring primary and secondary payers send required data to this source.
466697 J.2.	We will waive the pharmacy network access requirements described at 423.120(a)(3) of the proposed rule in the case of an MA-PD plan that provides access (other than through mail pharmacies) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization if we determine that the organization's pharmacy network is sufficient to provide comparable access for enrollees under the plan.	We have clients who own and operate their network of pharmacies who would qualify for the waiver. We encourage provision of such waivers where ever and whenever applicable to qualified MAs.
466698 J.4.a	**"** a. Employer Group Waivers**….**extends the waiver authority that is provided for MA organizations related to part C…of the Act and implemented at 422.106(c) to prescription drug plans related to Part D.	We will need to work closely with our MA plans as well as our direct employer group clients to assure that the appropriate waivers are captured and that the coordination of wrap around benefits are appropriately designed and reviewed for 2006. We will need to develop IT systems and reporting to provide needed data to allow employers to capture tax subsidies for enhanced and wrap around programs. We will need to examine every aspect of Part D to assure that employers optimize their retiree Part D investments.

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46699 J.5.	5. Medicare Secondary payer Procedures. ..provides that an MAS organization may charge or authorize a provider to seek reimbursement for services from a beneficiary or third parties to the extent that Medicare is made secondary payer under section… 6. Coordination of Benefits with Other Providers of Prescription Drug Coverage "c. Pharmacy dispensed drugs covered by Part B…are NOT reimbursed unless the pharmacy has a Medicare supplier number; thus a beneficiary could lose Part B coverage by filling a prescription at the wrong pharmacy. 1. Encourage Part D plans to enroll pharmacies with Medicare supplier numbers. 2. Encourage part D plans to inform beneficiaries whether their network pharmacies have Medicare supplier numbers… 3. Develop educational materials reminding pharmacies without Medicare supplier numbers that they must refund any payments collect from beneficiaries enrolled in Part B for part B drugs unless they first notify the beneficiary (through an advanced beneficiary notice (ABN) that Medicare will likely deny the claim."	Network pharmacies have no way of knowing whether beneficiaries are receiving Part B drugs incidental to an office visit unless advised as such by the patient. Education materials from Medicare should provide this information. Likewise, network pharmacy staff will need to inquire of their patients when DME drugs, immunosuppressive drugs, and oral anti cancer drugs are prescribed for Medicare beneficiaries. This is a major area of concern for coordination of benefits. PBMs planning to be Part D contractors or subcontractors will need to begin communicating with their participating pharmacies months in advance to urge filing for Medicare supplier numbers. Network contracts may need to be revised to require having such to be a participating pharmacy in the forthcoming Medicare Part D networks.

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46701 J.6	User fees for data transmission	Recommendation on User fees for the transmission of COB information: • Need to determine this for accurate Administration expenses. If the determination of the transmission fees is after the submission of Applications, then allowances should be considered once this is finalized. • For more accurate Administration expense calculation, a flat fee would be the best alternative. If transmission volume is used, it will be a variable expense, and adversely affect those entities that service large utilizing populations. It will also entail more accounting and administrative effort for verification and auditing. • Recommendation for fee billing is quarterly to reduce administrative overhead. • Payment method should be the discretion of the entity that performs this service (see Comment below for the recommendation on Option 2 for TROOP coordination).
46705 J.6.e.	Tracking True Out of Pocket (TrOOP) Costs	We support the notion of Option 2 where CMS would procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary or secondary. We believe that PBMs do not have the IT systems nor corresponding NCPDP standards in place to coordinate benefits from the wide range of entities offering some degree of prescription drug coverage which count as incurred costs to reach the annual limit. The law requires the system to be in effect January 1, 2006. We urge CMS to proceed in developing the business requirements and seeking bids from contractors to provide the single point of contact services essential to the success at the POS as well as for CMS financial process requirements. Advantages of Option 2 are: • TROOP information can be sent from all entities involved to a single point of contact using one standard record transmission format. The alternative is an administration impossibility. • Facilitator can manage all information to be available to all Part D entities (one single data repository). Facilitator can manage billing for transmission fees effectively. The alternative would be difficult to manage if information transmission fees were imposed.

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Part M: Grievances, Coverage Determinations, and Appeals

Summary: We are required to have grievance procedures in place. We are also required to have an exception process for non-formulary drugs and tiering of drugs. The non-formulary process appears to be consistent with our current non-formulary exception process, but the exception process for tiers may be more complicated. We are also required to have an appeals process.

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46718	*Appeals process for non-formulary drugs* "In addition, section 1860D-4(h)(2) of the Act specifies that appeals, involving coverage of a covered Part D drug that is not on a PDP's formulary, are permissible only if the prescribing physician determines that all covered Part D drugs, on any tier of the formulary for treatment of the same condition, would not be as effective for the individual as the nonformulary drug, would have adverse effects on the individual, or both"	1. PRIOR AUTHORIZATION processes currently in place would allow the review of denied claims. The PA process assures that the MCO MA will have final approval authority. Existing policies and procedures should suffice or have minor changes to adapt to the rules. Physicians may request PA at this time if only a non formulary drug meets the clinical requirements.
46720	*Exceptions to tiered-cost sharing structure* "…a PDP sponsor must establish an exceptions process that addresses each of the following sets of circumstances: (1) The enrollee is using a drug and the applicable tiered cost-sharing structure changes during the year; (2) the enrollee is using a drug and the applicable cost sharing structure changes at the beginning of the year; and (3) there is no preexisting use of this drug by the enrollee." "…Thus, in §423.578(a)(2) we have proposed a limited number of elements that must be included in any sponsor's exception criteria: (1) A description of the process used by the PDP to evaluate the physician's certification; (2) consideration of the cost of the requested drug compared to that of the preferred drug (3) consideration of whether the formulary includes a drug that is the therapeutic equivalent of the requested drug; and (4) consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested drug. We are also considering requiring a number of other exceptions criteria such as – (1) requiring PDP sponsors to establish a blanket rule permitting continued access to a drug at a given price when there is a mid-year change in the tiering structure;(2)	1. From a broad perspective, efforts to protect the beneficiary from tier changes may or may not be in the best interests of the patient or the program. If P & T makes a decision predicated on scientific evidence that an alternative drug is clinical equivalent and change is without risk, and there are significant cost savings, why would it not be permissible to change the patient through a well organized and managed process? If such a change is possible in the first quarter, the savings to the program achieved from a large volume of prescriptions are denied to the program for 9 months. Exceptions, of course, will be provided pursuant to physician data submittal. However, the tone of the proposed rules suggests that patients may be grandfathered or guaranteed a benefit irrespective of the clinical and scientific evidence supporting the change. We should likewise focus on assuring that the switch may be done legally and with sensitivity. 2. PDPs and MA-PD plans can adjust to the proposed CMS rules. It does not make good sense to negate the effectiveness of acquired discounts that were acquired after P & T approval. Any negotiated discounts will need to be adjusted for limited savings during any given year. For large populations, this could result in significant costs to the program. Cost forecasts submitted to CMS will need to be very conservative and adjusted for these restrictions. 3. The proposal to require patients to try a preferred drug and experience adverse effects before being permitted to resume use of an original drug will

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	requiring an enrollee who is using a drug that is subsequently removed from the sponsor's formulary or is no longer considered a preferred drug(s) to try a preferred drug(s), and experience adverse effects, before being permitted to resume using the original drug; (3) requiring a sponsor to establish exceptions criteria that are specific to particular classes of covered Part D drugs, such as cholesterol-lowering drugs; and (4) requiring sponsors to give enrollees an opportunity to request exceptions to a plan's tiered cost-sharing structure other than on a case-by-case basis. Additionally, we contemplated the possibility of establishing criteria for the review process used to evaluate plan formularies and tiering structures, and developing exceptions criteria are specific to classes of covered Part D drugs." "Like for tiering exceptions we are proposing that enrollees be required to request reconsideration by an independent review entity (IRE), as opposed to having these cases automatically forwarded to the IRE."	be very instrumental in helping our drug use management efforts. However, I have concerns that such a requirement diminishes physician judgment in determining the best medication for a given patient. In many cases, administratively requiring a patient who is taking a certain medication to try an alternative for the purposes of eliciting an adverse drug effect does not seem to be in the best interest of the patient. In addition to adverse effects, a particular drug may be ineffective for a given patient, which would be another appropriate reason to use an alternative drug 4. We can develop class specific exception rules. However, it seems to make more sense to have broad rules that are applicable across all drug classes. Please also consider that the Medicare book of business will be approximately 10-20% of our entire business as we still enjoy a large commercial segment of lives. We would like to keep singular policies and procedures to the degree possible. If we find that the CMS proposals make better sense across the board, we would certainly have no reluctance to propose them to our commercial clients. 5. The notion of an IRE is unique to PBMs who work closely with the Plan Sponsor to assure appropriate accessibility and reconsideration. We concur that it is not needed to automatically send all appeals to an IRE, BUT to have the enrollee request as such. However, we are likewise unfamiliar with the impact of an IRE process on the relationship between the enrollee, its health plan (MA) and the physician. Also, a work flow path would need to be developed such that the decision of the IRE is transmitted to the MA-PD, PDP, PBM in a timely manner. The appeal of tiers as well as drugs is an interesting notion that seems founded upon the assumption that all switches are predicated purely on cost without due consideration for quality. The draft of the CMS rules suggests that PBMS need to be able to utilize all its tools and technology to achieve best possible prices and cost management. Conversely, there are rules designed to offset those gains in an effort to protect the beneficiary. We suggest that CMS may safely assume that PBMs are focused on serving the needs of large populations and are sensitive to the potential negative impact of population based decisions on a very small percentage of individuals within that population. Please do not promulgate rules that compromise the value of the contribution to the vast majority of beneficiaries and to the overall program. 6. For the purposes of tiered cost sharing, we should clearly define the tier for single-source generic drugs (i.e. brand vs. generic copays?). Older generic

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		drugs may become single-source if all other manufacturers elect to discontinue production due to low use.

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Subpart Q: Guaranteeing Access to A Choice of Coverage (Qualifying Plans & Fallback Plans)

Summary: This section discusses the beneficiary's right to have access to a choice of at least two plans; the requirements and limitations on the bid submission; review and approval of fallback prescription drug plans; contract requirements specific to fallback plans; and the determination of enrollee premium and our payments for these plans.

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Subpart Q: Guaranteeing Access to A Choice of Coverage (Qualifying Plans & Fallback Plans)		
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46732 528	"…eligible fallback entity….meets all the requirements to be a PDP sponsor (except that it does not have to be capable of withstanding potential financial losses as a licensed risk bearing entity) and does not submit a bid under the risk bidding process for any PDP region for the first year of that contract period. An entity would be treated as submitting a bid under the competitive bidding process, and thus not be an EFE, if the entity was acting as a subcontractor for an integral part of the drug benefit management activities of a PDP sponsor that is submitting a bid for a prescription drug plan. An entity would NOT, however, be treated as a submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as a PDP sponsor with respect to a prescription drug plan, rather than offering an MA-PD plan. We anticipate that some eligible fallback entities may contrct with other entities for the performance of some required pharmacy benefit management functions…. As the result of this restriction, in bidding, eligible f allback entities would have decided not to submit either a full risk or limited risk bid in any region (either as a direct contractor, or as a subcontractor for a PDP sponsor) in order to be eligible to submit a fallback prescription drug bid in any region. …applies this restriction in the first year of a contract period.	Please validate and clarify the following: An organization may bid for Fall Back if: (1) No risk or limited risk bid submitted in any region as contractor or subcontractor to PDP. (2) PBM has no risk with MA partner to do MA-PD and NOT a PDP An organization is BARRED from bidding as Fall Back if: (1) Submitted bid to be PDP at risk in any region. (2) Submitted bid to be at risk with MA for MA-PD (3) Submitted bid as PDP subcontractor BARRED AS FALLBACK FOR: (1) 2^{ND} & 3^{RD} Year of contract cycle if bid for 1^{st} year. BARRED FROM RISK BID IF: (1) Wins Fall back in that region, barred for 4 years as risk bidder in that region. (2) Wins Fallback , barred everywhere for 3 year contract (3) Submitted a bid to be fallback plan in 2009, where 2009 is 1^{st} year of multi year fall back contract (4) Already approved as fallback in any PDP region for 2009. (5) Offers a fallback in 2008 for same region for which they would be submitting a 2009 risk bid. (6) Entity acts or will act as subcontractor for fallback plan of another entity. We would encourage CMS to have a most liberal interpretation of the law to encourage competition in the fallback bidding. Risk assumption is not something most PBMs would consider. However, PBMS have many MCO and MA clients who are considering entering the market as MA-PDs. Some MAs may request the PBM subcontracted to provide PD services to undertake some degree of risk. Thus, it would appear that this would preclude that PBM from being a fallback even in a different region. While the bidding process is geared to prevent the need for fallback, it may be wise to keep options open-especially since the number of Regions for Part D has not yet been determined.

CMS-4068-P-1221

Submitter : Mr. Johnny Bell **Date & Time:** 10/04/2004 08:10:31

Organization : Vital Care, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Pls see attached comments

CMS-4068-P-1221-Attach-1.doc

Dear Sir or Madam:

Vital Care Home Infusion Services is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Vital Care is a system of individually owned and operated infusion pharmacies specializing in providing high-tech services to rural and urban patients throughout the United States. With over 120 locations in 14 states, Vital Care can provide fast, efficient, and personalized to patients across the nation. Vital Care is based in Meridian, Mississippi and has been treating infusion patients since 1986. To date, Vital Care has treated approximately tens of thousands of patients. Vital Care was established for the purpose of providing a comprehensive scope of high-quality infusion therapies for stabilized patients in the home setting.

Vital Care appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home

administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B *has not resulted in additional access to home IVIG under Medicare*. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm.

CMS should establish **specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies** to ensure adequate enrollee access to home infusion therapy under Part D.

CMS should require **specific standards for home infusion pharmacies** under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

CMS should adopt the **X12N 837 P billing format** for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

CMS should **mandate that prescription drug plans maintain open formularies for infusion drugs** to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Johnny Bell
President/ Owner
Vital Care, Inc.

CMS-4068-P-1222

Submitter : Mrs. Jody Horak **Date & Time:** 10/04/2004 08:10:18

Organization : Toledo IV Care

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

please see attached comment.

CMS-4068-P-1222-Attach-1.doc

Toledo IV Care is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Toledo IV Care is an independent home infusion company based in Toledo, Ohio. We have been providing quality home infusion to patients for over a decade. Our patient/customer satisfaction scores for 2003 averaged 96.5%. Our services include a wide range of infusion medications that are acceptable to administer in the home care setting.

Toledo IV Care appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA")plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and

standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

* Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion perdiem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as itdoes in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at
http://www.nhianet.org/perdiemfinal.htm
http://www.nhianet.org/perdiemfinal.htm

* CMS should establish specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require specific standards for home infusion pharmacies under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the X12N 837 P billing format for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should mandate that prescription drug plans maintain open formularies for infusion drugs to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,
Jody Horak
Billing Manager
Toledo IV Care

Submitter : Edward Rivalsky **Date & Time:** 10/04/2004 08:10:03

Organization : Clinical Specialties Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

CLINICAL SPECIALTIES, INC (CSI) is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

CSI is in our 17th year of operation, with two locations in Ohio, Cleveland and Columbus, both of which are JCAHO accredited. We are a statewide independent provider of infusion therapy services, and a Medicare provider since 1988. We have access to payor contracts representing 7 million lives in Ohio. In addition to Medicare, Medicare Managed Plans, Ohio Medicaid, Pennsylvania Medicaid, Kentucky Medicaid, Michigan Medicaid, Indiana Medicaid, and the Ohio Bureaus of Workers Compensation representing over 90% of all lives in Ohio. We maintain an overall patient satisfaction of 99%, whereby written survey 99% of our patients say they would use our service again. CSI is currently providing over 4,000 courses of infusion therapy annually.

As President of CSI, and as a pharmacist practicing in infusion therapy field for the last 21 years I would like this opportunity to present my concerns regarding compensation for our services under the new Medicare Part D benefit. The dilemma is that while it is significantly more cost effective to treat infusion therapy patients in the home rather than in the hospital, what is the level of care needed to insure a safe and effective course of treatment, and how to compensate for it. Today an infusion therapy pharmacy bridges the care from the acute care setting to the home and there are many challenges that can be associated in the transition.

HISTORICAL PERSPECTIVE

During the 1980?s many of the commercial payors provided compensation for these services at a relatively high level, justifying the ?savings? as compared to a hospital stay. As providers became more experienced in providing these services, and as more providers entered this market, rates for services dropped dramatically, primarily due to competition. Accordingly, many providers exited from this market.

LEVEL OF CARE AND PATIENT OVERSIGHT NEEDED

In evaluating any compensation schedule, there is a need to look all components. In as such, home infusion unique because it does involve home nursing services (already compensated for under Medicare Part A, thus not necessary to be included), Home Medical Equipment, in the form of IV poles and infusion devices, generally covered as a Medicare Part B benefit, provided it is an `approved? therapy (and as such does not need to be compensated for under Medicare Part D. Also included in the services are various supplies, dispensing services, clinical monitoring services, care coordination services and numerous other pharmaceutical/patient `need? services to assure a safe and uneventful (adverse events can range from under or overdosing of therapy to re-hospitalization or treatment failure?it is rare for patients to report suffering extensively due to rather close monitoring that does occur in this field) course of treatment! In addition, there needs to be:

1) Tight coordination between all professionals to ensure a successful start of therapy,
2) On-call services, 24 hours, 7 days a week by all clinicians,
3) Patient initial instruction and on-going interviews to assure appropriate progress in the treatment regimen and in assuring patient involvement and compliance, once again to prevent treatment failure, identify adverse reactions early or to prevent re-hospitalization!

While simply stated above, these services are not easily performed at home, as you no longer have a controlled environment, such as a hospital or skilled nursing facility! As one would imagine, other administrative and support costs need to be considered.

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

OVERSIGHT OF PROVIDERS

? JCAHO, CHAPS, AAHCA or other accreditating body
? State Boards of Pharmacy. In our case, Ohio, Michigan, Indiana, Kentucky and Pennsylvania
? The Drug Enforcement Agency (DEA)
? OSHA
? CMS
? State Medicaid Programs
? USP 797 Standards, which may dramatically affect our ability to maintain our cost structure we currently operate under

CSI appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both MMA itself and CMS?s proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggest an interpretation of the Part D benefit to include not only the drugs that can be administered in patients? homes but the essential services, supplies and equipment that are integral to the provision of home infusion therapy (?dispensing fee option 3? as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage (?MA?) plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important ?demonstration project? of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

? Dispensing fee options 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS ?S? codes, already used by commercial and Medicate managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payor sector.
Thank you for your time and consideration!
Edward J Rivalsky
President & CEO
Clinical Specialties Inc

CMS-4068-P-1224

Submitter : Mr. Lawrence Lewis **Date & Time:** 10/04/2004 08:10:00

Organization : Mr. Lawrence Lewis

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Dear Review Committee,

This letter is from a concerned indivdiual living with HIV. I am fortunate to work full-time and have insurance that covers the medical care and needed prescriptions to manage living with HIV disease. However as a previous member of the St. Louis Ryan White Title I Planning Council, I was made aware of the potential changes to Medicare Prescription Drug Benefits and found myself extremely worried. Worried that individuals living with HIV/AIDS who qualify for Medicare or Medicaid are among the sickest and poorest of people living with HIV/AIDS, may no longer receive the quality of treatment previously afforded them. For many Medicare/Medicaid represented the last best option for their survival. Being among the sickest and poorest also means that they may be more susceptible to opportunistic infections and viral mutations. This puts them in a great need for various treatments. Not allowing such an indivdiual full access to avaialble treatments would be disappointing, especially in an error when many believe that more attention is being payed toward the Third World, than people in need treatment access right in the United States. Insuring that US citizens have access to needed treatment does not negate our responsibility to the world, but lets make sure we take care of our own. Please make whatever adjustments to this Prescription Drug Benefit Plan that are needed to insure that individuals currently receiving Medicare/Medicaid do not receive less benefits than they currently do and that new enrollees may have access to the best treatment option available for them. Shouldn't the treatment option best for the client be left to the client and the treating physician?

Respectfully,

Lawrence Lewis
4135 Potomac St.
St. Louis, MO 63116

CMS-4068-P-1225

Submitter : Patricia Wilson **Date & Time:** 10/04/2004 08:10:57

Organization : Associates

Category : Individual

Issue Areas/Comments

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Comments on proposed 42 C.F.R. parts 403, 411, 417 & 423, 69 Fed. Reg. 46632

ELIGIBILITY, ELECTION, AND ENROLLMENT

Comments on proposed 42 C.F.R. parts 403, 411, 417 & 423, 69 Fed. Reg. 46632

CMS-4068-P-1225-Attach-4.doc

CMS-4068-P-1225-Attach-2.doc

CMS-4068-P-1225-Attach-1.doc

CMS-4068-P-1225-Attach-3.doc

CMS-4068-P-1225-Attach-1.doc

CMS-4068-P-1225-Attach-3.doc

CMS-4068-P-1225-Attach-4.doc

CMS-4068-P-1225-Attach-2.doc

Associates & Wilson
1084 East Lancaster Avenue
Rosemont, PA 19010
AssocWilsn@AOL.com

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4068-P
Submitted to http://www.cms.hhs.gov/regulations/ecomments

Re: CMS-4068-P (Proposed 42 C.F.R. parts 403, 411, 417 & 423). 69 Fed. Reg. 46632, 8/3/2004.

Dear Sir or Madam:

This letter constitutes our comments on the Medicare Modernization Act and the proposed rules cited above. Also attached are three other papers which have been previously distributed that elaborate on some points addressed in this letter. This letter with attachments is being submitted electronically to www.cms.hhs.gov/regulations/ecomments as a Microsoft Word document. The submission was made before the deadline of 5pm on October 4, 2004.

1. **II.B. Eligibility and Enrollment, Paragraph 6 "Disenrollment by the PDP (§ 423.44)" 69 Fed. Reg. 46641-42**

Comment: Can you tell if the same individual is enrolled in more than one plan (either PDPs and/or MA-PDs). If you cannot make this determination, the potential for fraud or abuse arises.

The legal concept of 'residence" depends in large part on where the individual "intends" to reside. Perhaps other agencies, e.g., the IRS, already have a definition of "residence" that could be adopted by CMS.

2. **II. B. Eligiblility and Enrollment, Paragraphs 9 "Approval of Marketing Materials and Enrollment Forms (§ 423.50)" 69 Fed. Reg. 46643.-44**

Comment: The taxpayer is paying for drugs and drug management, not marketing of other services. Permitting PDP sponsors to mix prescription drug services and other business ventures targeted to enrollees could be asking for trouble. Additionally, it could confuse enrollees. The new drug benefit is confusing enough. The PDP sponsor should focus on one thing – drug management – and make that efficient and economical.

3. II.D.2.a & b. Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans. 69 Fed. Reg. 46666-67

Comment: Minimum Utilization Standards

You asked whether there were "industry standards" and whether CMS should adopt them for all utilization management programs. We think you are the responsible entity for setting minimum standards for all plans. It bears repeating that regardless of "industry standards" heath care costs, and particularly drug costs, continue to escalate to record highs. At the same time, the quality of American health care is lower than that enjoyed by Canadians or Europeans and at a cost much less than ours. The reality is that the government is going to pay billions of dollars for drugs. Relying on "transparency" and information on price discounts to motivate plans to "innovate and adopt the best techniques available" is uncertain at best. We suggest you can do better. On behalf of taxpayers, exercise responsible leadership and impose minimum standards that foster cost-effective utilization management programs.

Section 1860D-(c)(1)(A) provides that utilization programs must include incentives to reduce costs such as use of multiple source drugs, but does not preclude the Secretary from imposing other standard elements of utilization management. The regulation should mandate certain *minimum* utilization standards that must be implemented by all plans.

Specifically, we urge you to mandate one basic requirement for all utilization programs; namely, that the *prescription must include the diagnosis or diagnoses for which the drug is prescribed; the directions for use (i.e., the "sig" information), the quantity and strength dispensed and, in the case of certain drugs used in complex cases, require prior approval by an individual with special training or specialty certification.*[1]

It is assumed that this information will be electronically managed and available at the time of dispensing the drug.

Imposing this basic requirement is the corner stone for all other edits and reviews that support cost control, quality improvement, medication therapy management, and fraud and abuse detection. Among other things, it will:

- Allow smart drug utilization review (DUR) before the script is filled
- Allow screening for age appropriateness, etc.
- Create a drug record for each patient which can be used for therapeutic evaluation and to target disease management, wellness programs, etc.
- Create a drug record that can be screened for fraud and abuse. *Id.*

[1] See May 2002 *Statement on the National Action Plan to Assure the Appropriate Use of Therapeutic Agents in the Elderly Part 1* by Patricia L. Wilson and Loren G. Lipson, M.D.(submitted to DHHS/OS/OPHS/ODPHP) (copy attached).

Additionally, you could by regulation also impose a few other *minimum* requirements that should be included in all utilization programs[2]. These edits address both safety and fraud issues. Suggested edits include those that:

- Identify the prescribed dosage as more or less than the recommended dosage for a diagnosed condition.
- Correlate the daily or other frequency of dose for the specified period to a specific number of pills/agent, etc. to be covered. (e.g., four pills for a once a week use constitutes 30 day supply).
- Compare the above two (e.g., if one pill a day for 30 days is prescribed, but the recommended dose is two pills a day, the prescription must be checked). These edits will preclude stockpiling or other fraud.
- Identify prescriptions for initial dose versus maintenance doses (to assure that the correct dosage recommendation is followed).
- Identify off- label use such as edits that identify prescriptions for adjunctive agents,
- Identify prescriptions that preclude use of a generic.
- Identify whether the prescriber is licensed in the U.S.
- Are derived from evidence-based guidelines (e.g. "step therapy' or guidelines on clinically preferred drugs) that set either a dollar threshold and/or particular drugs for which prior approval must be obtained and/or utilization monitored.

The regulation should also mandate that utilization programs must identify the specific steps to be taken in the event that the edit is tripped, particularly steps for obtaining justification from the prescribing physician for the prescription. Under current practice for many PBMs, nothing more than a pharmacy override obtained by inputting several computer key strokes allows claims to process at two times the maximum recommended daily dose. This is not an adequate safeguard – nor is it an eligible claim.

The regulation should also require utilization programs to establish specific guidelines for:

- Determining if a drug requiring prior approval or specialist review is a Medicare Part B covered supply and medically appropriate in a particular case. This review should also establish the covered quantity for a specific period of time (i.e., weekly, 30 days, 90 days, etc.)
- Overriding any concurrent drug utilization review edit.

CMS should include in the regulation a provision that it will from time to time publish in the Federal Register a list of drugs susceptible to overutilization or abuse. You can rely on your own Office of the Actuary to identify drug candidates or take input from others who observe questionable utilization. Neurontin[3] is an example of a drug, FDA approved for adjunctive

[2] See October 2003 *Prescription Drug Benefit Management: Improving Quality, Promoting Better Access and Reducing Cost* by Patricia L. Wilson, prepared on behalf of the American Association of Health Plan's (AAHP) (copy attached).

[3] See November 2002 *Statement on the National Action Plan to Assure the Appropriate Use of Therapeutic Agents in the Elderly Part 2 – An Example - Neurontin* by Patricia L. Wilson and Loren G. Lipson, M.D.(submitted to DHHS/OS/OPHS/ODPHP) (copy attached).

therapy for epileptic seizures and postherpetic neuralgia, with excessive utilization. It was prescribed for almost a dozen unapproved off-label uses as a result of questionable non-peer reviewed "clinical" studies and financial incentives to hundreds of prescribing doctors, both paid for by the manufacturer.

Pharmacy and Therapeutics Committees have not been universally effective in setting up cost-effective coverage and utilization management programs. Often they view their job at the population management level. In this instance their guidance must be applied to individual enrollee circumstances. They should be involved, but the payer (you) should have the last word; that means, the authority to review the claims being paid, question any inaccurate or inappropriate payment, and impose specific remedies as appropriate. The regulation should thus specifically reserve CMS' authority to review, assess, and remedy utilization errors.

Comment: Quality Assurance 69 Fed. Reg. 46667

You asked for comments of what elements should be required for a quality improvement program. The proposed regulation fails to mandate minimum quality assurance standards. You should require at a minimum all of the desirable elements discussed at 46667 (electronic prescribing, clinical support, education interventions, bar codes, adverse event reporting, provider/patient education). To state that you do not expect the plans to adopt all of these elements is inexplicable.

Comment: Medication Therapy Management Programs 69 Fed. Reg. 4668-69

Targeted beneficiaries are those who:

- Have multiple chronic diseases
- Take multiple drugs, and
- Are likely to incur annual Part D costs that "exceed a level specified by the Secretary."

You propose not to set the amount of annual costs that qualify for receipt of MTMP services. You state that you do not have sufficient evidence, and assert that the plans would have better knowledge of the patients and therefore should set the amount.

We suggest that if it was intended that plans set varying amounts based on their unique populations, Congress would have said so. Given that this is an eligibility criterion in a national program, we submit that you, as the plan sponsor/financier, should establish the criterion on an even-handed basis that is not dependent on where an individual happens to live. We suggest it is doubtful that you have the authority to delegate the establishment of an eligibility criterion to private entities.

Upon consideration, should you agree with our observations, the question remains as to what you should do. You could review case management data from the Medicaid programs (or other sources) for guidance, and revise the amount as more data is reviewed. However, merely because the plans may have a more direct relationship with enrollees does not assure that they are in any better position to determine what the annual amount should be.

4. II.C.a. Covered Part D Drug, 69 Fed. Reg. 46646-47 (Proposed section 423.100 on Definitions at 69 Fed. Reg. 46815)

Comment: In defining covered drugs, the proposed regulatory definition first begins with the requirement that the supply is used by the enrollee for a medically accepted indication (proposed section 423.100 on Definitions at 69 Fed. Reg. 46815). The term "medically accepted indication" means "any use for a covered outpatient drug approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i)." What this all means is that the enrollee must have an illness or injury and that the use of the drug to treat that illness or injury must be an FDA approved use or a use supported by peer-reviewed, evidence-based literature and referenced as such by an authoritative group that can not be unduly influenced. Past references to sources not meeting these criteria have been removed.

A cornerstone therefore of efficient administration is to have the intended use (diagnosis or Dx) on the script (Rx). We refer to this as Dx on Rx.

An important corollary for efficient administration is to understand clearly what is not covered. For example, just because US Pharmacopoeia has a drug class or category for erectile dysfunction medication does not mean that they are covered. What we know from the exemplary work of the Institute of Medicine (IOM) on the quality of care in America, is that it is not where it needs to be. It urges improvements in systems of care that help physicians' help their patients. At its heart, the functioning of this Medicare Part D benefit can move us forward with a quantum leap or move us backward. Without guidance from those charged with regulatory authority on coverage criteria derived in part by defining what you don't cover (the exclusions), you run the risk of creating a monster that will do less than both seniors and tax payers deserve. Money will be wasted and care compromised. We urge CMS to be more definitive concerning coverage or more specifically exclusions. Let me use Periostat to explain the comments. The Medicare benefit is not a dental benefit. Periodontal treatments are not covered. And, Periostat is used for periodontal treatment. The largest PBMs who will function in this new marketplace (Medco, Caremark, Express Scripts) do not think as insurance companies or at-risk providers. As such, without guidance, a Periostat drug claim submitted will be a paid claim. Other functionaries such as Aetna and Prescription Solutions have background as both insurers and at-risk providers and as such are likely to do as inferred by failing to cover dental benefits under Part A and B and exclude Periostat under Part D. Beneficiaries in different parts of the country should receive the same treatment with respect to statuary exclusions. Without guidance from you, it will not happen.

The US taxpayer will pay much of the bill and guidance on coverage (meaning an eligible *and* ineligible claim) should be given by CMS as the plan sponsor/financier. It should not be left solely to a PDP or MA-PD.

Under a recent settlement involving Medicaid fraud between Pfizer and the US Attorney of Massachusetts, Neurontin claims for other than seizures (as adjunctive therapy) or for the pain associated with shingles were deemed fraudulent claims. In a Pharma Audioconference on June

23, 2004 (*Lessons of the Pfizer Settlement for Off Label Promotion – Compliance Issues and Practices*), referenced under comments with number 3 above, the Assistant United States Attorney for Massachusetts confirmed that the only legitimate Medicaid claims were for the 2 FDA approved uses - not the 80% of off-label use. While this case is an egregious one, it is not all that uncommon.

5. II.C.4.b Formulary Requirements, 69 Fed. Reg. 46659-60 (proposed section 423.120(b), 46 Fed. Reg. 46818-19) and Section 1860 D-4 (b)(3)(c)(ii) Beneficiary Protections for Qualified Prescription Drug Coverage

Comment: A formulary (a.k.a. preferred drug list) can serve several purposes:

1. It can address plan design in two ways:
    - To limit plan coverage to drugs on the list, unless a patient has gone through a review process to determine coverage eligibility,
    - To provide lower patient co-payments for formulary, and correspondingly, a higher patient share for non-formulary drugs.

    The first approach is what is commonly referred to as a "closed formulary" - limiting prescription coverage to only formulary medications – with the exception that if the listed drugs are not effective for the patient, a non-listed drug becomes preferred. The "preferred' approach (second alternative) differentiates the patient's share of prescription costs - with patients responsible for a higher share of covered, but non-formulary medications.

2. It can be a tool to help both physicians and patients select appropriate and cost-effective medications when there are multiple similar ("me too") medications available

As required by the statute, you have asked US Pharmacopoeia to develop categories and classes of prescription drugs that constitute a model guideline for formulary development. Their proposed guideline is now in the comment phase. However the charge and the model formulary guideline only addresses plan design (item 1 above). It does nothing to address item 2 above, the concept of which is implied under the "protection" title heading.

We encourage you to extend the concept of a model guideline for formularies to include, as a minimum, the following additional information:

- Notations about inappropriate use if a senior, a child or pregnant
- Notations when dose reductions should occur for seniors
- Notations where prior authorization is required to receive coverage since not all drugs on the formulary are covered for all individuals in all circumstances
- Notations about cost typically done currently by a relative ranking notation system.

A PDP or MA-PD could vary what notations apply to which drugs just as it changes which drugs are on or off the formulary. The PDP or MA-PD could also choose to use no notations, but would not be subject to the safeharbor treatment. What CMS does however is to encourage your intermediaries to give useful information to beneficiaries and physicians.

In addition, a truly useful formulary - one that helps both physicians and beneficiaries with care options - may also contain additional information including the best practice guidelines recommended by the body of experts for a specific condition such as hypertension, elevated cholesterol, mild, or moderate or severe asthma. For example, for hypertension, the 'preferred' drug list might show treatment recommendations from The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7). The explanations could be detailed including various degrees of hypertension (mild to severe), and with or without other conditions (diabetic, previous heart attack, etc.).

The rules as they are now proposed are strict for modification to a formulary. But the concept of formulary envisioned included the list of drugs covered under the formulary and not the expanded notion of appropriate use parameters that should be contained in the formulary. Therefore the proposed requirement that a formulary can only change once a year and then only with proper notice should be limited only to the drugs named on it. Changes about appropriate use can and should be made more frequently as evidence-based information presents itself. As an aside the requirements for an annual event change in the formulary must be modified to accommodate changes such as the removal of Vioxx from the marketplace because of increased health concerns. This could be either and FDA mandated withdraw, or a manufacturer-directed recall.

While time has not permitted us to fully review your proposed regulations, we hope these initial comments are both intelligible and useful. Should you have any questions, please call (610-519-0602).

Sincerely,

Patricia L. Wilson

Patricia L. Wilson
Consultant

Attachments:

- *Statement on the National Action Plan to Assure the Appropriate Use of Therapeutic Agents in the Elderly Part 1,* May 2002
- *Prescription Drug Benefit Management: Improving Quality, Promoting Better Access and Reducing Cost,* October 2003
- *Statement on the National Action Plan to Assure the Appropriate Use of Therapeutic Agents in the Elderly Part 2 – An Example – Neurontin,* November 2002

Prescription Drug Benefit Management: Improving Quality, Promoting Better Access and Reducing Cost

Excerpted from a Report Prepared by:

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October, 2003

Table of Contents

Executive Summary

As the Medicare conferees work towards a Medicare prescription drug benefit proposal for Medicare-eligible beneficiaries, it is important to reemphasize the tools that can improve the quality of care while protecting seniors from the high cost of prescription drugs. In this report, we focus on past and current programs to highlight pharmacy benefit management techniques that accomplish these important goals.

- ***Escalating prescription costs are particularly problematic in programs that do not utilize benefit management techniques. This is especially true for and in senior populations.*** It is important to understand the value of management of prescription drug benefit plans. This report uses data from the recently released Families USA study – *Out-of-Bounds: Rising Prescription Drug Prices for Seniors.* The study is based on the experience of the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE), a program that does not fully utilize prescription drug benefit management techniques. And specifically, we use PACE data to show how the use of a variety of management tools can reduce costs substantially while improving quality of care.

- ***Pharmacy management tools lower costs and improve access and improve quality of care.*** To illustrate the value of these management tools, prescription drug examples were chosen based on drug utilization data for the top 50 drugs under the PACE program and practices prevalent with marketplace innovators. Examples include:

  - *Step-therapy*. Step-therapy is used to ensure patient safety and reduce cost by placing the focus on drug value. This tool promotes use of proven therapies first before moving to newer, but not necessarily better and almost always more costly treatments. It aids doctors in focusing on what others recognize as appropriate, first-line care, rather than the drugs most recently advertised and promoted through pharmaceutical company sales efforts.

    Plavix, an anti-platelet agent, is an example. Common aspirin has been shown to be clinically equivalent to Plavix. Extensive marketing has made Plavix the fourth most utilized drug on PACE list, with annual charges of over $1,500 per user. If Plavix is made a non-formulary drug subject to prior authorization, patients are protected from the risk of potentially dangerous side effects and significant cost savings are achieved.

  - *Competitive pricing and care enhancements*. By negotiating dispensing rates and prices at retail pharmacies and limiting coverage to prescriptions filled at preferred network pharmacies, managed prescription drug benefit plans have generated significant savings. Consequently, any willing provider mandates will decrease the ability to develop a high-quality network at the lowest cost.

  - *Promotion of clinically preferred drugs*. New practice guidelines released by the National Institute of Health/National Heart Lung Blood Institute's Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC7) indicate diuretics (at less than $100 per year) as the preferred treatment for those

with uncomplicated hypertension – producing better outcomes than new medications. Yet diuretics are at the bottom of the PACE/Families list in terms of utilization. ACE inhibitors are not even on the list, and they are first-line therapy for those patients recovering from heart attacks. Using the PACE data, the use of these alternative drugs could produce potential savings ranging from $95 to $308 per person per year.

- ***Pharmacy management tools are critical to reducing medication errors.*** Pharmacy management tools and technology can and should be used to reduce errors and support health care practitioners.

- ***Pharmacy management tools are necessary to increase use of equally effective but lower cost products such as generics.*** With the advent of direct-to-consumer advertising of prescription drugs and more sophisticated pharmaceutical marketing to physicians, plan design and tools are necessary to provide incentives to use equally effective, but lower cost products.

- ***Pharmacy management tools include an integrated mail service pharmacy that reduce costs through greater efficiency.*** Mail service prescriptions are an integral part of the managed pharmacy system. The patient benefits from 90-day prescriptions for maintenance (long-term) medication delivered directly to their home. Beneficiaries appreciate the cost savings and the enhanced quality resulting from efficient delivery systems. Under PacifiCare's Prescription Solutions program, costs savings of approximately 14%, or an average of $146, per year using mail service instead of retail pharmacies for a brand-name drug were realized. The General Accounting Office (GAO) has also confirmed the cost savings due to pharmacy benefit management techniques. In the January 2003 study of the Federal Employees' Health Benefits Program, the GAO concluded that the average mail-order price was 27% lower for brand-name drugs and 53% lower for generic drugs than the average cash-paying customer price. The PACE Program could reduce drug cost by 10% if using competitively priced mail service pricing - and dispensing fees with only 60% of brand-name drugs switching from retail.

- ***Expanding Pharmacy management technological tools are key to the management of health care.*** Pharmacy benefit managers are proficient in developing, installing, communicating, and maintaining complex prescription drug benefit structures for large groups of beneficiaries. While capabilities are expanding, costs are declining.

  As shown above, by effectively managing the drug benefit, the government can spend less and improve integrated health care for Medicare beneficiaries. If PACE used all of the marketplace innovator tools, it could cut costs by 40%. Additionally, better management of prescription drugs can help reduce medical expenditures, including hospitalizations and emergency care due to adverse drug events. Proven management tools will help the federal government provide a more valuable prescription drug benefit and improve the quality of life for Medicare beneficiaries.

Acknowledgments

Associates & Wilson wishes to acknowledge the many people and organizations that made this report possible. First and foremost we thank the American Association of Health Plans (AAHP) and its members for giving us the opportunity to present ideas to important decision makers at a time when the United States is moving forward on healthcare policies. What happens this fall, as Congress works to reconcile differences in the bills passed by the House and Senate, will have far-reaching effects on both the national economy and the healthcare of older Americans.

Special thanks goes to marketplace innovators listed in this report as well as all those who are committed to improving care quality. To complete this report we drew upon their ideas and the words they wrote. We encourage all to read the thoughts of others referenced in the "For more information" sections that appear throughout the report.

In addition, we would like to acknowledge Loren Lipson, M.D. for generously contributing his time and expertise during our lifetime collaboration on retiree healthcare improvements.

Introduction

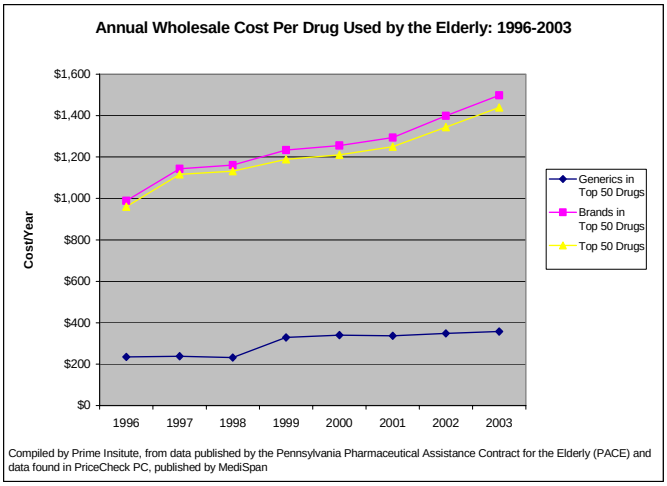
In July 2003, Families USA published a report entitled *Out-of-Bounds: Rising Prescription Drug Prices for Seniors* using data from the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE) program. Focusing on the 50 drugs most frequently used by this elderly population (See Exhibit 1), the findings include:

- Prices rose 3.4 times the rate of inflation in 2002.
- On average, prices for generics rose less rapidly than brand-name drugs while generics also cost significantly less. It is important to note that there is significant variability in price increases between drugs.
- Only 15 of the 50 most frequently used drugs were generics.

The PACE program has been suggested as a model for a Medicare drug benefit, but the program does not use most pharmacy benefit management techniques. This paper focuses on the drugs highlighted in the Families USA report to show how the use of prescription drug benefit management tools developed by marketplace innovators can reduce cost substantially while improving the quality of care and safety for beneficiaries.

The PACE Program as an Example

The *Out-of-Bounds: Rising Prescription Drug Prices for Seniors* report recently published by Families USA provides useful information about the cost of medications taken most frequently by seniors.
The report is based on the drug market basket for the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE) with information compiled by the PRIME Institute at the University of Minnesota.



- PACE has been a leader in many pilot and research projects, yet it uses few of the pharmacy benefit management tools used by a variety of other organizations to manage health care quality and cost.

If PACE used all of the marketplace innovator tools, it could cut costs by 40%.

- The outlook for increased use of pharmacy benefit management tools is promising. On May 29, 2003, the Pennsylvania Governor's Office of Health Care Reform and the Management and Productivity Council announced several changes to the PACE program that will focus on negotiating more competitive drug prices.

For more information:
- Visit www.familiesusa.org for a copy of publication No.03-106.
- Visit www.aging.state.pa.us/aging/lib/aging/pace_01annl.pdf for a copy of the Annual Reports to the Pennsylvania General Assembly for the PACE program.

The PACE program provides limited prescription coverage for low to moderate income older Pennsylvanians. Its sister program PACENET (Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier) extends coverage to a higher income levels with somewhat different copays but subject to the same management features. Established in 1984, with an on-line claims adjudication system implemented in 1991 and the addition of PACENET in 1996, PACE is the largest public pharmaceutical program for seniors. Some key design features include:

- Predominately uses independent and chain pharmacies. Pharmacies who deliver by mail including retail stores who register as mail service providers must enroll and meet special requirements
- Supplies limited to 30 days or 100 pills - whichever is less.
- $6 copay per script for PACE and $8 for generics and $15 for brand-named medications for PACENET.
- Generic substitution for multi-source brands is required wherever there is an FDA A-rated generic.
- Specific prospective drug utilization review criteria are used for the maximum initial dose, the maximum daily dose, and the duration of therapy or duplicate therapy. In order for reimbursement to occur under the program for any claim subject to a prospective drug utilization message, the physician or the pharmacist must document the medical necessity.

Important Factors in Healthcare Delivery

Disease Management Programs

Education, compliance programs, and the avoidance of drug interactions contribute to improved quality of care. Pharmacy Benefit Managers (PBMs) have been involved in many successful disease management programs designed to improve compliance with specific pharmaceutical regimens, such as treatments for beta-blocker therapy post acute myocardial infarction, and depression treatment. For example, asthma education programs can improve care by fostering the use of effective anti-inflammatory drugs and other long acting medications. A recent study by Merck-Medco found that overall health care costs were decreased, mainly due to decreased use of asthma inhalers (short-acting beta-agonists)[1]. Other studies confirm this and document the reduction in emergency visits and hospitalizations after appropriate interventions[2].

Verizon, together with a pharmacy service organization, has developed a program to identify members at risk of hip fracture or diagnosis of osteoporosis. These patients are then screened for medications that are known to increase the risks of fall, such as painkillers, sleeping aids, and antidepressant drugs. Communications including information on prevention of falls and alternative drug therapies are sent to both the member and physician for consideration. This type of program reduces health care expenditures while improving quality of life for seniors[3].

PBMs can use pharmacy claims data to identify patients as risk for noncompliance and share this information with treating physicians who can use the data to improve care of their patients[4]. Centralized data collection for pharmacy claims can also help prevent potentially harmful drug interactions; AdvancePCS was able to avoid three million potential adverse drug interactions through the use of their on-line process with immediate drug utilization review[5].

Healthcare Quality

Each year, an estimated 44,000 to 98,000 people die from medical errors. That's more than the number of people who die from car accidents (43,458), AIDS (16,516), or breast cancer (42,297). The statistics in recent studies are concerning – 25% of outpatients had an adverse drug event, 13% were serious and 20% were preventable (See Exhibit 2). Seniors are particularly at high-risk. The Institute of Medicine (IOM) suggests a systems-driven solution: "Human beings, in all lines of work, make errors. Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing. In healthcare, building a safer system means designing processes of care to ensure that patients are safe from accidental injury."

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[1] Feifer, RA, Gutierrez B, Verbugge RR. Impacts of a PBM-based Disease Management Program on Asthma Medication Use. American Journal of Managed Care 2001; 6: 460-467. (Medco)

[2] Owens GS. Measuring Outcomes of Asthma Patients after Clinical Pharmacy Educational Intervention. AMCP Annual Meeting, October 1996. (FHP)

[3] Rabinowitz E. Preventing Falls and Fractures, Verizon program monitors senior medications. HealthPlan Nov/Dec 2002; 16-18.

[4] Bieszk N et al. Detection of Medication Nonadherence Through review of pharmacy claims data. Am J Heath-Syst Pharm 2003; 60 (4): 360-366. (Henry Ford Health System)

[5] AdvancePCS Patient Safety Study Finds Alerts to Pharmacists avoided 3 million potential adverse drug reaction in one year. CNET.com February 27, 2003.

Generics
Generics have chemically identical active ingredients, are available from multiple manufacturers, cost less, and are equally effective as brand-name drugs. Marketplace innovators use generics whenever they can and make them the cornerstone of drug classes to deliver cost-effective, quality care. Many employers and state Medicaid plans encourage generic drug use as a part of their fiduciary and management responsibilities. With significant numbers of brand-name patents due to expire in the near future, we expect more plans to get even more aggressive in encouraging use of generics.

Increased Direct-to-Consumer Advertising
The pharmaceutical industry spends billions of dollars each year to market its products. Studies show pharmaceutical advertising is working: the 25 most advertised drugs account for 40% of recent increased spending on drugs. Increased attention to direct-to-consumer advertising encourages employers, states, and health plans to seek value for their money.

Health Plan Focus on Patient Safety and Quality of Care
There has been a significant increase in attention to patient safety since the Institute of Medicine (IOM) released its report, To Err Is Human: Building a Safer Health System, in 1999, highlighting the magnitude of this problem. The IOM report estimates that medication errors account for over 7,000 deaths annually. Incidence rates of adverse drug reactions vary from 2 per 100 admissions to 7 per 100 admissions among hospitals that have conducted such studies according to the Agency for Healthcare Research and Quality.

Health plans believe that patient safety is a critical component of quality of care and actively address patient safety concerns as part of their efforts to improve health care quality. By design, health plans have an infrastructure that can support patient safety. As part of this infrastructure, health plans employ tools that support physicians and other caregivers and systematically identify patients at risk for medication errors, contraindications and pharmacy recall—at the time when the patient goes to the pharmacy and fills the prescription to help to prevent potential problems before patients begin taking the medications. These activities have been purposely created to reach one of the many IOM safety recommendations: implementing proven medication safety practices that include systematic tracking of drug interactions and dosing.

Management Tools – Their Effect

While the PACE program uses some unique concurrent drug utilization review screening techniques, it employs few of the cost and quality management tools used by health plans and other States in their prescription drug programs. Those tools include formularies with designs that either encourage use of a preferred drug or require a preferred drug as first-line treatment unless care would be compromised. Additionally, PACE does not utilize step-therapy or prior authorization, which are both key management tools in health plans. PACE uses retail pharmacies almost exclusively, and the prices it pays to retail pharmacies are substantially higher than payments made by other entities, including employer-sponsored programs or health plans. Another potential opportunity is the substantial savings from mail service efficiencies.

To address the impact of some of these management tools, we have reviewed the drug utilization data for the top 50 drugs under the PACE program and have attempted to quantify, where appropriate, the potential cost savings on a per user basis for:

- the use of an alternative, but equally effective drug
- lower negotiated prices through dispensing pharmacies
- mail service efficiencies

.

The following treatment examples illustrate potential savings using the management tools: cholesterol-lowering statin agents; proton pump inhibitors that are used to treat various digestive disorders; cardiac medications to treat hypertension; Plavix, used to prevent heart attacks; and drugs used to increase bone mass and prevent/mitigate osteoporosis.

A Word about Calculations

Pace/Families USA Reported Annual Cost:
This represents the annual cost of the drug as documented in the July 2003 "Out-of-Bounds" report that was produced by Families USA.

Alternative Annual Cost:
This number was calculated for a drug viewed as an effective therapeutic alternative to the drug used under the PACE program. We used the drug's per pill/capsule Average Wholesale Price (AWP) as reported in the July 2003 Drug Topics Red Book. The per pill AWP was multiplied by either 365 (one pill once a day) or 730 (one pill twice a day). The result was reduced by 13% for a brand or 55% for a generic drug to produce a conservative proxy for a negotiated annual ingredient cost for a retail purchase in a managed health plan for a maintenance medication. $36.00 was added to this discounted ingredient cost to account for pharmacy dispensing and administrative fees.

Negotiated Cost:
This number was calculated for the drug utilized under the PACE program using the drug's per pill/capsule AWP as reported in the July 2003 Drug Topics Red Book. The per pill AWP was multiplied by either 365 (one pill once a day) or 730 (one pill twice a day). The result was reduced by 13% for a brand or 55% for a generic drug to produce a conservative proxy for a negotiated annual ingredient cost for a retail purchase in a managed health plan for a maintenance medication. $36.00 was added to this discounted ingredient cost to account for pharmacy dispensing and administrative fees.

Cholesterol Drugs

The cholesterol-lowering drugs of the statin class are the most prescribed medication for any age group. They are also among the most expensive. The accompanying chart illustrates the PACE usage ranking for the statins. It is important to note that the generic lovastatin (Mevacor) is not on the list of the 50 most prescribed drugs.

Families USA	
Drug Ranking (by claims)	**Drug Name**
1	Lipitor 10mg
8	Zocor 20mg
11	Lipitor 20mg
31	Zocor 40mg
34	Zocor 10mg
38	Pravachol 20mg

Drug management is especially important for this class of drugs, as often, these very powerful cholesterol lowering drugs are prescribed when the patient only needs a 10%-20% drop in LDL cholesterol. Additionally, every cholesterol-lowering statin drug has the potential for serious side effects on liver and kidney function and muscles, and the potential side effects are of great concern for elderly beneficiaries.

This class of drugs represents an exceptional opportunity for step therapy. Since the lowest dose possible presents the lowest risk, step therapy suggests that the patient start with a low dose. After inspecting the results and monitoring any side effects, the physician and the pharmacy benefit manager can move the patient up to a higher dose if necessary. This procedure protects patient health and saves money.

Drug Name	Pace/ Families USA Reported Annual Cost	Alternative Drug	Alternative Annual Cost	Annual Savings Per User
Lipitor 10mg	$871.00	lovastatin 20mg	$425.00	$446.00
Lipitor 20mg	$1,330.00	Lipitor 20mg	N/A	N/A
Pravachol 20mg	$1,124.00	lovastatin 20mg	$425.00	$699.00
Zocor 10mg	$959.00	lovastatin 20mg	$425.00	$534.00
Zocor 20mg	$1,674.00	lovastatin 40mg	$737.00	$937.00
Zocor 40mg	$1,674.00	Zocor 40mg	N/A	N/A

The chart to the left illustrates the cost savings if an alternative drug is used. Conservative savings estimates range from $446 to $937. Lovastatin was not subject to competitive market forces at the time of this data collection; however, it is presently a multi-sourced drug and additional savings can be realized.

Drug Name	PACE/Families USA Reported Annual Cost	Negotiated Cost	Annual Savings Per User
Lipitor 10mg	$871.00	$794.00	$77.00
Lipitor 20mg	$1,330.00	$1,193.00	$137.00
Pravachol 20mg	$1,124.00	$1,014.00	$110.00
Zocor 10mg	$959.00	$871.00	$88.00
Zocor 20mg	$1,674.00	$1,492.00	$182.00
Zocor 40mg	$1,674.00	$1,492.00	$182.00

The annual savings shown to the left are conservative estimates of savings obtained by negotiating rates for retail pharmacy dispensing. Taking advantage of the efficiencies of mail service would reduce costs further.

Proton Pump Inhibitors (PPIs)

Proton Pump Inhibitors (PPIs) reduce acid formation in the stomach, and this therapy is FDA approved for up to eight weeks for the treatment of Gastroesophageal Reflux Disease (GERD) (For more serious but relatively infrequent conditions, use is continuous). However, if the patient is still experiencing GERD symptoms after eight weeks, it may be a sign of a more serious disease. Step therapy programs help identify patients' needs and focus appropriate care based on symptoms and previous experience. A PPI step-therapy program can also be used to recognize and cure stomach problems caused by the bacteria H. pylori.

Families USA	
Drug Ranking (by claims)	**Drug Name**
5	Prilosec
9	Prevacid
26	Protonix
33	Nexium

Actively managed prescription drug benefit plans who utilize step therapy recommend OTC products for occasional heartburn. More severe cases warrant the use of a generic like ranitidine (Zantac) in prescription strength.

Drug Name	PACE/Families USE Reported Annual Cost	Alternative Drug	Alternative Annual Cost	Annual Savings Per User
Nexium 40mg	$1,614.00	Protonix 40mg	$1,282.00	$332.00
Prevacid 30mg	$1,690.00	omeprazole 20mg	$718.00	$972.00
Prilosec 20mg	$1,684.00	omeprazole 20mg	$718.00	$966.00
Protonix 40mg	$1,282.00	omeprazole 20mg	$718.00	$564.00

Step therapy programs can reduce drug spending between 15% and 25% for most classes of drugs while increasing patient safety and reducing potentially harmful side effects.

Omeprazole shown in the table above as a formulary preferred drug choice is the newly approved generic for Prilosec – once the gold standard in the PPI class. As more generic manufacturers are approved, prices will fall. This will produce even larger savings than those shown above, ranging from $500 to more than $900 per patient.

Drug Name	PACE/Families USA Reported Annual Cost	Negotiated Cost	Annual Savings Per User
Nexium 40mg	$1,614.00	$1,430.00	$184.00
Prevacid 30mg	$1,690.00	$1,522.00	$168.00
Prilosec 20mg	$1,684.00	$1,501.00	$183.00
Protonix 40mg	$1,282.00	$1,141.00	$141.00

An additional tool is negotiating more competitive pricing at retail. These are conservative estimates, and actual experience in the competitive market will vary.

Plavix

Plavix is the fourth highest utilized drug on the PACE/Families USA list, with an annual cost of $1,539 per beneficiary. The drug is an anti-platelet agent used for the secondary prevention of an atherosclerotic event. Common aspirin has been shown to be clinically equivalent to Plavix. See Exhibit 5 on page 31 for more information on the drug.

Families USA	
Drug Ranking (by claims)	**Drug Name**
4	Plavix 75mg

Management tools in PACE could reduce cost of Plavix by about $8 million – or 2% of its *total* program drug costs.

Plavix use in actively managed prescription drug plans is typically limited to patients who have pre-existing cardiovascular problems such as stent placement, heart attack or stroke, or patients who are allergic to aspirin.

Typically, in a plan that utilizes benefit management techniques would classify Plavix as a non-formulary drug that requires prior authorization. This system protects patients who do could achieve equal health benefits with aspirin from the risk of potentially dangerous side effects.

Additionally, lower negotiated prices at retail pharmacies would save the taxpayers and beneficiaries an additional $214 annually, if Plavix is taken continuously. Mail service efficiencies could decrease annual drug costs by an additional $100.

Drug Name	PACE/Families USA Reported Annual Cost	Negotiated Cost	Annual Savings Per User
Plavix	$1,539.00	$1,325.00	$214.00

Bone Building Drugs

Families USA Drug Ranking	Drug Name	Pace/Families USA Reported Annual Cost	Negotiated Cost	Annual Savings Per User
3	Fosamax 70mg	$894.00	$859.00	$35.00
32	Evista 60mg	$895.00	$858.00	$37.00

For many health conditions, there is definitive drug treatment with a presumptive diagnosis. This is often the case with bone loss. In many health plans, these drugs are prescribed even though less than 50% of the time there is no definitive need as evidenced by a bone density test. Additionally, if these drugs are not taken properly, the individual will often take a PPI to counter stomach irritation. Effective marketplace innovators utilize alternative, effective treatments, including:

- Preventing bone loss through lifestyle changes, and
- Minimizing the risk of broken bones by reducing the risk of a fall. Often this involves eliminating drugs that cause dizziness or instability of gait.

Hypertension Treatment

Drugs used to treat hypertension are the most common types of medication prescribed for the elderly population. The PACE/Families list is interesting because it does not contain any ACE inhibitors, and diuretics are at the bottom of this list. With the new practice guidelines just released by JNC7, diuretics whose cost is less than $100 per year still are the preferred treatment for those with uncomplicated situations – producing better outcomes than new medications.

Families USA	
Drug Ranking (by claims)	**Drug Name**
2	Norvasc 5mg
7	furosemide 40mg (Mylan)
10	Norvasc 10mg
13	Toprol XL 50mg
19	metoprolol tartrate 50mg (Mylan)
23	metoprolol tartrate 50mg (Teva)
27	Cozaar 50mg
28	atenolol 25mg
30	furosemide 20mg
37	atenolol 50mg
40	Toprol XL 100mg
42	hydrochlorothiazide 25mg
45	furosemide 40mg (Geneva)
49	Diovan 80mg

Norvasc, in positions 2 and 10 in magnitude of utilization, is a calcium channel blocking agent that causes arteries to expand and drops blood pressure. Other drug categories are preferred over calcium channel blocking agents because they produce better outcomes. Geisinger, a Pennsylvania health plan identified as a marketplace innovator, has a preferred drug list that does not contain calcium channel blockers, and most of the other drugs used to treat hypertension are generic. What makes this so compelling is that Geisinger has such a low rate of hospital admissions (.8 per 10,000 members) for hypertensive patients. Geisinger, and many health plans that use prescription drug management tools, review the use of Angiotensin II inhibitors like Cozaar and Diovan, and coverage is granted in circumstances where an improved outcome is likely to be produced.

This point about some drug classes like calcium channel blockers having no preferred drugs on formulary is an important one regarding management control. For example, if the final bill reported out of the Medicare conference committee requires one drug in each class, there will be never ending pressure to further subdivide therapeutic classes in ways that will not provide added value to beneficiaries. The arguments could be endless – is a Cox II really a different class with different outcomes than non-steroidal anti-inflammatory drugs (NSAID)? If judged yes, it will get 100% of the market and its advertising budget will promote its exclusive position.

While these drugs are not as expensive as newer drugs in other categories, money can still be saved while improving outcomes (see chart below). These savings are on an order of magnitude of $100 to $300 per patient with hypertension. Given the prevalence of hypertension in the PACE population, this could translate to billions.

If we saved *only* $100 annually per patient through better management of hypertension drugs, that's $1.2 billion to spend on other beneficiaries who need prescription drug coverage.

Drug Name	PACE/Families USA Reported Annual Cost	Alternative Drug	Alternative Annual Cost	Annual Savings
Angiotensin II Inhibitors				
Cozaar 50mg	$553.00	enalapril 20mg	$286.00	$ 267.00
		lisinopril 40mg	$294.00	259.00
Diovan 80mg	$567.00	enalapril 20mg	$286.00	281.00
		lisinopril 40mg	$258.00	309.00
Beta Blockers				
Toprol XL 50mg	$277.00	metoprolol tartrate 50mg	$128.00	149.00
Toprol XL 100mg	$416.00	metoprolol tartrate 100mg	$167.00	$ 249.00
Calcium Channel Blockers				
Norvasc 5mg	$549.00	Sular 20mg	$417.00	132.00
Norvasc 10mg	$794.00	Sular 40mg	$417.00	377.00

For drugs treating hypertension, there is less opportunity to reduce costs through pricing negotiation since the initial cost of the drug is less. However, the total savings are significant because of the number of people treated for hypertension. Since about 70% are not treated to an acceptable blood pressure goal, these savings can be spent on treating more people and treating them more effectively.

Drug Name	PACE/Families USA Reported Annual Cost	Negotiated Cost	Annual Savings
Angiotensin II Inhibitors			
Cozaar 50mg	$553.00	$541.00	$12.00
Diovan 80mg	$567.00	$528.00	$39.00
Beta Blockers			
atenolol 25mg	$298.00	$172.00	$126.00
atenolol 50mg	$304.00	$241.00	$ 63.00
metoprolol tartrate 50mg	$405.00	$128.00	$277.00
Toprol XL 50mg	$277.00	$277.00	$ ----
Toprol XL 100mg	$416.00	$398.00	$18.00
Calcium Channel Blockers			
Norvasc 5mg	$549.00	$512.00	$37.00
Norvasc 10mg	$794.00	$725.00	$69.00
Diuretics (loop)			
furosemide 20mg (Mylan)	$52.00	$47.00	$5.00
furosemide 40mg (Mylan)	$59.00	$51.00	$8.00
furosemide 40mg (Geneva)	$57.00	$51.00	$6.00
Diuretics (Thiazide)			
hydrochlorothiazide 25mg	$29.00	$28.00	$1.00

Additional Cost Savings from Mail Order

Throughout this section, we have mentioned that marketplace innovators have negotiated contracts with retail drug stores – or buy and distribute using their own pharmacies – producing costs even lower than the conservative estimate of "negotiated cost." Further, most experience even greater savings when utilizing the efficiencies of mail service dispensing. Costs are significantly lower than retail costs even if retail can dispense a 90-day supply through plan design.

In the PACE example, they could reduce drug cost by 10% if using competitively priced mail service pricing - and dispensing fees with only 60% of brand-name drugs switching from retail.

Prescription cost of ten drugs commonly prescribed for seniors (Retail vs. Mail)[6]

The average savings is 14% or $146 per year on a branded drug

Drug	30 day Retail	90 day Retail	90 day Mail	Savings per 90 days	Annual Savings	Percentage Savings
Pravachol	$121	$365	$325	$40	$160	11%
Lipitor	98	293	261	33	130	11
Lisinopril (g)	22	67	60	7	28	10
Lotensin	33	99	85	14	56	14
Plavix	112	336	302	34	142	10
Metformin (g)	31	92	86	6	24	6
Protonix	104	313	253	60	240	19
Fosamax	76	229	180	49	196	21
Premarin	26	79	57	22	88	28
Zocor	123	368	328	40	160	11

The General Accounting Office (GAO) has also confirmed the cost savings due to pharmacy benefit management techniques. In the January 2003 study of the Federal Employees' Health Benefits Program, the GAO concluded that the average mail-order price was 27% lower for brand-name drugs and 53% lower for generic drugs than the average cash-paying customer price.[7]

Some Conclusions

If PACE had utilized all of the management tools used by marketplace innovators, its costs could have been reduced by as much as 40%. Since the program is funded largely by the state, this would reduce the cost to taxpayers and it could be used to expand the program. On May 29, 2003, Pennsylvania announced plans to expand the groups covered by the PACE program and to negotiate changes in drug purchasing contracts. This is one of many steps that will allow PACE to save money through smarter purchasing. Other steps may focus on eliminating waste and change the mix of what is delivered through the program – not just the price they pay for it. Assuring the use of prescription drug management tools in the Medicare prescription drug benefit will reduce the cost to the government and directly help beneficiaries through higher quality care.

[6] Data derived from PacifiCare of California pharmacy claims January – March 2003.

[7] United States General Accounting Office, Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies. January 2003.

Marketplace Innovators

In this section, we briefly highlight entities that address health management and delivery using all of the tools available within the sophisticated pharmacy management arena to improve quality. Since health plans usually integrate prescription drug benefits and medical care, they actively work to promote appropriate drug use to reduce medical costs, including hospitalizations and emergency care.

Health Plans

Below are two health plans (PacifiCare and Geisinger), selected because of their unique characteristics. However, they use many common practices concerning pharmacy benefit management. These plans, whether serving their own health plan, or providing management services to other health plans or employers, provide a host of management services delivered through their pharmacy management unit including:

- Targeted disease intervention programs from Attention Deficit Hyperactivity Disorder (ADHD) to Syndrome X (the insulin resistant state)
- Focused initiatives and education for improved Health Plan Employer Data and Information Set (HEDIS) measurements from asthma to post heart attack
- Specialty pharmacy disease therapy management
- Formulary development and management including the groups that support their Pharmacy and Therapeutics Committees having members with varied specialized training and expertise to insure clinically-sound and cost-effective options
- Prior authorization based upon evidence-based guidelines to insure safe, appropriate, and cost-effective use of prescription medications
- Health outcomes research, epidemiological studies, predictive modeling, decision analysis, and a host of other services that look to future improvements.

PacifiCare Health Systems serves more than 3 million health plan members. The Secure Horizons division of PacifiCare is one of the nation's largest Medicare risk programs, with more than 700,000 members enrolled in its Medicare + Choice plan.

PacifiCare's pharmacy program is managed by Prescription Solutions, a wholly-owned PacifiCare subsidiary. Prescription Solutions serves 5 million beneficiaries, about 55% are from PacifiCare's health plans and 45% represent external clients. Prescription Solutions uses a contracted network of retail pharmacies along with company owned and operated mail service facilities to supply members with their required drugs. Prescription Solutions uses in-house developed coverage management systems and techniques to minimize member risk, utilization and cost. Its generic utilization rate is approximately 55% for its commercial business and almost 60% for its senior products. Additional information on PacifiCare can be found at their website: www.pacificare.com. Information on its pharmacy benefit manager, Prescription Solutions is at www.RxSolutions.com.

Geisinger Health Plan is among the largest rural health care plans in the nation and covers a 20,000 square mile area in northern and central Pennsylvania. Many of the residents in the area participate in the PACE Program reported in the Families USA Study. Geisinger Health Plan serves residents in 40 of Pennsylvania's 67 counties with a variety of health plan options.

Geisinger Health Plan created its own Pharmacy and Therapeutics committee to develop and maintain a specific list of preferred drugs. After using the services of an outside pharmacy benefit manager, it decided to develop its own capabilities, buying support services on an as-needed basis. Its current generic utilization rate is now 57%. Additionally, it has the enviable position of producing some of the best outcomes in the Pennsylvania Healthcare Cost Containment Council report, having the lowest hospital admission rate for hypertension of 0.8 per 10,000 members. More information on Geisinger can be found at: www.thehealthplan.com.

Employers

Health plans are not the only driving force behind the healthcare management tools that are being used to manage rising costs and improve quality of care. As the financier of the majority of Americans' health benefits, employers have a critical role. With double digit annual healthcare cost increases and drug cost trends in excess of 20%, employers need to maintain their ability to continue offering affordable, quality healthcare benefits. Successful and innovative employers develop tools that encourage cost effective and appropriate healthcare use and encourage employees to be smart healthcare consumers (see Exhibit 3 for one company's explanation of "What is a Preferred Drug List?").

Verizon Communications is the largest providers of wireline and wireless communications in the United States. A Fortune 10 company with approximately 190,000 employees, and 900,000 individuals covered by its health care programs, Verizon's global presence extends to 45 countries in the Americas, Europe, Asia and the Pacific.

In 2002, Verizon spent more than $2.4 billion on direct healthcare costs – slightly more than 3.5% of annual revenue. Spending for prescription drugs is over $600 million. Verizon's team is constantly evaluating and implementing new ways to provide quality healthcare that is cost effective for both employees and shareholders. Initiatives include:

- **The Leapfrog Group -** Verizon is a founding member of this group of large healthcare purchasers committed to improving healthcare. Leapfrog initiatives include paying incentive bonuses to hospitals that implement the following changes:
  - ➔ Computerized prescription orders in hospitals to avoid adverse drug events. Requiring hospital doctors to use a computerized order entry system would reduce the errors from hard-to-read handwriting.
  - ➔ Evidence-based hospital referrals.
  - ➔ Attention to critical care.

- **The Dx on Rx Initiative –** This initiative was drafted by Verizon's healthcare team and endorsed by the Pharmacy Council of the Washington Business Group on Health (WBGH). *Dx on Rx* is a proposal to place the diagnosis on a prescription. This can prevent medical errors by making sure that the dose matches the diagnosis and by eliminating the confusion caused by drugs with similar names and different uses. Medical plans won't pay medical claims without this information, and prescription drugs should be treated in a similar manner.

- **HEDIS and Beyond –** The Health Plan Employer Data & Information Set (HEDIS) is a data reporting system that has become an industry standard. And Verizon was one of 3 pilot cases to refine its original work. In the coming years, Verizon plan members will receive data on health plan quality ratings that can help inform their purchasing decisions.

- **The Pennsylvania Project –** This program, run in conjunction with Omnicare, Inc, a geriatrics healthcare company, addresses appropriate drug use and safety through pilot pharmaceutical case management projects. These include:
  - ➔ **Cisapride –** integrated pharmacy data identified patients and reduced the use of cisapride linked to adverse events in seniors, including death. The analysis of Verizon data found the odds of cisapride users dying was nearly 62% higher than for non-cisapride users, and cisapride users had 85% higher total medical and prescription drug costs (see Exhibit 4 for a description). This project produced fact-based information to share with physicians necessary to facilitate a change in drug treatment. It raised awareness that many of the current review protocols are not sufficient and/or appropriate for many individuals (in this case, seniors). Specifically, it raised awareness about cisapride and subsequently the FDA severely restricted use of this product.
  - ➔ **Heart Failure –** a project to increase physician prescribing of ACE inhibitors to retirees with a history of heart failure. It was based on analysis that showed two-thirds of Verizon's retirees and dependents with heart failure were *not* receiving these drugs, which are considered the standard of care under the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC7). The analysis also found that the odds of an ACE inhibitor user with congestive heart failure dying are 25% lower than they are for non-users.
  - ➔ **Falls and Fractures –** Approximately 350,000 hip fractures occur annually in seniors, and the mortality rate of these hip fractures is 25%. Long-term disability, including depression, occurs for an even greater percentage. The Verizon program aims to prevent falls and fractures in seniors by reducing the use of specific drugs linked as contributors to these events, often due to side effects such as dizziness or instability of gait. The specific drugs identified through this project were based on patient data.

States' Initiatives

Innovation is not limited to health plans and leading edge employer initiatives. States, either individually or collectively, are using proven techniques to make evidence-based decisions in selecting drugs covered under their programs with or without the need for more information. Many of the initiatives are driven by Medicaid, but all focus on spending money wisely so that programs can continue to serve the greatest number of beneficiaries with the highest quality of care. Managing drugs better also reduces other health care costs.

Drug Effectiveness Review Project – a Multi-state Initiative - States are leading the way among governments in finding ways to maintain and improve quality while purchasing drugs more economically.

In order to control costs and maintain quality, states are showing a growing interest in head to head comparisons of effectiveness in drugs within classes (e.g. between the various cholesterol lowering drugs known as statins or between the various anti-inflammatory drugs know as non-steroidal anti-inflammatories).

To obtain accurate information, the Institute for Evidence-based Policy at Oregon Health and Science University is leading a collaboration among interested states to commission evidence-based systematic reviews of worldwide research to find which drugs within a given class are most effective. The reviews are conducted by Evidence-based Practice Centers (EPCs). EPCs are research organizations designated by the U.S. Agency for Healthcare Research and Quality as fully qualified to perform evidence-based reviews for the U.S. Government. These reports are then used by the participating states to determine which drugs to cover for first line treatment. Since evaluation and selection is based on the facts presented in peer-reviewed studies, states using the information in the drug management process can be confident about the quality of the drugs selected. They can then encourage price competition among drug companies with similar products.

Among the top 50 drugs listed in the Families USA article, in classes already reviewed under the state-driven initiative the states found that:

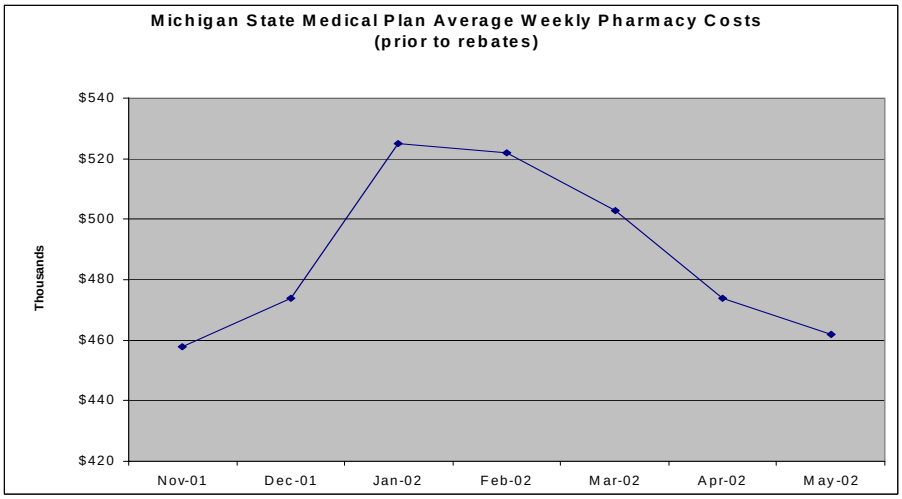
- Among cholesterol-lowering statin drugs lovastatin, a generic, was found to have equal to or better outcome data for the vast majority of individuals than all brand-name drugs in the same class at a fraction of the cost.
- Among proton pump inhibitors to prevent stomach acid formation, all agents had similar outcomes so states could confidently buy the least expensive of the class.
- Non-steroidal anti-inflammatory drugs—far more expensive brand-name medications showed virtually no significant additional benefit in reducing pain and inflammation than over-the-counter medications costing one-tenth as much.

For more information:

- On the results of the evidence-based reviews of therapeutic classes visit www.OregonRx.org and click on the "Reports" hyperlink in the middle of the page. There is also a hyperlink from www.AARP.org to the same material.

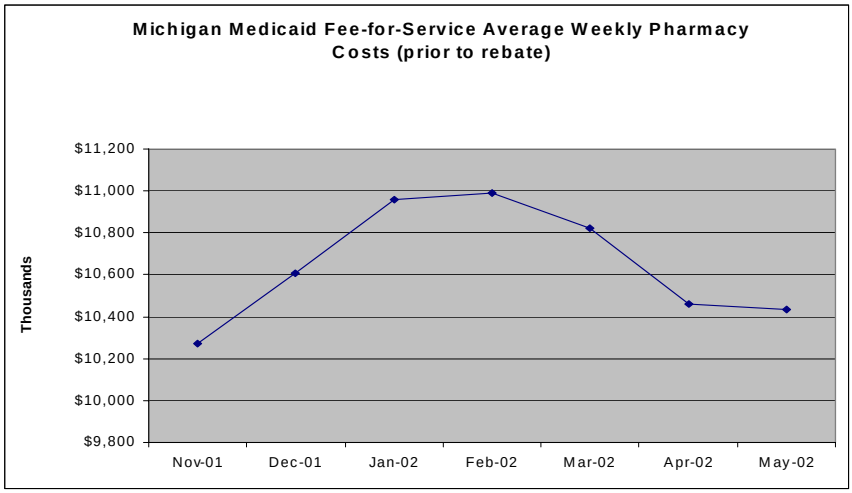
Michigan Pharmaceutical Best Practices Initiative

In 2001, Michigan was spending $1.1 billion in annual drug expenditures for beneficiaries covered under the Michigan Department of Community Health Program. Additionally, Medicaid recipients were growing at a rate of 10,000 per month.



The State decided to implement a "Pharmaceutical Product List" as a statewide drug program management tool to: maintain clinical efficacy in State drug program, improve health outcomes and patient quality of life, increase the number of recipients served and improve cost efficiency and overall healthcare cost management**.**

It accomplished this task by creating a Pharmacy & Therapeutic (P&T) committee, establishing and maintaining a pharmaceutical product list, managing start-up activities and prior authorization volumes and criteria.



Since the implementation of the Michigan Pharmaceutical Product List, the weekly pharmacy expenditure for the Medicaid fee-for-service and the State Medical Program has declined steadily and are over $620,000 below the average weekly expenditures of January 2002. Additionally, the average claim cost has been reduced by over $3.60 per claim.

For more information:

- For information presented by James K. Haverman, Jr. – Director, Michigan Department of Community Health at the October 26,2002 meeting of the National Conference of State Legislators see: www.kaisernetwork.org/health_cast/uploaded_files/MI-Rx-Viele-02Jul.pdf
- See www.michigan.gov for the Michigan Pharmaceutical Product List (MPPL)

Summary

When the federal government begins providing prescription drug coverage for Medicare beneficiaries, the government will have the power to influence the delivery system to provide the most appropriate care. By effectively managing the drug benefit, the government can spend less and improve integrated health care for Medicare beneficiaries. Additionally, better management of prescription drugs can help reduce medical expenditures, including hospitalizations and emergency care due to adverse drug events. Proven management tools will help the federal government provide a more valuable prescription drug benefit and improve the quality of life for Medicare beneficiaries.

Exhibit 1 – Cumulative price change of the top 50 drugs (by number of claims) used by the elderly (PACE program)

Rank by # of claims	Drug Name	Strength	Therapeutic Category	Cumulative Change 1998-2003	Multiple of CPI 1998-2003	2003 Cost/Year
1	Lipitor	10 mg	Lipid-Lowering Agent	30.80%	2.6	$ 871.00
2	Norvasc	5 mg	Calcium Channel Blocker	16.50%	1.4	$ 549.00
3	Fosamax	70 mg	Osteoporosis Treatment	nm	nm	$ 894.00
4	Plavix	75 mg	Anti-Platelet Agent	nm	nm	$ 1,539.00
5	Prilosec	20 mg	Gastrointestinal Agents	22.50%	1.9	$ 1,684.00
6	Celebrex	200 mg	Anti-Inflammatory/Analgesic	nm	nm	$ 2,102.00
7	furosemide	40 mg	Loop Diuretic	135.20%	11.4	$ 59.00
8	Zocor	20 mg	Lipid-Lowering Agent	25.20%	2.1	$ 1,674.00
9	Prevacid	30 mg	Gastrointestinal Agents	33.30%	2.8	$ 1,690.00
10	Norvasc	10 mg	Calcium Channel Blocker	0%	-	$ 794.00
11	Lipitor	20 mg	Lipid-Lowering Agent	29.20%	2.5	$ 1,330.00
12	Klor-Con M20	20 meq	Potassium Replacement	nm	nm	$ 386.00
13	Toprol XL	50 mg	Beta Blocker	42.80%	3.6	$ 277.00
14	Xalatan	0.005%	Glaucoma Treatment	34.80%	2.9	$ 186.00
15	Vioxx	25 mg	Anti-Inflammatory/Analgesic	nm	nm	$ 1,050.00
16	Lanoxin	0.125 mg	Cardiac Glycoside	36.60%	3.1	$ 88.00
17	Synthroid	0.1 mg	Synthetic Thyroid Agent	63.60%	5.4	$ 153.00
18	Synthroid	0.05 mg	Synthetic Thyroid Agent	63.80%	5.4	$ 136.00
19	metoprolol tartrate	50 mg	Beta Blocker	15.80%	1.3	$ 405.00
20	isosorbide mononitrate	30 mg	Anti-Anginal Agent	nm	nm	$ 407.00
21	Digitek	0.125 mg	Cardiac Glycoside	nm	nm	$ 69.00
22	isosorbide mononitrate	60 mg	Anti-Anginal Agent	nm	nm	$ 429.00
23	metoprolol tartrate	50 mg	Beta Blocker	20.30%	1.7	$ 405.00
24	Synthroid	0.075 mg	Synthetic Thyroid Agent	63.60%	5.4	$ 150.00
25	Zoloft	50 mg	Antidepressant	19.60%	1.7	$ 966.00
26	Protonix	40 mg	Gastrointestinal Agents	nm	nm	$ 1,282.00
27	Cozaar	50 mg	Angiotensin II Inhibitor	25.30%	2.1	$ 553.00
28	atenolol	25 mg	Beta Blocker	16.40%	1.4	$ 298.00

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Exhibit 1 – Cumulative price change of the top 50 drugs (by number of claims) used by the elderly (PACE program)

Rank by # of claims	Drug Name	Strength	Therapeutic Category	Cumulative Change 1998-2003	Multiple of CPI 1998-2003	2003 Cost/Year
29	Premarin	0.625 mg	Estrogen Replacement	88.50%	7.5	$ 324.00
30	furosemide	20 mg	Loop Diuretic	136.40%	11.5	$ 52.00
31	Zocor	40 mg	Lipid-Lowering Agent	25.20%	2.1	$ 1,674.00
32	Evista	60 mg	Osteoporosis Treatment	23.90%	2	$ 895.00
33	Nexium	40 mg	Gastrointestinal Agents	nm	nm	$ 1,614.00
34	Zocor	10 mg	Lipid-Lowering Agent	25.20%	2.1	$ 959.00
35	Combivent	1 mg	Respiratory Agent	54.00%	4.6	$ 10,868.00
36	Miacalcin	200 IU/act	Calcitonin Replacement	43.60%	3.7	$ 7,132.00
37	atenolol	50 mg	Beta Blocker	12.80%	1.1	$ 304.00
38	Pravachol	20 mg	Lipid-Lowering Agent	49.40%	4.2	$ 1,124.00
39	Paxil	20 mg	Antidepressant	31.70%	2.7	$ 1,031.00
40	Toprol XL	100 mg	Beta Blocker	42.80%	3.6	$ 416.00
41	Celexa	20 mg	Antidepressant	nm	nm	$ 880.00
42	hydrochlorothiazide	25 mg	Thiazide Diuretic	360.50%	30.5	$ 29.00
43	Glucotrol XL	10 mg	Oral Antidiabetic Agent	27.20%	2.3	$ 308.00
44	Klor-Con M10	10 meq	Potassium Replacement	72.10%	6.1	$ 342.00
45	furosemide	40 mg	Loop Diuretic	123.70%	10.4	$ 57.00
46	potassium chloride	10 meq	Potassium Replacement	81.50%	6.9	$ 221.00
47	Lanoxin	0.25 mg	Cardiac Glycoside	36.60%	3.1	$ 88.00
48	Claritin	10 mg	Non-Sedating Antihistamine	51.20%	4.3	$ 1,178.00
49	Diovan	80 mg	Angiotensin II Inhibitor	nm	nm	$ 567.00
50	HCTZ/triamterene	25-37.5 mg	Potassium Replacement	0%	-	$ 137.00

Notes:
nm - Not marketed during part or all of the period indicated

Data from the July 2003 Families USA Report. Source of data: Compiled by PRIME Institute from data published by the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE) and data found in PriceCheck, PC, published by MediSpan.

Exhibit 2 – Adverse Drug Events

Medication Errors
Evidence from three recent medical journal articles suggests patients, insurers and plan administrators should give a careful consideration to the issue of medication errors.

- Seniors are especially likely to suffer from medication errors. According to the April 2, 2003 issue of the *Journal of the American Medical Association*, elderly patients hospitalized for drug toxicity, such as hypoglycemia, digoxin toxicity, or hyperkalemia were up to 20 times more likely to have been prescribed an interacting drug in the week before hospitalization.
- Outpatients are at an even higher risk then hospitalized patients of some kind of medication error, says a study in the April 17, 2003 issue of the *New England Journal of Medicine*. 25% of the patients in the study had adverse drug events; 13% of these events were serious and 20% were preventable. Beneficiaries who are prescribed drugs outside of the hospital are not under constant supervision, they see their doctors sporadically, and they may not report all of their symptoms, side effects, and other medications. This is especially problematic when the patients are seniors, on several medications at once, and fill their prescriptions at different pharmacies or have memory problems.
- According to an editorial in the same issue of the *New England Journal of Medicine*, preexisting conditions such as Parkinson's or diabetes may increase the likelihood of medication errors.

In 1994, nearly 5% of all hospital admissions (for individuals of all ages) were attributable to drug reactions and interactions. Studies show at least 20% (some show almost 30%) of hospital admissions for Medicare-eligible patients are due to a medication error.
Causes are varied and include:

- Taking too many of one drug
- Taking too few or none of a prescribed drug
- Taking them inappropriately (before or after meals, with alcohol, etc.)
- Allergic reactions
- Drug-to-drug reactions
- The wrong product for the individual's health status

Seniors are more likely to have complications from taking medications. Complications may be minor or they may be severe and may result in death (see *Exhibit 4 - Propulsid*). The more drugs seniors take, the more complications they have. Many seniors take 1,000 pills a year. Repeated studies have identified drugs that should never be used by those 65 or over because of their side effects. Yet more than 15% of all prescriptions for seniors are for inappropriate drugs.
For seniors it is especially important to screen for duplicate therapy, adverse interactions with other prescription drugs, and contraindications of health conditions being treated by different doctors. OTCs, herbs and home remedies create additional complexities

Because of the imperfections of the medical system, patients must be smart healthcare consumers. They must:

- Monitor themselves carefully and report all symptoms to their doctors
- Disclose all medications that they are currently on, both prescribed and over-the-counter
- Help their doctors communicate with each other
- Realize that the drugs contained in their medicine cabinets can both save and cost lives.

Exhibit 2 – Adverse Drug Events

For More Information:

- See "Patient Safety: Adverse Drug Events in Ambulatory Care," *New England Journal of Medicine*, April 17, 2003, Vol. 348, No. 16
- See "Adverse Outpatient Drug Events – A Problem and an Opportunity," *New England Journal of Medicine*, April 17, 2003, Vol. 348, No. 16
- See "Drug-Drug Interactions Among Elderly Patients Hospitalized for Drug Toxicity," *Journal of the American Medical Association*, April 2, 2003, Vol. 289, No. 13

What Can Help

One way of remedying human mistakes is to increase the use of technology in medical settings. An article in the same issue of the *New England Journal of Medicine* states that "computer-based decision support can improve physicians' performance and, in some cases, patient outcomes." The IOM also urges a "paperless" healthcare system. Technology can monitor patients, analyze the data, compile it, and even suggest a course of action to the doctor. It can identify potential problems before a medical professional notices them. With technology, there can be fewer problems from calculation errors, patient mix-ups, drug interactions, doctors' infamous illegible handwriting, and more. However, this technology isn't perfect yet, so other problems in the system must be addressed too. Yet the one area which grew up in the technology age is outpatient pharmacy management. Here eligibility, coverage management and claim payment plus tens of thousands of edits on drug interactions and dosing are all handled electronically.

For More Information:

- See "A Broader Concept of Medical Errors," *New England Journal of Medicine*, December 12, 2002, Vol. 347, No. 24
- See *Crossing the Quality Chasm: A New Health System for the 21st Century*, Committee on Quality Health Care in America, Institute of Medicine, 2001.
- See "Errors Today and Errors Tomorrow," *New England Journal of Medicine*, June 19, 2003, Vol. 348, No. 25
- See *Fostering Rapid Advances in Health Care*, Committee on Rapid Advance Demonstration Projects: Health Care Finance and Delivery Systems, Institute of Medicine, 2003.
- See "Improving Safety with Information Technology," *New England Journal of Medicine*, June 19, 2003, Vol. 348, No. 25
- See "Patient Safety: Views of Practicing Physicians and the Public on Medical Errors," *New England Journal of Medicine*, December 12, 2002, Vol. 347, No. 24
- See *Priority Areas for National Health Action: Transforming Health Care Quality*, Committee on Identifying Priority Areas for Quality Improvement, Institute of Medicine, 2003.
- See *To Err is Human: Building a Safer Health System*, Committee on Quality Health Care in America, Institute of Medicine, 2000.

Exhibit 3 – Verizon Formulary Description

What is a Preferred Drug List? (a.k.a. "Formulary")

Background

The "sustainability" of comprehensive prescription drug coverage requires the integration of multiple plan components designed to align the clinical and financial interests of patients and plan resources. In brief – to encourage patient utilization of prescription medications on the same basis as if they were spending their own money while, at the same time, providing patients:

- Clinical support – about treatment options that (a) they may not be familiar with, and/or (b) that might be harmful to them, and
- Economic support – especially for an increasing number of high cost medications that patients might otherwise forego if drug coverage was not available.

The multiple plan components include:

- A commitment of coverage for safe, appropriate, and cost-effective prescription medications;
- Effective use of Retail and Mail Order resources – to balance both acute care and maintenance medication needs cost-effectively, and
- Effective use of (a) preferred, and (b) generic drugs when appropriate for the patient.

This supplement provides supporting information regarding **What is a Preferred Drug List (a.k.a. "Formulary")** as part of "sustainable" prescription drug coverage.

Preferred Drug List

The purpose of the proposed 'preferred' drug concept is to focus both prescribers and patients on the most clinically appropriate and cost-effective medication when there are multiple similar ("me too") medications available. Given a preferred drug list, plan design can work in two ways:

- to limit plan coverage to drugs on the list, unless a patient has gone through a review process to determine coverage eligibility, or,
- to provide lower patient co-payments for 'preferred drugs', and correspondingly, a higher patient share for 'non-preferred' drugs.

The first approach is what is commonly referred to as a "closed formulary" –limiting prescription coverage to only 'preferred' medications – with the exception that if the listed drugs are not effective for the patient, a non-listed drug becomes preferred. The "preferred' approach (second alternative) differentiates the patient's share of prescription costs – with patients responsible for a higher share of covered, but 'non-preferred' medications.

Exhibit 3 – Verizon Formulary Description

Preferred Drugs: The List

Any 'preferred' drug list does not limit patients to a single drug, a single manufacturer, or just a few options for each drug type. The list usually indicates a variety of 'preferred' drugs – often with considerable cost variance.

- Additions to the list of 'preferred' drugs are made as new branded products (or limited-use-generics that treat rare conditions) are approved by the Food and Drug Administration (FDA). Following FDA approval, drugs are evaluated for coverage and management in accordance with best-practice clinical guidelines, the plan's coverage criteria, etc. and may be selected for addition to the 'preferred' drug list.
- Deletions can also occur – drugs previously designated as 'preferred' can be moved to a 'non-preferred basis' – frequently when a new medication is found to be more effective or offer a higher value.

The 'preferred' or 'non-preferred' status will influence the patient's share of the prescription expense – but does *not* exclude coverage for 'non-preferred' drugs for those for whom it is deemed medically necessary on a "closed formulary," or for anyone on an increased cost formulary.

Preferred for Some Patients

Notations concerning appropriateness of use can also change from time-to-time as information about use for the broad population becomes available. In addition, as problems are identified with use in a particular population, a product that is generally 'preferred' could be footnoted as *not* preferred for children or seniors. For example, a footnote might indicate: *"Use by people 65 and older is generally not recommended. The side effects may not be obvious, but may be serious. Safer medication may be available. If used, lower dosages are recommended."*

Sometimes there may be other references footnoted in the 'preferred' drug list – to aid prescribers such as to caution a reduction in dose below the usual guidelines printed in the FDA-approved labeling. This type of footnote often results from experience concerning a drug's use after the clinical trial phase done to secure FDA approval. Pharmacy managers also use reports and clinical findings based on broad, population-based experience. In this case a footnoted text might be something such as *"The recommended dose for children under age 12 – or weighing less than 60 pounds – is often lower than the manufacturers' usual dosing guidelines."*

'Preferred' drug lists may also contain additional information including the best practice guidelines recommended by the body of experts for a specific condition such as hypertension, elevated cholesterol, mild, or moderate or severe asthma. For example, for hypertension, the 'preferred' drug list might show treatment recommendations from The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7). The explanations could be detailed including various degrees of hypertension (mild to severe), and with or without other conditions (diabetic, previous heart attack, etc.).

Costs such as indicators of relative costs of specific drugs or actual costs for a typical supply (such as $ or $$$$) are included in some preferred drug lists to assist physicians and plan members in making cost-effective choices appropriate for their condition.

Exhibit 4 – Pharmacy Intervention to Reduce Medication Risk

Reducing Cisapride Use Through a Targeted, Evidence-Based Intervention in At Risk Retirees of a Telecommunications Company.

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Purpose. This initiative was conducted to reduce risks of cisapride (Propulsid®)-associated arrhythmias in a telecommunications company's Medicare-eligible plan members with medical and/or drug risk factors. The telecommunications company, a founding member of The Leapfrog Group, undertook this initiative to improve the safety and overall value of its healthcare benefit for retirees. **Methods**. Cisapride was chosen because of its Unacceptable rating for treatment of GERD by Omnicare's *Geriatric Pharmaceutical Care Guidelines®*. An analysis of death rates between Medicare-eligible indemnity plan members who used cisapride (N=445) and members who did not (N=17,732) demonstrated that for those with both a medical and drug risk factor, the odds of a cisapride user (N=163) dying were 62% higher than for a non-cisapride user (N=4202) ($p<0.09$). Intervention "cases" were selected based upon presence of a medical risk factor (ICD9) and drug risk factor (NDC). Cases were forwarded to Omnicare pharmacists, who called targeted prescribers to request discontinuation of cisapride. If the prescriber could not be identified, the retiree was called directly. If the prescriber refused without sound clinical justification, a geriatrician then called. Drug therapy changes resulting from the intervention were forwarded to Verizon's pharmacy benefit manager. **Results**. 144 retiree cisapride users were identified with both medical and drug risk factors. Cisapride was discontinued in 112 (77.8%). At the close of the intervention, 15 (10.4%) prescribers had been contacted but had yet to make a change, 3 (2.1%) refused to discontinue without providing clinical justification, and 2 (1.4%) chose to continue the drug providing informed clinical justification. In 5 (3.5%) cases, no prescriber could ever be identified. **Conclusions**. A targeted, evidenced-based intervention by Omnicare pharmacists changed prescriber behavior by reducing the use of cisapride in at-risk retirees, thus improving the safety of a telecommunications company's drug benefit. The at-risk retirees, when called directly, were fully supportive of the intervention, forthcoming in their discussions, and thankful for the telecommunications company's efforts.

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Exhibit 5 – Plavix drug summary

How it works	FDA approved uses	FDA recommended dosing/PDR
• Keeps blood platelets from sticking together and forming clots • Shown to work only somewhat better than Aspirin	• The reduction of atherosclerotic events (myocardial infarction, stroke, and vascular death) in patients with atherosclerosis documented by: - recent stroke - recent myocardial infarction or - established peripheral arterial disease	• Recommended dose is 75 mg once daily with or without food • No optimal length of dosage provided in PDR • Only strength approved for manufacture is 75 mg • Average wholesale price (AWP) for 30 pills of 75 mg each is $114

Some FDA precautions (see attachment for full FDA labeling insert)

- While clinical trial data was deemed statistically significant, the results were marginal when compared with aspirin. Trial data is:

Outcome Events

	Plavix	Aspirin
Ischemic stroke*	438	461
Myocardial infarction*	275	333
Other vascular deaths	226	226

*fatal or not

Note: The event is the time to first occurrence of the new event

- For clinical trial "recent" was deemed to be:
  - within 6 months for stroke (with at least a week of residual neurological signs)
  - 35 days for myocardial infarction
- For clinical trials, peripheral arterial disease was objectively established
- Should be discontinued 7 days prior to surgery
- Should not be used when the patient has a tendency toward conditions that cause bleeding such as peptic ulcers or intercranial hemorrhage
- Patients should be notified that it takes longer than usual to stop bleeding and that they should report any unusual bleeding to their physician

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Exhibit 5 – Plavix facts and experience

Facts	Experience
Aspirin has been shown effective in reducing the recurrence of heart attack and stroke if taken daily	• Studies suggest aspirin alone has been shown to limit the formation of blood clots, reducing the risk of heart attack, stroke, or death by 30% in people with heart disease
Effectiveness of Plavix in preventing heart attack and stroke has been tested against over-the-counter aspirin (CAPRIE Study – Clopidogrel vs. Aspirin in Patients at Risk of Ischemic Events)	• Patients with recent history of heart attack, stroke, or arterial disease were separated into two groups – one given Plavix (75 mg/day), the other aspirin (375 mg/day) Patients received randomized treatment averaging 1.6 years • The overall incidence rate of heart attack and stroke for these patients was 10.6% for the aspirin group and 9.8% for those on Plavix. In other words, of these patients, 10.6% of those who took aspirin had recurrences to only 9.8% of those on Plavix. • Statistical significance of the relative reduction in risk by using Plavix vs. Aspirin was borderline, however (p=.045)
Researchers in the New England Journal of Medicine have recently conducted a study of the cost-effectiveness of aspirin and Plavix as a preventative measure in patients with coronary heart disease	• Plavix costs $3.22 per pill while aspirin is roughly $0.04 • Using a computer simulation of the United States population with relevant coronary heart disease rates, researchers found the following: - Extending aspirin therapy from its current level to all eligible patients (those for which aspirin isn't contra-indicated, or about 95% of the population) would cost about $11,000 per quality adjusted year of life gained - Giving clopidogrel to that 5% of the population that can't take aspirin would cost about $31,000 per quality adjusted year of life gained - If, however, you were to give clopidogrel to everyone, the tremendous additional cost combined with the relatively minimal positive outcome would cost more than $130,000 per quality adjusted year of life gained • These researchers therefore suggest, on the basis of relative cost effectiveness, the prescription of clopidogrel only in cases where the patient cannot take aspirin for some reason

Sources:

- New England Journal of Medicine; June 6, 2002 "Cost Effectiveness of Aspirin, Clopidogrel, or Both for Secondary Prevention of Coronary Heart Disease." Gaspoz, Coxson, Goldman, et al.

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Written Statement Submitted to

Department of Health and Human Services

Office of the Secretary, Office of Public Health and Science, Office of Disease Prevention and Health Promotion

on

National Action Plan to Assure the Appropriate Use of Therapeutic Agents in the Elderly

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Part 1

You have asked for comments identifying the most important priorities to be considered in the development of a national action plan to assure the appropriate use of therapeutic agents by elderly Americans. We regret that many competing priorities precluded us from submitting comments earlier. However, we subscribe to "better late than never." We are now pleased to contribute our thoughts developed based on full careers as individuals (Loren Lipson as a patient-caregiver, researcher and teacher and Pat Wilson as a consultant to employers and health plans) and in our more than 15 years of collaboration on aging issues. Since drug overuse, underuse and misuse contribute to or impairs the health status of seniors, much of our work involves managing pharmacy to manage health.

Introductory Comments

When looking at large populations, use of healthcare services increases with age and services change from acute health episodes to continuous treatment of chronic conditions. Medicare beneficiaries tend to have more chronic health conditions, resulting in more physician visits and prescriptions, than younger individuals. Drugs are the primary treatment for most chronic conditions –hypertension, heart conditions, diabetes, etc. While drugs can be beneficial, they can also harm if they are not appropriate for a specific individual. Interactions, overmedication, doses too high, side effects like instability of gait, confusion– all of these endanger health and raise overall healthcare costs. And because the side effects of a particular drug, or combination of drugs, begets more side effects, more drugs are prescribed. It is a never-ending cycle. And those that suffer most are seniors.

Any Federally sponsored program has a significant effect- both positive and negative- on the economy and on health status. By providing the money, the financier dictates what will be delivered. Providing too much money for whatever the healthcare system and its myriad of practitioners want to deliver, is a formula for disaster. The disaster is both in terms of care and in terms of cost to taxpayers and beneficiaries.

Most of us have our own experiences with the effect of too many or the wrong drugs for our aging relatives. Unfortunately, many of these misadventures ended in death. If you have no experience, just go read the first paragraph of the Executive Summary of The Institute of Medicine's report *To Err is Human*. That report deals with a healthcare system that needs fixing. Two of the three medical misadventures used to make its points real to all of us, deal with drugs. And while this report focuses on problems in hospitals, drug "management" outside is no better. Various reports, including HHS-sponsored studies, document that for the Medicare-eligible population, between 20% and 30% of all hospital admissions result from a drug misadventure. The wrong drug, too high a dose, failure to take a needed medication are some examples, but the list goes on.

No one intends harm. They just don't know what they don't know. Additionally, the healthcare practitioners are not supported by *systems* that have as their goal helping them do their jobs better. Sometimes that means preventing errors. Sometimes that means helping pick products appropriate for Aunt Sophie, given her various medical conditions and the current mix of drugs deemed necessary by her various caregivers. Other times that means picking the least costly drug that will be effective for Cousin Ed.

In the design of a new Medicare program, we believe that money should be treated as a precious resource. Spending money on healthcare services and supplies that deliver value to the patient is a worthwhile goal. Spending money on healthcare services and supplies that do harm to patients is just dumb! And doing it in a program that at its core is based on electronic patient- and drug-specific data that is instantaneously accessible and usable, is the dumbest of all. A *smart system* can know all about Aunt Sophie and can know all about the side effects of different drugs, as they are likely to pertain to *her*. A *smart system* can support caregivers in choosing cost-effective products that work for Aunt Sophie. The choices made for her can be quite different than for Uncle Jim. The result is that care is better, value is delivered and money is not wasted on needless and harmful services.

With the graying of America, more services are needed. Few physicians specialize in geriatric medicine. As recent reports have so well documented, there aren't enough of these specialists to provide adequate service to seniors today much less to the aging baby boomers. And of those who specialize in geriatrics, only some specialize in managing drugs. However, most retirees go to general practitioners that may be not as well equipped to monitor prescription drug use and are currently not incented by Medicare to coordinate care with others attending to patient needs. Retirees tend to see multiple doctors and often no one has all of the important facts – not even the patient or a family member. *Smart systems* can help. And a Medicare-sponsored program can either lead or impede their development. For the benefit of all, we hope you will lead.

Important Priorities

You have asked that those contributing to the debate be selective in making suggestions about the most important priorities for a national program. We suggest the following five:

- Design for an electronic infrastructure
- Look at the service or supply you cover – you should set the rules
- Develop your own formulary. Close it. And develop rules that allow appropriate expansions of coverage in individual circumstances
- Use generics whenever you can and make them the cornerstone of drug classes wherever you can
- Be creative, flexible and take nothing for granted.

1. Design for an electronic infrastructure - When card and mail plans were first introduced, plan sponsors were looking for discounts on drugs and lower administrative fees than were paid for the paper claim approach. That's all. Nothing more. Few understood the value of data and what is at the heart of every PBM- electronic networks, infrastructures and computer-driven data manipulation. Remember that what now goes under the name of Medco Health Solutions started as a small division of CSC (Computer Sciences Corporation). The speed with which data is captured and used is mind boggling.

Today, PBMs are not all the same in how they view their job. Some view their job as being efficient claims processors, but do little to judge whether claims are eligible for coverage. A script written is a claim paid, albeit one that is tracked electronically. Some view themselves as drug managers. And some as health managers who help physicians select products that are

effective for their patients within the context of coverage rules. The coverage rules would include effective for the condition, supported by evidence and practice guidelines, safe, least costly etc.

The technology that PBMs use captures important data that can easily be transformed into useful information. Current uses vary from: determining eligibility for benefits, to what are the covered benefits, to prices to be paid to pharmacies and fees to be collected from plan members. But with more data, more is possible. For these reasons some employers and PBMs are looking to use the existing and new information in creative ways to manage their drug and medical plan and to improve the quality of care for patients. HHS should understand the possibilities and expand on them as the basis of coverage decisions. Some easy requirements that would benefit HHS management, improve efficiency and the likelihood that supplies meet the coverage rules to be established are to require:

- The diagnosis on the script
- The directions for use (e.g. *bid*, short for *bis in die* and meaning for us non-Latin scholars twice a day) be included as part of the electronic claim, along with the quantity and strength dispensed
- Special training or certification in a specialty for certain drugs treating complex conditions (whether as a consultant or as the script writer).

Electronic processing costs less than the antiquated paper claims approach and it allows drug utilization review (DUR) to occur before the script is filled – screening for allergies, interaction with other drugs the patient may be taking, age appropriateness, etc. It also creates a drug record for each patient which can be used to target disease management, wellness programs, and for additional DUR after the script is filled – screening for fraud, abuse and therapeutic evaluation. Coupled with patient-specific data even more important screenings can occur to identify and eliminate potential problems.

The relationship between prescription drug programs and medical plans and the data that each has is important for managing costs and care. The goal of integrating all components of the healthcare system is to decrease costs for a disease and improve care and quality outcomes. The development of electronic data interchange creates the ability to integrate medical and pharmacy data. Integrated plans can have one vendor who manages the medical and drug components, or they can have different vendors who share data. The number of vendors is not the issue, but rather how sophisticated their systems are and how well the vendors perform. HHS as a design sponsor can influence the development of *smarter systems*.

2. Look at the service or supply you cover- you should set the rules - To manage anything well, you must go beyond both the price for any service or supply and how much, if any, of it gets delivered (utilization). To get at the heart of the health cost problem requires managing not only *who pays*, but *how much* and *for what*. Management doesn't really exist unless you know exactly what you are purchasing. And care is compromised if the unit of service or supply is not what the patient needs. This focusing on the unit of service provided - a factor most overlook - we believe is the essence of an effective healthcare plan. A unit of service could be a lab test, a surgical procedure, a drug etc. Most efforts to reduce price and utilization have assumed that the

unit of service remains constant; in reality, it is continually changing. Those that focus on price and utilization are not asking questions like:

- Is the service or supply necessary for Aunt Sophie?
- Will she benefit and if so, in what way?
- Is it a generally accepted practice?
- Is it a new approach, but well grounded in science and likely to provide significant benefit?
- Is it elective, cosmetic or a custodial treatment not treating an illness or injury and not an eligible charge covered under the plan? etc.

In the case of drugs, the unit of service is constantly changing. From an H2RA to lifetime therapy with PPIs. From ibuprofen to COX 2s. From ACE inhibitors to angiotensin II receptor blockers. In many cases, the patient is no better off. But, because of dynamic pressures, exerted by those with an interest in influencing providers and patients, care changes because someone – the plan sponsor or funder of services – allows it to change. They are not exercising an appropriate but different pressure on the dynamic marketplace. This failure to anticipate dynamics and respond appropriately leaves the marketplace subject to special-interest pressures.

We approach healthcare with a few simple premises. Whenever evidence indicates that the newer therapy delivers value, it should be covered. Wherever there is no evidence and it costs more, as most new things do, it should not. Congress and the federal government are the funders of the Medicare program in that they collect dollars from various taxpayers and funnel it to various providers for covered services. State legislatures and administrations are sponsors of the Medicaid programs. As such, all should have a say in establishing coverage rules, if they simply have the resolve to set them.

Analyzing the unit of service goes beyond defining physical parameters or looking for unbundling, etc. It raises issues of quality and appropriateness of care. Both affect the rate of growth in health benefit costs. So as we consider expansion of drugs under the Medicare program, it is important to define what you cover and establish the rules for how you will determine if the rules are satisfied. Fortunately you have an electronic and data-driven system so this can be done efficiently *if you* set the rules.

Do not assume that a PBM will do it for you. You must tell them. Focus on what you mean by "medically necessary" or skip the term altogether and go to the elements of coverage. Things like "must treat an illness that the individual has" are made easy because you now have the diagnosis on the script. One rule that should be important for a plan administered by HHS is that the individual should have a condition for which the FDA has approved the use of the drug. Off label use should only be covered when there is sufficient evidence to indicate that it is effective. The evidence should be such that those who are tied to the pharmaceutical manufacturers do not unduly influence it.

Just as it is important to set the rules for what you cover, you should set the rules for what you don't. Listed below are the most common exclusions from employer and managed care plans.

Most common plan exclusion:

- Drugs that don't meet the coverage criteria (e.g. appropriate and effective for the individual etc.)
- Drugs used for experimental purposes
- Drugs for cosmetic purposes including Rogaine, Vaniqua, Solage and Retin-A when used for age spots and as a wrinkle cream
- Weight loss aids
- Drugs that don't treat an illness or injury
- Prescription and OTC vitamins
- Nicotine gum and other smoking deterrents whether OTC or prescription
- Drugs that are highly elective. This could include Viagra, Lamisil for toenail fungus, etc.
- Fertility drugs
- Biologicals unless they are a named inclusion

But the devil is the details. There is significant discrepancy between *how* plans are actually administered by the various administrators- in this case a PBM. For example, you could exclude either experimental drugs or drugs used for experimental purposes, and cover growth hormones for dwarfism but deny coverage to increase muscle mass in the bedridden elderly. Similarly plans might cover Botox for cervical dystonia because it would generally fall under the definition of an illness but deny claims for galbellar lines. No to wrinkles!

There are important distinctions between *exclusions* where a particular drug or type of drug is not covered at all and *restrictions* where use of a drug is limited in some way. It is often hard to enforce these rules in an indemnity plan because information about the use of the drug is often not captured. For example, in many plans, prescription vitamins are only covered during pregnancy, but information about whether or not the patient is pregnant is not captured during drug claim processing. Or, a drug may be FDA approved for a certain use, but experimental for treatment of another condition and the claims processor doesn't know which is applicable. By having the diagnosis on the script, it will be mush easier to efficiently process claims and to deny those that should not be covered under the program. That gets us back to Priority 1 and the importance of a data-driven system. - **Dx on Rx** is the mantra**.**

3. Develop your own formulary. Close it. And develop rules that allow appropriate expansions of coverage in individual circumstances. - A formulary is described by most folks as a list of preferred drugs for use in a specific plan. If properly developed, it is useful in managing both care and its cost. Negotiated manufacturer rebates may also lower cost but may not be a factor in a national plan. If a factor, the rebate should only be an issue in determining the cost of a drug to compare to another choice to determine where the most value is delivered. Formularies – whether or not manufacturer rebates continue or are dealt a fatal blow - are important management tools for drug plans and influence drug selection by doctors and patients.

Any formulary as currently conceived and established only addresses the issue of treatments that are *generally* safe and effective. On a patient by patient basis, this is an irrelevant concept. The only important issue is what is safe and effective for me, or for Cousin Jim or Uncle Bruce. So

while the most cost-effective treatment for most cases will come from Formulary Drugs X, Y and Z, if there is evidence that another treatment is necessary, it should be covered. But to quote a client, the reasons can't be based on "might as well healthcare".

Drug manufacturer marketing both to physicians and to patients makes the closed formulary an important design tool. But given the clout of the pharmaceutical industry, it may be difficult to implement. Yet without it, we believe you doom a national program to failure. We cannot afford a program that simply allows patients to fill prescriptions for whatever a physician chooses to prescribe. Just turn on the television or flip through a magazine and you'll find pharmaceutical companies advertising their drugs directly to the public. The ads direct patients to ask their doctor about their product and may even include a list of doctors or a monetary incentive to see a doctor. The ads never mention costs and often the information about side effects, effectiveness and when using the drug would be inadvisable is in small print and may not even appear on the same page as the advertisement. This advertising is causing patients to ask their doctors for the miracle drugs they've read about or ask why they prescribed one medicine and not the other they saw advertised. The problem is that many of these drugs are no better than older alternatives. Switching to them means we can't gain the advantage of a competitive marketplace with multiple manufacturers.

As you contemplate the design of a national program, you may assume that patients may find the answer "it's not on your formulary" unacceptable. While patient resistance is an issue, it's only one factor. An equally important factor is the continued sustainability of the plan itself. Without controls inherent in the initial plan, you doom it to failure.

4. Use generics whenever you can and make them the cornerstone of drug classes wherever you can - Generics have chemically identical active ingredients, are available from multiple manufacturers, are not patent-protected, and cost less – in many cases, significantly less. Given our premise that money is a precious resource, paying more than you have to for something that is no better - or even marginally better - is imprudent.

Employers and state Medicaid plans have learned the lesson. Plans who only gently encourage generics are a dying breed. More forceful tactics are required. Dying are the days where plan sponsors are reluctant to influence a doctor's decision in any way. While resolve to tackle the issues has been slow in coming, many are exercising their fiduciary and management responsibilities and duties. With significant numbers of brand name products' patents due to expire, we expect even more plans to get even more aggressive in encouraging use of generics in the future.

Some employers' plans call for generic substitution unless the prescription is marked DAW (Dispense As Written). In some states this is permissible, in other states the physician must actually prescribe a generic for it to be dispensed. But all too often the physician just writes DAW for the brand with only a belief, based largely on drug company marketing, that the generic is inferior. But you already have some effective tools to use to counter the ill founded beliefs. We particularly like the one from the inside back cover of the September-October issue of FDA Consumer.

"If you're experiencing anxiety about taking your

generic drug,

read this ad and repeat as needed.

The FDA ensures that your generic drug is safe and effective. All generic drugs are put through a rigorous, multi-step approval process. From quality and performance to manufacturing and labeling, everything must meet the FDA's high standards. We make it tough to become a generic drug in America so it's easy for you to rest assured.
Visit www.fda.gov/cder/ or call 1-888-INFO-FDA to learn more.

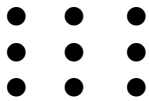
Generic Drugs: Safe. Effective. FDA Approved."

The following chart shows the methods managed plans most typically use to encourage generics.

How plans encourage generics:

- Copay/coinsurance is less for generics
- Closed formulary that is based on generics only in many classes(H2RAs, Ace Inhibitors)
- Charges for branded drugs limited to cost of generic- member pays the full difference in cost even if the physician indicates that the Brand is to be Dispensed as Written(DAW)
- Communicate about price differences- to both patients and physicians
- Communicate about quality control of generic manufacturing process
- Establish a *short* list of drugs that are available as Brands and as generics for which the patient will not be penalized by having to pay more for the Brand. Publish the list and describe why these drugs are treated differently
- Establish procedures to handle the exception for the patient who can't take the generic – when a nonformulary brand is the preferred agent for Aunt Sophie
- Pay pharmacist a higher dispensing fee for generics

5. Be Creative, Flexible And Take Nothing For Granted - Here's a problem we've seen used many times: How do you connect all these dots with just four lines – without lifting your pencil from the paper?



If you're like us, you may forget the solution. You'll have trouble finding it if you're constrained by what you think are the rules of the game or if your focus is too narrow. The key to this puzzle lies in looking outside the grid of nine dots. There's a lesson here for those of us grappling with rising healthcare costs- particularly for those 65 and over. The healthcare system is dynamic, and the rules are constantly changing. To be effective, our thinking must be creative and flexible.

A creative approach to benefit cost management is looking for ways to buy better medical services for less money. There's much room for improvement in the quality of retiree healthcare. The elderly tend to be over-medicated, over-dosed, and over-scalpeled – and their care tends to be under-coordinated. Improving quality of care – and reducing the price you pay for it – takes the resolve to deal with providers – including drug manufacturers, physicians, pharmacists, etc. - not as adversaries but as cooperative business partners, like any other supplier of goods and services.

Healthcare has become big business, and plan financiers who drive the system – governments, employers, etc. - can gain advantages by following sound business practices in dealing with providers. They must use their purchasing power, negotiate, and shop for the best value and exercise their responsibility to say what the plan covers. Retirees can also play a role in improving the quality of care they receive – if all help them become better healthcare buyers.

One way to control retiree healthcare liability is to give more of the financial responsibility to retirees. Another way is to broaden focus beyond the dollars which finance care to the care itself. By managing the type, number and quality of services delivered to retirees or purchased by them, plan financiers – including the U.S. Government can create a win-win situation for themselves and plan beneficiaries.

Closing Comments

In providing financing of drug coverage for Medicare beneficiaries, the government also has the power to influence the delivery system to provide more appropriate care to covered groups. He who has the gold makes the rules! By spending *smarter*, we can spend less – and improve quality of life. Better management of prescription drug benefits can help eliminate other expenditures; for example, hospitalizations due to inappropriate medications, or extended hospital stays from overuse of sedatives. If you fail to exert your power – some would say your responsibility – and you simply expand coverage without addressing what's wrong with how care is now delivered, we all assuredly will spend more. And older Americans will continue to lose out in a healthcare system that doesn't serve their needs as well as it should.

The health and security of our retired American's should be assured through thoughtful, informed change to our current system. This call for ideas before you finalize plans represents but a first step in that process – a process in which we all should become involved.

An Example - Neurontin (gabapentin)

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on

National Action Plan to Assure the Appropriate Use of Therapeutic Agents in the Elderly

Part 2

Earlier this year, we responded to Health and Human Service's call for ideas on the most important priorities to consider in developing a national action plan to assure the appropriate use of medications by seniors. In our previous statement, we suggested the following top five priorities for a national program:

- *Design for an electronic infrastructure*
- *Look at the service or supply you cover – you should set the rules*
- *Develop your own formulary. Close it. And develop rules that allow appropriate expansions of coverage in individual circumstances.*
- *Use generics whenever you can and make them the cornerstone of drug classes wherever you can*
- *Be creative, flexible and take nothing for granted*.

We selected those ideas formulated during a lifetime of work involving identifying and solving problems. We tried hard to choose words to make the concepts real to readers. As is usually the case, *the linkage* between ideas is as important as each idea is as a unique concept. In other words, what is possible manifests itself when the ideas are linked together and put into practice.

The national debate to develop a sustainable expansion to Medicare's existing comprehensive physician and hospital benefits was center stage in the recent 2002 elections. The specific initiative has yet to be developed in sufficient detail so that a sustainable drug benefit becomes a reality. In part that program would deliver medications appropriate for covered individuals.

Examples make concepts clearer. This paper is an example of how the 5 selected priorities come into play using just one drug- Neurontin (gabapentin). It is intended to illustrate how our suggestions promote better healthcare and appropriate coverage and could be used in an environment where pharmacy is managed in a systematic way to deliver benefits appropriate for a covered individual. In part that means we will point out how things work now in the "managed" pharmacy environment. And to provide additional clarity, we will mention how some could think things work, but don't.

We do not presume in this paper to cover all of the details concerning the drug's specifics. Nor do we presume that the readers of this paper have, or should have, a medical background - in fact one of its authors has no medical school, nursing or pharmaceutical training. Yet it is important to look at some information about a drug and its coverage under any plan of benefits (whether Medicare, Medicaid or an employer or union-sponsored program) if the goal is to provide coverage for care appropriate for the individual and an expense appropriate for coverage under any benefit plan. We have created summaries to help readers become familiar with background on the drug, with additional references for those who want to read more. We welcome edits and improvements and other thoughts that contribute to the goal of appropriate coverage of medications for all.

Neurontin

Background on the Drug

Under the standards established to safeguard Americans, the Food and Drug Administration (FDA) is responsible for determining if medications (whether drugs or biologicals) are generally safe and effective for use. As part of the initial investigation, whenever a medication is found to be unsafe for use for any subset of the population, information is presented in the labeling approved by FDA. This might relate to use:

- During pregnancy
- By someone with another condition (like kidney problems)
- While taking another medication where a severe interaction has been identified, etc.

Doctors can (and do) prescribe drugs in any way they believe will best help their patient. The prescribing may be for conditions that have not been approved by the FDA as both safe and effective. This is called off-label prescribing. The hope is that there is:

- Fact-based evidence readily available to the prescriber of the benefits of a non-FDA approved use
- Time for the prescriber to review it
- No undue influence by those who benefit from use
- Value delivered to patients for the treatment selected by the physician
- No harm done to the patient.

While it is legal for the prescriber to write scripts for off-label uses, it is, however, illegal for a drug maker to actively promote a medicine for conditions where it has not been demonstrated to the FDA that it is safe and effective for that purpose.

Until recently the only FDA approved use of Neurontin was as adjunctive (add-on or in addition to) therapy in the treatment of partial seizures for patients with epilepsy. Recently (June 2002) the FDA approved Neurontin for postherpetic neuralgia (the treatment of pain after herpes). According to a lawsuit, Warner-Lambert (which has since been acquired by Pfizer) has been actively marketing Neurontin for 11 specific off-label uses. The FDA has now approved one of those 11 uses. There are reports that the off-label marketing was often supported with nothing but anecdotal evidence often sponsored or created by the drug company, with little or no hard data. For some conditions they also promoted dosages that exceeded FDA-approved guidelines. See the next section for more on the misconduct allegations and the attached documents with more drug specifics.

Why we chose it as our example

1. It's in the news - It's topical. In part that means that some readers can relate to the information presented here because it is not new. Others who have not read recent articles about Neurontin can easily search out information for themselves. Here are some of the actions reported in articles in *The New York Times*[1], the *Wall Street Journal*[2] and in *Worst Pills Best*

[1] The New York Times. Melody Petersen: March 14, 2002, May 15,2002 and October 29, 2002
[2] The Wall Street Journal. Rachel Zimmerman: November 8, 2002

Pills News[3], a publication of the Public Citizen Health Research Group. Reports were based on interviews, basic legwork and court documents in the lawsuit brought by Dr. David P. Franklin, a former Warner-Lambert employee. The allegations are:

- In exchange for money, physicians allowed pharmaceutical sales reps into their examining rooms to meet with patients, review medical charts and recommend off-label use.
- Marketing executives at Warner-Lambert urged their superiors to let them promote Neurontin for unapproved uses rather than perform the clinical studies needed to prove the medicine was safe for such patients. They recommended against doing studies because of the short time that they expected the company to be able to sell the drug exclusively before the patent expired. They recommended that Neurontin be promoted for the unapproved condition through educational courses.
- Warner-Lambert tried to influence doctors who wrote medical journal articles about Neurontin by paying them, sometimes secretly, and hiring a marketing company to write first drafts. Warner-Lambert hired two marketing firms to write articles about the unapproved uses of Neurontin and to find doctors willing to sign their name to them as authors. According to an invoice from one of the marketing firms, Warner-Lambert agreed to pay the firm $12,000 for each article and $1,000 for each doctor willing to serve as author. Internal memos detail how the marketing firm often wrote a first draft, but sometimes had problems finding an author. The articles were then reviewed and approved by Warner-Lambert before they were sent to journals for publication.
- Warner-Lambert gave financial incentives to hundreds of doctors to prescribe Neurontin for unapproved uses by inviting them to dinners and weekend trips to resorts. They also paid doctors to speak about Neurontin and to prescribe it to patients who were enrolled in the company's clinical trials.
- Warner-Lambert tracked prescriptions written by doctors after they attended dinner meetings paid for by the drug company at which Neurontin was discussed. Doctors attending the dinners wrote 70% more prescriptions for Neurontin than doctors who did not attend.
- Although Neurontin is approved as adjunct therapy for epilepsy, a marketing executive at Warner-Lambert in a recorded voice-mail message that is part of the lawsuit told sales reps to promote monotherapy.

In a public interview, Dr. Franklin, a former research fellow at Harvard Medical School said he was most troubled by the company's insistence that he press doctors to prescribe Neurontin in much higher doses than had been approved. Several marketing executives had told him that because Neurontin appeared to be safe in high doses it was reasonable to encourage doctors to try it for almost any neurological condition "just to see what happened."

The list of reported questionable tactics goes on and the drug manufacturer will answer charges in court. At the very worst, much of the evidence of effectiveness is tainted. That in turn may have resulted in harm being done to those who used the drug. At the very best, individuals and firms who often appeal to us as working to improve patient care and reduce suffering, come off as a Ron Popeil competitor for the marketing genius award for the year. But marketing pills is not the same as marketing chicken rotisseries.

2. We got snookered (a technical term). Making a mistake should always be a learning experience. This time perhaps others can learn by seeing where we went wrong. What we did

[3] Worst Pills, Best Pills News. May and September 2002

was to violate one of our work standards - take nothing for granted when it comes to managing pharmacy to manage health. It is so important that we selected it as one of only five for your consideration.

Here is what we did. Several years ago we looked at use of Neurontin because it moved into the top 20 for drug spend. Seeing that at that time its only approved use was for epilepsy, we *presumed* that further management should not be a high priority. Reasoning went like this. Most patients were under the care of neurologists. Neurologists were managing use so that it was both standard- and fact- based and the resulting care was appropriate with costs being an eligible expense under either employer-sponsored and self-insured ERISA medical plans or health plans where we provide consulting services.

What should we have done? Some simple calculations to determine if experience is reasonable! According to the U.S. Bureau of Vital Statistics there are about 5.1 epileptics per 1,000 Americans. One client has 537,000 lives in all 50 states covered under several plans but managed by one PBM. That means we could expect about 2,738 epileptics. If we wanted to cross check the number based on the age characteristics of the group, we would expect about 2,937. And then not all of the epileptics would use Neurontin as part of their therapy. If the number is even as high as 50%, that would mean that we should expect about 1,400 users. We could further refine the process for sexes and geographic characteristics but all are in the same ballpark.

So how many Neurontin users are there in this population? 8500! It is interesting to note that this is right in line with the quoted off- label use-83% here vs 78% referenced in articles and court documents. Having identified inconsistencies, we would then have looked further to explain the experience. We did not because **we took for granted** that all users were epileptics and that treatment is evidence-based and appropriate. Had we not violated an important principle (Take nothing for granted) we should not have had to rely on the testimony from the court case now pending to determine that use was off by many multiples of what was reasonable. We believe that experience under any plan is a result of what many do or fail to do. By checking the experience, we can determine the factors driving it and whether the experience is reasonable given current plan provisions and the goal of appropriate care under a sustainable plan of benefits.

Medicaid got snookered too! Since epilepsy prevalence is not linear and is most prevalent in young children and in older seniors (the two groups who make up the largest numbers of covered lives under any Medicaid program), their reasonable estimate would be based on age bands– perhaps with some adjustment for economic variables. Then they too would have known that use was out of kilter and they should look further to explain the experience. They would not just now be trying to recoup inappropriately billed charges.

3. It's a big number and it matters. In 2000, Neurontin earned $1.3 billion. Media reports that as much as 78% of these sales were for non-FDA approved uses without evidence that the drug was safe and effective. *Drug Topics*, a magazine for pharmacists, and based on statistics from Scott-Levin, lists 2001 Neurontin sales in retail drugstores:

- $1,485,674,000(ranked 16th for $s)
- 13,261,000 scripts(ranked 31st for scripts)
- Average price per Rx of $112.

4. It's not just about money and whether it is wasted. It's about care appropriate for all, including Aunt Sophie.

Given the side effects of this product, use by some is likely to cause problems that may continue if not linked back to the drug. Those side effects may be attributed to other things including depression. The prevalence of both dizziness and drowsiness are significant. It would appear that it is this side effect that takes the edge off, that may cause it to have been promoted for these off-label uses like ADD, pain, and bipolar disorder. Yet for seniors, both of these side effects are more significant since they can lead to a slip and a fall with a resulting fracture.

While the labeling suggests that dosing should be carefully selected in seniors, the maximum dose edit in pharmacy benefit manager (PBM) systems are set at what we refer to "as kill a horse" levels-3600 mg per day. Anything less than this and no edit is triggered even if the member is age 80. Further there is no distinction between dosing appropriate for epilepsy or postherpetic neuralgia. Why? Because the PBM does not routinely know the diagnosis. And even if they did also have the medical claims with its codes, the PBMs have not refined their systems to make smart edits that go beyond the general rules. Nor have they demanded that the vendors from whom they buy their basic screening modules, do it differently. Nor is there any edit for an initial script where the starting dose is at maintenance level rather than at the recommended starting dose. It would be reasonable to assume that many of these edits are built in as system safeguards. They are not and because they are not, Aunt Sophie may get more than she should.

Applying our 5 priorities to Neurontin

Here is how the Neurontin example applies to each of the 5 important priorities we previously submitted.

1. ***Plan for an electronic infrastructure***: An electronic infrastructure provides many tools for checking for appropriate and safe use of medications. Using a smart systems' approach, here are some ways to identify appropriate use of Neurontin that should be covered as an expense under a plan:

- Identify all patients taking the drug who are on other epilepsy (Neurontin is recommended as add -on treatment) or herpes drugs. Those scripts could process without further inquiry - whether done by the system or involving physician outreach. For other scripts, establish procedures to ask questions about its intended use.
- If you planned ahead and required the diagnosis on the script (**Dx on Rx**) check the diagnosis against one or two tables input in the claims adjudication software. One table could contain only the FDA approved uses. Another could contain uses that might be approved by various groups as appropriate treatment. For example, if you accepted *Facts and Comparisons* as a source for generally accepted off-label uses, your table for acceptable off label use would contain the following:
  - tremors associated with multiple sclerosis
  - neuropathic pain
  - bipolar disorder
  - migraine prophylaxis.
- Identify the patient's age and determine if the dose is within guidelines. This might require multiple dosing tables for different conditions and for other circumstances-with age being the

most prevalent. Effectively the smart system would have a 3 dimensional array of tables containing dosing information and the patient's characteristics would pick the appropriate one.

- Periodically review the drug data against other significant medical events. For example, look at the Part A data for frequency of slips and falls with a resulting broken bone. We suspect you would find more than you expect. Why? Because the dose may be too high for seniors and the side effect profile, much like sleeping pills, is such that it contributes to the fall and the resulting broken bone.
- Identify the prescriber as an individual licensed to write scripts in the U.S. If not licensed, the claim is denied.
- Identify the *sig* and correlate the quantity dispensed for a specific duration of time (say 30 days) to the number of pills being dispensed. Further check this against the drugs dosing recommendations to determine if it is reasonable. For example, if 30 pills are being requested for 30 days of treatment, yet dosing guidelines are for multiple pills a day, there is a disconnect. Too much product is just as much an issue as too little. Yet this is a simple edit, made possible by the *sig* if the goal is appropriate care. Further if the ultimate sharing of costs between beneficiaries and CMS is a flat dollar copay design instead of a percentage coinsurance, this is an important edit to preclude stockpiling and other fraud.

The list goes on. The important point is that if the system planned for an electronic infrastructure, it could provide a diagnosis code, *sig* code and other important data that could be used to screen for appropriate use, inappropriate off-label use, etc. Systems/programs (coverage review, denial/appeal process, etc.) could then be designed to determine when and under what circumstances coverage of a drug is acceptable in a Federally sponsored program when that drug has not been sanctioned by the FDA as safe and effective for that use. The end result is data connected in an on-line, real time system, creates improvements in care.

A second important point is that drug choices are expanding (with both new chemical compounds and DNA derivatives) at a time when there is significant time pressure on physicians. Many physicians are not able to stay current with these rapid changes. The electronic infrastructure supports them in getting the information they need to make the best choice for each of their patients.

2. *Look at the service or supply you cover – you should set the rules:* The FDA is the primary resource for determining coverage criteria in terms of approved uses and dosage. Off-label use may be appropriate when endorsed by sub-specialties or a broad or common consensus. One example is DESI drugs. They are still currently used by many and should be considered as covered drugs under a federally sponsored plan, even though they may not have been approved by the FDA.

Off-label use should only be covered when there is sufficient evidence to indicate that it is effective. And the evidence should be such that those who are tied to the pharmaceutical manufacturers do not unduly influence it. In the Neurontin case currently pending, allegedly the drug manufacturer illegally and falsely represented the drug's benefits to doctors and patients who then use it so that it becomes an accepted off-label use. The current evidence for off-label use for Neurontin does not pass the sniff test.

CMS should set the rules for coverage. Those rules should also address the strength, step dosing and administrative rules for routine follow-up. For example, Neurontin is recommended to start at a low dose and then be titrated up. These rules can all be easily built into the electronic infrastructure that adjudicates claims. The design of a Medicare-sponsored drug program can make it happen. Alternatively, Medicaid can set requirements for PMBs who process their claims.

In setting rules you can look to the literature to determine where value is delivered and for which subsets of the population it becomes a covered product. The litmus test is that it is appropriate, treats the illness or injury, evidence-based, in accordance with generally accepted guidelines, least costly effective therapy, etc. These become the general coverage criteria used to guide all future decisions about coverage rules in specific circumstances. The point is that Neurontin - as an example of any product - is not always covered or always excluded. The rules will determine that. But you should set the rules that are administered by any PBM. This also ensures that coverage will be the same based on similar facts and circumstances and the rule you establish rather than the vagaries of one administrator who may administer your program in a specific geographic area.

3. ***Develop your own formulary. Close it. And develop rules that allow appropriate expansions of coverage in individual circumstances:*** A thorough review by a national P&T committee set up for this purpose would be necessary to determine whether Neurontin would be on a formulary for a senior population. Currently the drug is being used off-label as a chemical restraint in nursing homes. While with proper dosing and monitoring this may be beneficial to a select population, there have been reports of egregious abuse of this drug in nursing homes. One case alleges that high dose (off-label) usage contributed to lethargy, loss of appetite and dehydration, which lead to immobility, bedsores, and eventually amputation of both legs.

Neurontin also has significant side effects that can lead to serious complications for seniors. See the attached *Neurontin – facts and experience* for more information on side effects. It's likely that inclusion of Neurontin on a formulary for seniors would be limited to a select population, low dosages and require proper monitoring-including creatinine levels. Currently many PBMs set a single *kill a horse dose* for Neurontin that applies for all uses and for all groups, including the elderly. An edit is not triggered unless this maximum dosage is exceeded. Dosing edits need to be customized so that each individual gets the right amount. The system knows lots about covered individuals. That information can be used in improved systems of care that make it appropriate for Aunt Sophie.

Purepac Pharmaceuticals, a subsidiary of Alphapharm, is in approvable status to manufacture a generic. Once the generic is available, you need to decide whether Neurontin™ would then continue to be covered or whether it would be considered non-formulary and then either excluded (if a closed formulary as we suggest) or subject to a different copayment structure. If it continued to be on formulary, would it affect the price the covered individual would pay if they chose the brand over the generic. You might conclude that even in a closed formulary when the drug is used currently by a Medicare beneficiary to treat epilepsy or another seizure disorder that you judge as appropriate, you would cover the brand for existing patients. All new patients would however start on the generic. Price is an issue because it contributes to the sustainability of the program. But appropriateness is the overriding issue.

Drug development and sales is a business, and the product pipeline is important. The pipeline includes both new innovative products with lifesaving benefits as well as marginally different products with few, if any benefits. These new drugs are sold with highly-effective marketing to physicians and users. Most often these new products are brought to market just in time to precede loss of exclusivity for a marginally different drug. Pfizer has been working on pregabalin, the replacement for Neurontin (gabapentin). In 2000 press releases, Pfizer anticipated filing in 2001 in the US for 7 major indications. Some are for the 10 off-label uses of Neurontin. Clinical trials are also under way for today's big money making "illnesses" – generalized or social anxiety disorders. According to Pfizer's September 6, 2002 press release, pregabalin will now not be submitted to both the FDA and European regulators until 2003. CMS's coverage decision about the new drug when available, should be made in light of the then existing brand Neurontin and its generic gabapentin. Cost is one issue, since there is no money to waste. But equally important is the rules under which each product becomes the covered preferred agent.

4. ***Use generics whenever you can and make them the cornerstone of drug classes wherever you can.*** Currently this priority doesn't directly impact the Neurontin example. The patent is due to expire in 2003. However our guess is that now that it is a blockbuster drug (number 16 on the top 200 brand-name drugs by retail sales in 2001 with total retail sales exceeding 1.4 billion dollars), Pfizer will employ the usual drug manufacturer machinations to extend the patent and delay the generic. A 30-month extension could get them beyond an anticipated approval date for pregabalin, the presumed pipeline replacement drug. But when in consort with priorities 2 and 3 you could determine that gabapentin is the preferred drug, with both the brands (Neurontin and the to be determined trademarked name for pregabalin) generally not covered. You could also set a HCFA (when will the name change to CMS MAC?) MAC sooner rather than later, so that you benefit from a competitive price even though there may be only one generic manufacturer.

Coverage exceptions could be made where evidence exists that either brands are the preferred agent for subsets of the population. In all cases, system-edits should be put in place in the electronic infrastructure (priority 1) to check for a dose appropriate for Cousins Jim and Bruce or Aunt Sophie.

5. ***Be creative, flexible and take nothing for granted.*** The healthcare system is dynamic and the rules are constantly changing. As drug companies change the rules, health plans must be prepared to identify the behind the scene moves and refine the plan to adapt. As claims for Neurontin rose well beyond the incidence of epilepsy, alarms should have gone off and set in motion a review procedure and actions to adapt to the change. We got snookered and failed to identify the significant off label use that should have been subject to further scrutiny.

Neurontin is a perfect example of *take nothing for granted* and the consequences of not adhering to this principle.

- Do not take for granted that you know what it is used for, and that its uses will be appropriate for any one individual.
- Do not assume that the off-label use has been or should have been approved by a physician specialty group as acceptable therapy.

- Do not assume that dosing will be checked in any PBM system so that someone is checking for excessive dosing for seniors.
- Do not take for granted that any PBM system will check dosing for children even though the label contains specific recommendations.

Closing Comments

While drugs provide safe and effective treatment options that improve well being for those in specific circumstances, they are not necessarily safe and effective for any one individual. Drug manufacturers are doing what any business should do. They develop a product and market it as well as they can to generate sales. Financiers- whether it is Medicare, Medicaid, an insured health plan or a self- insured employer or union ERISA plan- need to decide when the product meets its coverage rules. Doing that effectively is the challenge. But it can be done in a way that supports physicians in the care they deliver to their patients. And failure to do it dooms any drug benefit – even one sponsored by Medicare. Besides seniors deserve better.

A post script about capture and use of patient data

The Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations are causing both head scratching and some steps backward in the managed pharmacy area. PBMs and retail pharmacies are at odds about what data they can and should capture as part of the electronic claim submission in light of HIPAA. Some are posturing under the guise of outright prohibition of even the most basic data. It may however represent a desire to spend less time on entering data. But data specific to the individual is necessary not only to determine if the drug for Aunt Sophie is an eligible claim under the health plan, but also to determine if it is safe and appropriate. We presume that clarification is needed since it was never your intent to force coverage of ineligible charges (an ERISA violation) or to process claims that may do harm. We assume that the Institute of Medicine's (IOM) ideas as outlined in its reports (To Err is Human and Crossing the Quality Chasm) will proceed unimpeded by HIPAA. Their thrust, like ours, is for data-driven systems, supporting physicians, to improve quality of care.

Neurontin (gabapentin)

How it works	FDA approved uses	FDA recommended dosing/PDR
• How it works in unknown – either to manage nerve pain after herpes or as a supplemental epilepsy treatment • Not metabolized by the body therefore it is not likely to have a negative effect on the liver • Excreted unchanged by kidneys	• Epilepsy as an add on therapy to other epilepsy drugs * * * • Pain after herpes (postherpetic neuralgia)[1]	• Epilepsy - Pediatric patients (3-12 years): 10-15 mg/day in 3 divided doses. Maximum interval time between doses should not exceed 12 hours - Adult patients (>12): 900 – 1800 mg /day given in divided doses (3x a day) using 300 or 400 mg capsules or 600 or 800 mg tablets. Starting dose is 300 mg 3x/day • Postherpetic neuralgia - 300 mg on day 1 – single - 600 mg on day 2 – divided in 2 doses - 900 mg on day 3 – divided in 3 doses - Can be increased as needed for pain relief to a daily dose of 1800 mg • Neurontin is given orally with or without food

Some FDA precautions (see attachment for full FDA labeling insert)

- Due to decreased kidney function, take care in dose selection for the elderly. Creatinine clearance values should be routinely checked
- Neurontin may cause dizziness, somnolence and other symptoms and signs of CNS depression. Accordingly patients should be advised not to drive a car or operate other complex machinery until they have gained sufficient experience on Neurontin to gauge whether or not it affects their mental and/or motor performance adversely
- Should be used in pregnancy *only if* the potential benefit justifies the risk to the fetus
- Should be used in nursing mothers *only if* the benefits clearly outweigh the risks

Notes:

[1]From www.pfizer.com, under *Health, Medicines & Lifestyles*, and then under US Prescribing Information, its posted labeling for Neurontin also lists this condition. Note: this has not yet been listed in the Physicians Desk Reference (PDR) or on the Food and Drug Administrations website (www.FDA.gov) because it has just been approved for this use.

Neurontin – facts and experience

<table>
<tr><th>Facts</th><th colspan="5">Experience</th></tr>
<tr><td>Clinical trials comparing Neurontin to a placebo showed a reduction in participants level of pain resulting from herpes</td><td colspan="5">• Using a scale of 0 (no pain) to 10 (worst possible pain) when the dose was increased, the approximate pain scores were:
- Placebo 6
- Neurontin 4
• Additionally between 29% and 34% (depending on the study) of individuals reported a 50% or more reduction</td></tr>
<tr><td rowspan="13">There are significant side effects in adults.</td><td rowspan="2">Side Effect</td><td colspan="2">Post herpes pain (from Pfizer website)</td><td colspan="2">Epilepsy (from FDA labeling)</td></tr>
<tr><td>Neurontin</td><td>Placebo</td><td>Neurontin</td><td>Placebo</td></tr>
<tr><td>Ataxia (involuntary muscle movement)</td><td>3.3%</td><td>0%</td><td>12.5%</td><td>5.6%</td></tr>
<tr><td>Abnormal gait or coordination</td><td>1.5%</td><td>0%</td><td>1.1%</td><td>.3%</td></tr>
<tr><td>Constipation</td><td>3.9%</td><td>1.8%</td><td>1.5%</td><td>.85</td></tr>
<tr><td>Diarrhea</td><td>5.7%</td><td>3.1%</td><td>---</td><td>---</td></tr>
<tr><td>Dizziness</td><td>28.0%</td><td>7.5%</td><td>17.1%</td><td>6.9%</td></tr>
<tr><td>Drowsiness</td><td>21.4%</td><td>5.3%</td><td>19.3%</td><td>8.7%</td></tr>
<tr><td>Dry mouth</td><td>4.8%</td><td>1.3%</td><td>1.7%</td><td>.5%</td></tr>
<tr><td>Fatigue</td><td>---</td><td>---</td><td>11.0%</td><td>5.0%</td></tr>
<tr><td>Nystagmus (rapid involuntary eye movement normally associated with dizziness)</td><td>---</td><td>---</td><td>8.3%</td><td>4.0%</td></tr>
<tr><td>Peripheral edema (fluid buildup under the skin)</td><td>8.3%</td><td>2.2%</td><td>1.7%</td><td>.5%</td></tr>
<tr><td>Tremor</td><td>---</td><td>---</td><td>6.8%</td><td>3.2%</td></tr>
<tr><td colspan="5">In the adult population, during clinical trials (but without measurement against a placebo), the following side effects were mentioned by patients and were characterized by the clinical investigators as frequent:
- Malaise - Bruising related to physical trauma - Hypertension
- Vertigo - Anxiety - Pneumonia - Abnormal vision</td></tr>
</table>

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Associates & Wilson

Neurontin – facts and experience

<table>
<tr><th>Facts</th><th colspan="3">Experience</th></tr>
<tr><td rowspan="6">When used in children, there are also significant side effects. Other than drowsiness they are different than the effects on adults</td><td colspan="3">Where Neurontin was used in clinical trials as in-addition-to therapy to treat epilepsy, in children 3-12 significant events include:</td></tr>
<tr><td>Side effects</td><td>Neurontin</td><td>Placebo</td></tr>
<tr><td>Viral infection</td><td>10.9%</td><td>3.2%</td></tr>
<tr><td>Fever</td><td>10.1%</td><td>3.1%</td></tr>
<tr><td>Drowsiness</td><td>8.4%</td><td>4.7%</td></tr>
<tr><td>Bronchitis</td><td>3.4%</td><td>.8%</td></tr>
<tr><td rowspan="4">Some side effects (like dizziness and drowsiness) are more of a problem with seniors because they are leading causes of falls. Fall are then a leading cause of fractures which in turn, significantly increase the rates of death.

Additionally, drowsiness may lead to inactivity which presents a whole host of different problems for seniors (loss of muscle, bedsores, etc.)</td><td rowspan="2">Trials</td><td colspan="2">Difference between Neurontin and Placebo</td></tr>
<tr><td>Dizziness</td><td>Drowsiness</td></tr>
<tr><td>Post herpes pain study (from Pfizer website)</td><td>20.5%</td><td>16.1%</td></tr>
<tr><td>Epilepsy (from FDA approved labeling)</td><td>10.2%</td><td>10.6%</td></tr>
<tr><td>For adults whose kidneys are not functioning normally, extra care should be taken with Neurontin because the drug may be in their body longer than for individuals with fully functional kidneys

Neurontin is not metabolized by the body. Rather it passes through the body and is eliminated through urination</td><td colspan="3">A drugs half-life is the period of time that half of the product is in your body. For adults with kidney problems, Neurontin’s half-life increases from a mean of about 6.5 hours to 52 hours. With continuous dosing, the drug builds up in the system.</td></tr>
</table>

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Neurontin – facts and experience

Facts	Experience
Actions by representatives of Warner Lambert (the drug company who developed the drug) and its new owner (Pfizer) are now the subject of litigation for illegally marketing the uses of the drug to physicians. 11 non-FDA approved uses have been cited in newspapers and court documents	The uses being promoted by the drug company but for which there is not FDA approved use indication include: • Bipolar disorder • Pain syndrome peripheral diabetic neuropathy • Stand alone treatment for epilepsy (FDA approved use of Neurontin in addition to other primary epilepsy drugs) • Reflex sympathetic dystrophy – pain or tenderness following a traumatic injury to an arm or leg • Attention Deficit Disorder • Restless leg syndrome • Trigeminal neuralgia • Essential tremor periodic limb movement • Migraine • Drug and alcohol withdraw Severe pain following herpes virus infection was cited in the court case as inappropriately promoted but a FDA indication has just been granted. New studies (and therefore not listed in the court cases) are now appearing to sing the praises of Neurontin as a treatment for hot flashes. This is a lucrative market because of concerns raised about Premarin.

Sources:

- www.pfizer.com under US Prescribing Information for Neurontin
- www.fda.gov and Physician Desk Reference labeling for Neurontin
- New York Times articles on March 14, May 15 and October 29, 2002
- Worst Pills, Best Pills News, May and September 2002, a publication of The Public Citizens Group
- John McMahon et al vs. Guardian Post-acute Services, Contra Costa Superior Court, #MSC01-00471

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CMS-4068-P-1226

Submitter : Mr. Chuck Bell **Date & Time:** 10/04/2004 08:10:00

Organization : Vital Care, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Pls see attached comments

CMS-4068-P-1226-Attach-1.doc

Submitter : Ms. Margaret Thomas **Date & Time:** 10/04/2004 08:10:07

Organization : Horizon HealthCare Services

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-4068-P-1227-Attach-1.doc

Horizon Healthcare Services is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Horizon Healthcare services the home infusion needs of thousands of patients in south central Pennsylvania every year including many Medicare recipients. Founded in 1984, our highly trained healthcare professionals have the experience and skills necessary to create positive clinical outcomes for the patients we serve while at the same time conserving scarce healthcare dollars by treating patients at home and avoiding costly hospitalizations.

Horizon Healthcare Services appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

* Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm <http://www.nhianet.org/perdiemfinal.htm> .

* CMS should establish specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require specific standards for home infusion pharmacies under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the X12N 837 P billing format for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should mandate that prescription drug plans maintain open formularies for infusion drugs to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Margaret F. Thomas RN

Intake Coordinator

Horizon Healthcare Services
2106 Harrisburg Pike, Suite 101
Lancaster, PA 17601

CMS-4068-P-1228

Submitter : **Date & Time:** **10/04/2004 08:10:19**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I support increased utilization of generic prescriptions, when available. I would also like to see a "universal" card for Medicare (drug benefits) recipients. With this universal card, the customer could go to any pharmacy and receive the same benefit. Give pharmacist "Provider" status, so that when performing DURs (drug utilization review) of patients prescriptions, the pharmacist will have some real power to act on duplicate therapy and make therapy changes, instead of just making or noting meaningless comments in the patient's profiles.

Many other health care professionals have been given provider status, and I feel that pharmacist should also be given this same status because the pharmacist is the one "Provider" that a patient has easy access to w/r/t other healthcare professionals (i.e physician, nurse, etc.) and pharmacists receive numerous calls/questions from patients on a daily basis..much more so than many other "providers".

CMS-4068-P-1229

Submitter : Dr. Mark Riley **Date & Time:** 10/04/2004 08:10:15

Organization : Arkansas Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment from the Arkansas Pharmacists Association.

CMS-4068-P-1229-Attach-1.doc

Arkansas Pharmacists Association

417 South Victory • Little Rock, Arkansas 72201 • (501) 372-5250 • Fax (501) 372-0546

Mark S. Riley, Pharm.D.
Executive Vice President

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Sir or Madam:

I am writing today on behalf of the Arkansas Pharmacists Association concerning the proposed rules for Medicare Part B. I have several serious concerns about the rules as currently written.

Any Willing Provider/Access to Community Pharmacies

While the bill includes "any willing provider" language to explicitly address Congress' intent for access, the proposed rules pose problems in accomplishing this intent. TriCare Access standards will be circumvented if PDPs and MA-PDs are allowed to "average" the standards across a region. Many Medicare beneficiaries will have unequal access in all three designated areas: urban, suburban, and rural. By averaging the standard, Congress' intent for access is by-passed.

TriCare Access standards and any willing provider intent will also be avoided if plans are allowed to create "preferred" and "non-preferred" networks. Spreading the total savings across the whole network can maximize plan savings. PDPs and MA-PDs will attempt to meet TriCare Access standards with the network as a whole yet proceed to build a "preferred" network that may not meet those standards at all. Medicare beneficiaries in rural areas would be severely limited in their ability to receive the greatest possible savings.

In determining travel distances involved in meeting TriCare Access standards, "commercially traveled routes" should be applied, not the shortest distance between two points.

Level Playing Field for Mail Order Pharmacies and Community Pharmacies

Based on the medication received, rebates from drug manufacturers should be applied and passed on to the Medicare beneficiary equally in both mail-order and community pharmacy. In no case should the mail-order pharmacy employed by the plan be allowed to reallocate rebates received based on community pharmacy prescriptions in a way that would make the mail-order pharmacy seem less expensive. Many PDPs will be pharmacy benefit managers (PBMs), which own their own mail-order houses and will have a vested interest in routing prescriptions to them. Also, PBMs will employ numerous "games" to make discounts appear larger than they really are.

Conflict of Interest in the Use of Mail-Order Pharmacies

Plan sponsors who own mail-order houses SHOULD NOT be allowed to use their own mail-order pharmacies. This practice causes sponsors to attempt to unfairly disadvantage community pharmacies in order to move the prescriptions to their mail-order pharmacies (i.e. self-dealing).

Medication Therapy Management (MTM)

A minimum standard should be defined in the rules so that any Medicare beneficiary can be assured of the same care in the implementation of these services.

Minimum eligibility standards for MTM should be established (i.e. the number of medications and chronic conditions diagnosed for the patient). Without these minimum standards, eligibility could vary greatly between regions.

Payment for these services should be defined so that payment levels are not so low that pharmacies would not be able to afford to supply them. Lack of definition would force patients to receive their MTM services by telephone or some other method inferior to face-to-face care. Again, face-to-face care seemed to be the intent of Congress.

I thank you for allowing comment on these regulations and for your careful consideration of my concerns. Medicare beneficiaries should be allowed freedom of choice for their pharmacy providers. Survey after survey supports that senior patients want and expect that freedom.

Sincerely,

Mark S. Riley, Pharm.D.
Executive Vice President

CMS-4068-P-1230

Submitter : Mr. David Rogers **Date & Time:** 10/04/2004 08:10:18

Organization : Idaho Department of Health and Welfare

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

attached are our comments related to this proposed regulation.

CMS-4068-P-1230-Attach-1.doc

October 4, 2004

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid
Department of Health and Human Services
Attention CMS-4068-P
P.O. Box 8041
Baltimore, MD 21244-8014

Re: Medicare Prescription Drug Benefit – Comments to Proposed Rules

Dear Dr. McClellan:

The State of Idaho, Department of Health and Welfare respectfully submits the following comments regarding the proposed Medicare Prescription Drug Benefit Regulations, published in the Federal Register on August 3, 2004. Idaho recognizes CMS efforts to bring prescription coverage to our Medicare population and appreciates the opportunity to comment on these proposed regulations. Idaho's overriding concern is that the proposed regulations have the potential to increase administrative and financial burdens on the State.

Phase-Down Provision:

1. Section 423.910 (d) requires the States to submit an electronic file to CMS identifying each full benefit dual eligible enrolled in the State for each month with Part D coverage that is also determined to be full benefit eligible by the State for full Medicaid benefit.

   Issues related to this section:

   A. The process for submission has yet to be identified. The submission process is identified in the proposed rule as "a manner specified by the Secretary". Without knowing the manner or process that will be used the States cannot estimate what if any additional costs are going to be associated with this requirement and cannot determine how and when they can comply with this

requirement. The process needs to be identified and communicated as soon as possible so that States can meet the implementation timeline and identify new costs associated with this new process.

B. MSIS data is being used to establish the baseline however this process that will be identified by the Secretary will presumably not be from the MSIS reports. There is concern that once operational, the data used to determine phase down payments will not be consistent with the data used to develop the baseline.
C. In the preamble to the proposed rule it is estimated that this new process will place an additional burden on the States which is estimated to be 100 hours per State for start up and an ongoing burden of 122 hours per State per year. Since the manner/process is yet to be defined the actual burden on the States is really unknown. In fact Idaho has spent this amount of time preparing the baseline data – which has yet to be completed. This estimation appears to be exceedingly low.

2. Section 423.902 of the proposed rule states that the growth factor will be based on the most recent National Health Expenditure (NHE) projections for the years involved.

   Issues related to this section:
   A. The overall NHE projections do not reflect the inflation rate experience by Idaho or any specific Medicaid agencies.
   B. Using a national number, even if specific to Medicaid programs, is insensitive to the growth rates that have actually been experienced in each State. In affect, States that have made little or no effort to control the rate of growth of drug costs will be rewarded while States that have worked diligently to control drug costs will be punished.

      Using the Calculation of Phase-down Monthly Contribution for 2006 as described in the proposed regulations, best available data and the cumulative growth factor that we have experienced over the past 3 years we would estimate a monthly payment in 2006 of about $720,000. Each additional percent increase/year above our actual inflation experience represents an additional cost to Idaho of over $21,000 per month. For example, and estimated 11% inflation rate would cost Idaho an additional $65,416 per month or a total of $785,000 for calendar 2006.

3. Section 423 of the proposed rule states that 2003 calendar year is the base year upon which the monthly phase down payments will be based. There will be no adjustments made once this base year calculation is determined.

   Issues related to this section:
   A. Having a complete list of included and excluded costs are paramount for the States to determine the correct baseline rates. Without an approved list of

included and excluded drugs, as just one example, there is no way to determine an accurate baseline.

B. Since drug costs have experienced wide swings over the past few years – using a single year as the baseline and not allowing for any adjustments does not appear to be a fair approach for the States. See comments related to the rebate adjustment factor.

4. Section 423.910 (f) states that the Secretary establishes the rebate adjustment factor using total drug expenditures made and drug rebates received during calendar year 2003 as reported on CMS 64 Medicaid expenditure reports for the four quarters of calendar year 2003 that were received by CMS on or before March 31, 2004.

   Issues with this section:

   A. The assumption is that all of the rebates received during calendar year 2003 and prior to March 31, 2004 are related to the drug expenditure in calendar year 2003. This is an erroneous assumption as rebates can and are collected well after the actual drug expenditure. Baseline year calculation will not be accurate.
   B. The assumption is that the amount of rebates that States receive as a percentage of drug expenditures is a static number. This again is an erroneous assumption as the amount of rebates received by our State has continued to increase. Idaho has experienced over a 2.2% increase in rebates as a percentage of total drug expenditure between CY 2002 and CY 2003. This is not atypical for Idaho as the cumulative increase is over 8% from 1998 through 2003. Each percent difference in the rebate adjustment factor represents additional costs to Idaho of approximately $118,000 for the first year of the phase-down contribution.
   C. The rebate adjustment factor is figured on the total drug expenditure for the State – not just the dual eligible population. This population traditionally has higher drug utilization and presumably would represent a higher percentage of the rebates that the State receives, comparatively speaking. We request that an adjustment be made so that the rebate adjustment factor is more representative of the population in question.

Eligibility/Enrollment

1. Section 423.772 discusses family size. It is unclear what degree of relationship to the applicant is required to include an individual in family size.

2. Section 423.782 refers to cost sharing subsidy. Are individuals eligible for Medicaid HCBS considered “institutionalized individuals” for purposes of no cost sharing? This is not clear in the proposed regulations.

3. In section 423.904 – should the reference to the notice requirements be to 423.34(c) instead of 423.34(d)? Reference appears to be in error.

4. Section 423.904 states that the State agency must make eligibility determinations and redeterminations for low-income premium and cost-sharing subsidies. Section 423.906(a) specifies that regular Federal matching applies to eligibility determinations and notification activities for this Federal program. The State believes that an enhanced federal match should accompany the State's activity that supports this Federal program.

5. Section 423.42 (d) of the proposed rules provides that PDPs may disenroll participants for various reasons. Additionally and individual who is disenrolled for failure to pay monthly PDP premiums, disruptive behavior, or misrepresentation of third party reimbursement will not be provided a Special Enrollment Period permitting him/her in another PDP. Idaho encourages a thoughtful review of this section of the rule for the following reasons:

    A. Because Medicaid can no longer receive federal financial participation for paying for prescription drugs, dual eligible individual beneficiaries who are involuntarily disenrolled would face a significant hardship.
    B. The proposed rule creates a significant opportunity for a very vulnerable population to be denied access to needed medications. Without needed medications the participants, in particular those with mental health issues, have the potential to become unstable and may end up utilizing additional public funds to deal with crisis situations, institutional care, or imprisonment.
    C. Disruptive behavior is not defined in the proposed regulation. Disruptive behavior that is related to the participant's underlying diagnosis should not be a reason for disenrollment. Language used in 42 CFR 438.56(b)(2) that refers to managed care arrangements would also be appropriate in this setting. Without the addition of more defining language too much latitude will be given to the PDPs and there will be the potential that participants will be denied the medications they require to stabilize their condition.

Auto Enrollment

Section 423.34(d) states that full benefit dual eligible individuals who fail to enroll in a PDP or MA-PD plan during their initial enrollment period or special enrollment period under section 423.36(c)(4) will be automatically enrolled. The initial enrollment period is identified as November 15, 2005 through May 15, 2006.

Issues related to this section:

1. The actual process for auto enrollment is not identified in these regulations. The relationship between Federal and State responsibilities is not identified. Process,

roles and responsibilities for the State and Federal government must be defined as soon as possible.

2. Because Medicaid can no longer receive federal financial participation for paying for prescription drugs that are included in Part D, full benefit dual eligible individuals must be enrolled in a PDP by January 1, 2006. This provides a more limited period of the time for these beneficiaries to select a PDP of their choice. This seems to be in some conflict with section 423.859 "Assuring access to a choice of coverage."
3. Only a 45 day window exists for selection of a PDP or auto enrollment and the process is yet to be defined. Given the large volume of enrollment activity, there is significant opportunity for a number of full benefit dual eligible individuals, a vulnerable population, to have not be enrolled for part D benefits. Most importantly lack of prescription coverage for this vulnerable population could have a negative impact on their health. This could result in higher utilization of more expensive resources at additional costs to both the Medicare and Medicaid programs.
4. Not only will full-benefit dual eligibles not qualify for part D benefits if not enrolled, but also federal matching funds would no longer be available to the states for prescription drug coverage under Medicaid. As a result, this can have a significant financial impact on the states. It is imperative that the auto-enrollment process for full-benefit dual eligible individuals by completed by December 31, 2005.

Formulary

Section 423.120 of the proposed regulations covers access to covered Part D drugs. PDP or MA organization formulary must include at least two Part D drugs within each therapeutic category and class of covered Part D drugs. The covered Part D drug list is not included in these regulations.

Issues related to this section:

1. There will not be a single formulary for covered Part D drugs; rather each PDP will have their own formulary that need only include at least two Part D drugs within each therapeutic class of covered Part D drugs.
    A. A single formulary required of all PDPs would be an enormous aide to the States that desire to develop a wrap around drug program for dual eligible individuals.
    B. This approach is insensitive to a significant population of full benefit dual eligibles who are on multiple medications.

2. Recent correspondence from CMS (letter to Medicaid administrator dated September 9, 2004) has proposed a drug list for covered Part D drugs to be used only for the development of the program's baseline. It is explicitly stated in this correspondence that this is not the list that is to be used when the program is operational.

A. To coordinate drug benefits and assure adequate care for the dual eligible population the States need to know what drugs will be included and excluded in Part D as soon as possible. The coordination of State and Federal benefits will require system development and coordination that will take a significant amount of time. This cannot begin until the States have the included and excluded drug lists.
B. It is unclear to the State how having one list of included drugs for the development of the baseline year and a different list of included drugs for the actual Part D program can result in accurate calculation of Phase Down payments.

The State of Idaho appreciates the opportunity to comment on the Medicare Part D program proposed regulations. We are concerned that the proposed regulations have a significant opportunity to reduce the current drug benefit that is being experienced by full benefit dual eligible participants through State Medicaid programs. The proposed regulations do not define processes that will be an integral part of the Medicare Part D program and without this definition the cost to the States cannot be projected. It is our concern that the additional burden placed on the States may result in increased costs to the States and, in some cases, decreased benefit to the Medicare dual eligible population.

Sincerely,

DAVID A. ROGERS
Administrator

DAR/PL/ksl

cc: Karl Kurtz

Submitter : Mrs. Tammy Higgins **Date & Time:** 10/04/2004 08:10:07

Organization : Horizon Healthcare

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attached

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
DEPARTMENT FOR REGULATIONS & DEVELOPMENT

Please note, the attachment to this document has not been attached for several reasons, such as:

1. Improper format,
2. Submitter did not follow through attaching the document properly,
3. The document was protected and would not allow for CMS to attach the attachment to the original message.

We are sorry that we cannot provide this attachment to you at this time electronically, but you can view them here at CMS by calling and scheduling an appointment at 1-800-743-3951.

CMS-4068-P-1232

Submitter : Kathryn Kuhn **Date & Time:** 10/04/2004 08:10:23

Organization : National Community Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

See Attachment

CMS-4068-P-1232-Attach-1.doc

National
COMMUNITY
PHARMACISTS
Association

Formerly NARD, the National Association of Retail Druggists

NCPA
205 Daingerfield Road
Alexandria, Virginia
22314-2885
phone
703.683.8200
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www.ncpanet.org

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Proposed Rule—Medicare Program; Medicare Prescription Drug Benefit (CMS-4068-P)

To Whom It May Concern:

On behalf of the National Community Pharmacists Association (NCPA), I would like to submit the following comments regarding CMS-4068-P.

We support the use of a facilitator (FAC) in the processing of TrOOP and COB claims. Without a FAC, the burden placed on PDPs and claims processors could be exponential due to the complex nature of these claims (i.e., from reversals, resubmissions, etc.).

While we favor the FAC model, we also have some concerns with respect to using a prominent switch company (e.g., NDCHealth or another single entity) as a FAC. Our concerns primarily revolve around the net effect on pricing and freedom of choice with regards to switch companies.

1) Pricing - Today, the majority of pharmacy transactions are single switch transactions (provider - payer - provider). A small percentage of transactions require multiple switches (e.g., COB). The FAC model inherently involves a multitude of multiple switches to various payers, thus theoretically increasing the cost associated with full processing of a claim. Our concern for pharmacy, in general, is the fees associated with these complex processes. One common concern in the industry with respect to the Medicare Drug Program is the decreasing margins at the pharmacy level. While this logic is debatable, adding a higher switching fee for these types of complex claims would only add more fuel to the fire and continue to further decrease pharmacy margins.

2) Switch Providers - The fact that NDC is eyeing the opportunity to serve as a FAC concerns us as well. NDC is well known in the industry as the leader in claims switching (however, competitors such as eRx and WebMD continue to gain ground in this area). Our concern with placing a prominent switch company in the role as a FAC is the potential for an unfair advantage in the switch marketplace. This could result in decreased competition and create an environment susceptible to price increases for general claims switching services. Provisions would need to be made to allow equal access to the FAC by all switching companies so that no one switch provider would be placed at an economic disadvantage. In addition, measures should be taken to prevent any switch company serving as a FAC from creating a monopolistic environment.

The National Community Pharmacists Association (NCPA) represents the nation's community pharmacists, including the owners of 24,000 pharmacies. The nation's independent pharmacies, independent pharmacy franchises, and independent chains represent a $78 billion marketplace, dispensing nearly half of the nation's retail prescription medicines.

Thank you for the opportunity to provide these comments. Please feel free to contact me if I can provide you with any further assistance concerning this issue.

Sincerely,

Kathryn F. Kuhn, R.Ph.
Senior Vice President, Pharmacy Programs

CMS-4068-P-1233

Submitter : Ms. Lisa M. Getson **Date & Time:** 10/04/2004 08:10:17

Organization : Apria Healthcare

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

Please refer to Apria Healthcare's formal comments on this subject as found in the attached Word file.

CMS-4068-P-1233-Attach-1.doc

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Re: Comments on CMS-4068-P
The Proposed Rule for the Medicare Prescription Drug Benefit

Dear Dr. McClellan:

On behalf of Apria Healthcare Inc., I am pleased to submit these comments regarding the proposed rule to implement the new Medicare Part D prescription drug benefit. Specifically, these comments pertain to the recent notice published in the *Federal Register* on August 3, 2004.[1]

Apria is a leading provider of integrated home care services and products. Apria offers a full range of home infusion drug therapy, as well as home medical equipment and home respiratory therapy. Through 30 wholly-owned, licensed and JCAHO-accredited infusion pharmacies, Apria serves adult and pediatric patients with a wide range of infectious diseases, nutritional disorders, cancer and chronic illnesses such as Lou Gehrig's Disease and multiple sclerosis. Aside from the thousands of people covered by private managed care organizations who benefit from Apria's home infusion services, the company also cares for a significant number of elderly patients throughout the United States who have complex medical problems and multiple co-morbidities who require home infusion therapy and are covered by Medicare Advantage (MA. formerly Medicare+Choice) plans.

These comments are divided into the following sections:

I. General
II. Dispensing Fees for Home Infusion Drug Therapy
III. Contracting with Home Infusion Drug Pharmacies
IV. Formulary Development

[1] Medicare Program; Medicare Prescription Drug Benefit; 69 *Fed. Reg.* 46632 (Aug. 3, 2004).

I. General

We wish to commend CMS for engaging in the research necessary to understand many of the unique characteristics of home infusion drug therapy. These findings are reflected in the preamble of the proposed rule, which summarizes the various services and functions that are required to provide home infusion drug therapy safely and effectively in the home care setting.

We applaud CMS for recognizing in the proposed rule the clinical and cost benefits of home infusion drug therapy, as well as the essential role this area of therapy plays in the private sector health system and under Medicare managed care programs. The proposed regulation describes an interpretation of the Part D benefit that would include the essential services, supplies and equipment that are integral to the provision of infusion drug therapy provided in the home (see discussion of "Dispensing Fee Option 3" below).

If Dispensing Fee Option 3 is adopted in the final regulation, as we recommend, then the Medicare fee-for-service program can offer coverage of home infusion drug therapy comparable to what private sector health plans and Medicare Advantage plans have offered for years. In doing so, Medicare would realize the significant system-wide savings that come from the provision of infusion drug therapy in the most cost-effective setting.

A. Home infusion drug therapy provides an opportunity for Medicare Part D to replicate the success achieved by private sector health plans and Medicare Advantage plans.

Currently, many of the infusion drug therapies used commonly in the private sector, such as antibiotic therapy used in the treatment of severe infections, are not covered under the Medicare Part B durable medical equipment (DME) benefit. Coverage under the DME benefit is based on the use of an item of DME – in this case, an infusion pump − and extends only to a few designated drugs, most of which are used in the treatment of cancer and intractable pain. As a result, Medicare beneficiaries who could have received infusion drug therapy at home have been forced into far more costly settings, such as acute care hospitals, hospital outpatient departments, hospital emergency rooms and long term care facilities.

In contrast to the limited coverage that exists under Medicare Part B, Medicare coverage of home infusion therapy has worked well under Part C with the Medicare Advantage plans. Many if not most Medicare Advantage plans provide coverage for a broad range of home infusion therapies and related services as a <u>medical</u> benefit. Examples include Aetna US Healthcare, Humana Health Plans, PacifiCare's Secure Horizons plans and Presbyterian Salud in New Mexico. Clearly, these plans would not provide this optional coverage unless they were convinced that coverage of home infusion therapy in the home setting is cost-effective.

For Medicare Advantage plans, home infusion has provided significant system-wide savings by enabling beneficiaries to receive infusion therapy without incurring hospital or nursing facility costs. Medicare Advantage plans cover the homecare pharmacy, nursing and other in-home services, supplies, equipment and same-day, in-home delivery/patient teaching necessary for the provision of home infusion therapy. The effectiveness of home infusion therapy under Part C, and the manner in which Medicare Advantage plans define and cover this therapy, can be a model for infusion coverage under Part D.

B. Specific requirements must be established by CMS to ensure that Medicare Part D makes use of home infusion drug therapy in the same fashion as private sector and Medicare Advantage plans.

Stand-alone Part D prescription drug plans (PDPs), in the absence of specific requirements or direction from CMS, will not embrace drug therapies such as home infusion drug therapy because the PDPs will be rewarded for contributing to system-wide savings on the drugs alone. As a result, the financial incentives that have driven private payer acceptance and use of home infusion drug therapy will not exist for stand-alone PDPs.

As a result, specific requirements and direction from CMS are necessary for the coverage of home infusion drugs to work properly. We urge CMS to ensure that the Final Rule contains provisions relating to home infusion drug therapy on the issues discussed in the remainder of these comments, including such issues as dispensing fees, pharmacy access, formulary provisions and the formatting of claims.

II. Dispensing Fees for Home Infusion Drug Therapy

A. CMS should adopt Dispensing Fee Option 3, which is the only proposed option that would adequately recognize the services and items that are necessary to provide home infusion drug therapy.

Congress' definition of prescription drugs under the statute clearly includes infusion drugs provided in the home, and the proposed rule likewise reinforces the fact that infusion drugs (other than the few drugs currently covered under Part B) are included in the Part D benefit.

However, for the coverage of home infusion drugs to be meaningful for Medicare beneficiaries, CMS also must cover the services, supplies and equipment related to the provision of these drugs. Limiting coverage to the drugs only without the services, supplies and equipment will not produce meaningful coverage of infusion drugs in outpatient settings. This is because infusion pharmacies will be unable to provide infusion drugs without adequate payment for the services, supplies and equipment.

The most appropriate mechanism for such coverage of infusion services, supplies and equipment provided under the proposed rule is the dispensing fee. In the preamble, CMS sets out three options for defining dispensing fees under the new benefit and invites comment on each.

- Option 3 comes closest to accurately recognizing the fundamental elements – including the services, supplies and equipment – that are essential for the provision of home infusion drug therapy. Option 3 is the only option that reflects the fundamental elements of home infusion drug therapy (see additional discussion in subsequent sections of these comments).

- In contrast, Option 1 only provides the perspective of retail pharmacies and does not meet the needs of Medicare beneficiaries requiring home infusion drug therapy.

- Although Option 2 captures the supplies and equipment used in the provision of home infusion drug therapy, this option falls far short of recognizing the essential professional services required to provide home infusion drug therapy because it does not recognize the professional services that are required to provide safe and effective infusion therapy in the home.

B. CMS should adopt Dispensing Fee Option 3 because it is consistent with the well-established standards of practice for home infusion drug therapy.

The major independent accreditation organizations, including the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), have established extensive, detailed standards regarding the patient management, support services, facilities, patient safety, policies, procedures and functions that must be provided by home infusion pharmacies. These standards, which address issues ranging from the requirements for sterile preparation of infusion drugs to the oversight of patient therapy, are significantly different from the standards governing traditional retail pharmacies.

Option 3 is the only dispensing fee option that adequately reflects the content of these national accreditation standards. For example, one major difference between retail pharmacies and home infusion pharmacies is the urgency surrounding the initial referral from a physician or hospital and the resulting home delivery/patient education requirements. Due to the severity of the patient's illness (such as a serious infection which has not responded to oral medications), pressures on hospitals to discharge patients as soon as possible, and stability/refrigeration requirements for many medications, home infusion pharmacy staff frequently have to deliver directly to patients' homes the same day as the referral. This is considerably more expensive than a retail pharmacy model where the patient or caregiver visits the pharmacy in person to pick up the drug. All of this must take place in conjunction with insurance verification, coordination with the nurse who will teach the patient, compounding by a home infusion pharmacist, and eventually, billing third party payors and collecting patient co-pays – all activities that are not applicable to the retail setting.

The well-established understanding of the professional services involved in providing in home infusion drug therapy is not merely an industry definition. Payers, clinicians, clinical societies, providers and accrediting organizations share a common understanding of what is involved in providing these therapies in outpatient settings.

C. CMS should adopt accreditation requirements under Dispensing Fee Option 3 as a straightforward means to protect Part D enrollees.

As the first homecare provider to seek and obtain JCAHO accreditation in the 1980s, Apria has a longstanding commitment to ensuring that the professional services and functions we provide meet a demanding set of quality standards. Apria recently completed its latest triennial survey cycle, with a successful outcome in all infusion pharmacies, respiratory and medical equipment locations. Our company has served as a pilot for innovative survey techniques developed by the JCAHO, and our management has formally served on advisory committees of the organization. Today, our quality standards meet or exceed JCAHO's requirements, which is a requirement of the over 2500 private sector managed care plans with which we contract to provide home infusion services.

In the final rule, CMS should address the qualifications of the infusion pharmacies that may provide the elements of care described under Dispensing Fee Option 3. We recommend that CMS require every pharmacy providing infusion services to be accredited as a home care pharmacy by a recognized national accrediting organization. We also recommend that every entity that provides nursing services to Part D infusion patients be either accredited as a nursing agency as an extension of their existing home infusion accreditation, or be a Medicare-certified home health agency.

Private sector plans require accreditation as a basic assurance that the pharmacists and nurses are experienced and the pharmacies are staffed properly to provide the necessary care. The quality standards required of home infusion pharmacies and nursing agencies by the accreditation organizations have become the community standard for the provision of home infusion therapy.

D. CMS should use a refined version of Dispensing Fee Option 3 to define the full scope of necessary professional infusion pharmacy services.

All infusion patients, whether or not they qualify for the home health benefit, require professional pharmacy services that again differ from those found in the retail setting. The general categories of such services are:

- Compounding medications in a sterile environment
- Dispensing
- Ongoing Clinical Monitoring
- Care Coordination with other agencies involved in patient care

- Provision of Supplies and Equipment
- Multiple Categories of Pharmacy Professional Services, such as pharmacokinetic drug monitoring or parenteral nutrition formula development
- Administrative Services
- In-home delivery, patient and caregiver education
- Third party billing
- Other Support Costs

These services are described in greater detail in a number of accreditation materials and other forums, including a document on the website of the National Home Infusion Association describing the "per diem" model.[2]

We propose a modification to Dispensing Fee Option 3 to more explicitly describe the pharmacy professional services that are needed for home drug infusion therapy. The pharmacy services referenced above in the model per diem definition (and generally described in Dispensing Fee Option 3) should be included in the dispensing fee for all Part D infusion patients. Most of these functions would be captured in the Option 3 definition of dispensing fees.

Both private payers and Medicare Advantage plans use per diem payments that are tied to the intensity level of the particular infusion therapy. For over 20 years, these plans have essentially developed resource-based relative value scales to capture the intensity, in terms of time and resources involved in providing each infusion therapy safely and effectively. Thus, the plans do not use a single per diem amount for all infusion therapies. We recommend that the PDPs follow this approach under Medicare Part D.

E. CMS can establish easily-administered safeguards to avoid any duplicate payments for nursing services

CMS raises a question in the proposed rule regarding how to ensure that the services captured in Dispensing Fee Option 3 are not reimbursed under the home health benefit or otherwise.

The potential area of concern involves the infusion patients who also qualify for the Medicare home health benefit. For this subset of infusion patients who also qualify for the home health benefit, it would be a simple matter to first determine whether a beneficiary qualifies for the home health benefit before reimbursing Part D funds for nursing services. The majority of beneficiaries who require infusion drug therapy do not qualify for the home health benefit, and their nursing services should be paid under the Part D benefit as part of the dispensing fee.

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[2] National Home Infusion Association. National Definition of Per Diem. June 2003. *Available at* www.nhianet.org/perdiemfinal.htm.

Importantly, the home health benefit does not cover any of the pharmacy services described in the preceding subsection of these comments.

By first identifying beneficiaries who qualify for the home health benefit, the nursing component, when medically necessary, should be reflected in the dispensing fee but only for beneficiaries who do not qualify under the home health benefit for nursing services. Importantly, nursing care is not included in the model per diem definition (discussed above) nor in the HCPCS "S" coding structure (discussed below) used by private payers.

Private payers typically separate out nursing from the pharmacy-related costs represented by the per diem. They share the Medicare program's natural concern about nursing costs, and these plans have concluded the best means of tracking and controlling nursing costs is to use a separate payment mechanism for nursing.

F. CMS can establish easily-administered safeguards to avoid duplicate payments under Medication Therapy Management Programs.

CMS asks for comments regarding how to ensure that the Medicare program avoids making duplicate payments if the PDPs pay for infusion-related dispensing fees as well as medication therapy management services.

Generally, the dispensing fee as defined in Dispensing Fee Option 3 will capture most of the services and functions described in our per diem model plus the nursing component, and there will not be a clear need for a separate payment to infusion pharmacies for additional medication therapy management services. We believe that the primary situation where medication therapy management services may be indicated is where an infusion pharmacy has to coordinate the activities of another pharmacy.

However, if CMS does not choose Dispensing Fee Option 3 for defining dispensing fees, then CMS should not consider the medication therapy management program as a substitute for covering the services, supplies and equipment required to provide infusion drug therapy. The limitations on the applicability of the medication therapy management program (*i.e.*, it is limited to patients with chronic conditions and multiple medications) make it a poor vehicle for capturing the clinical monitoring functions required of infusion pharmacies for all infusion patients.

III. Contracting with Home Infusion Pharmacies

A. CMS should establish separate and distinct requirements for PDPs to contract with sufficient numbers of home infusion pharmacies to ensure adequate enrollee access to home infusion drug therapy under Medicare Part D.

CMS should establish specific safeguards for home infusion pharmacies to ensure meaningful enrollee access to home infusion drug therapies. A number of important differences exist between home infusion pharmacies and traditional retail pharmacies that highlight the need to create separate requirements for the two types of pharmacies. For example–

- Home infusion pharmacies provide specific essential services that are not provided by the vast majority of retail pharmacies or mail order pharmacies.

- Home infusion pharmacies must maintain facilities, equipment and safeguards for compounding and storing sterile parenteral drug solutions, which is not common among retail pharmacies.

- Home infusion pharmacies are responsible for the care of their patients 24 hours a day, seven days a week, while retail pharmacies are not.

- Home infusion pharmacies are subject to separate state licensure, regulations and accreditation standards from retail pharmacies.

- The contracts used by private health plans for home infusion pharmacies are structured differently from the contracts used for retail pharmacies.

- The total number of traditional retail pharmacies in the United States far outweighs the total number of home infusion pharmacies.

These differences are echoed in the preamble of the proposed rule, where CMS discusses its findings regarding important distinctions between home infusion pharmacies and retail pharmacies.[3]

To ensure that Part D enrollees have sufficient access to home infusion drug therapy, CMS should adopt its proposal to establish distinct access standards for home infusion pharmacies in the Final Rule. This would be consistent with Congress' general mandate that CMS must ensure enrollees have convenient access to pharmacies, as access to a retail pharmacy does not by itself meet the needs of a beneficiary who requires infusion therapy.

B. CMS should require use of the ASC X12N 837 claims format for infusion drug therapy, consistent with CMS' recent determination, because infusion claims formats are different from retail pharmacy claims.

CMS' Office of HIPAA Standards has carefully reviewed how home infusion therapy is provided, and recently issued a Program Memorandum[4] and a Frequently Asked Question (FAQ)[5] document on the CMS website summarizing its conclusion.

[3] 69 *Federal Register* at 46648 and 46658.

For example, the FAQ document states:

> …Home infusion therapy typically has components of professional services and products that include ongoing clinical monitoring, care coordination, supplies and equipment, and the drugs and biologics administered – all provided by the home infusion therapy provider.

In a letter dated April 8, 2003, Jared Adair, director of the CMS Office of HIPAA Standards, wrote:

> …we have determined that home drug infusion therapy services are different from services provided by retail pharmacies, and that the business model for home drug infusion therapy providers is fundamentally different from a retail pharmacy for dispensing drugs…. We also acknowledge that a requirement to bill home infusion drugs using the NCPDP format would fail to meet the administrative, clinical, coordination of care, and medical necessity requirements for home drug infusion therapy claims." (emphasis added)

As a result, CMS determined that the National Council for Prescription Drugs Program (NCPDP) claim format, which is the HIPAA standard for the processing of retail pharmacy drug claims, is not appropriate for the filing of home infusion drug therapy claims. Instead, CMS instructed that home infusion claims, to be compliant with HIPAA, must be filed under the ASC X12N 837 claims format.

Please note that the description of infusion therapy as described in the FAQ tracks very closely with the language of Dispensing Option 3 in the proposed rule. We recommend that the specific wording already posted on CMS's FAQ be included as the infusion claiming requirement in Part D regulations. To do so will increase the level of administrative standardization in infusion claims transactions per the objectives of HIPAA, while also ensuring that home infusion providers and Part D payers comply with the HIPAA regulation when implementing Part D claiming transactions. If CMS does not require that Part D home infusion therapy claims be submitted on the 837, then it would open up the possibility for some Part D payers to ignore the fundamental differences of home infusion therapy from retail pharmacy and implement only NCPDP claiming—forcing infusion pharmacies to be out of compliance with HIPAA.

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[4] Centers for Medicare & Medicaid Services, Program Memorandum, Carriers, Transmittal B-03-024 (4/11/03), *available at* http://cms.hhs.gov/manuals/pm_trans/B03024.pdf.

[5] Centers for Medicare & Medicaid Services, Frequently Asked Questions (FAQs), "Are Drug Transactions Conducted by HIT Providers Retail Pharmacy Drug Claim Transactions Billed Using NCPDP Formats?" (Answer ID 1880) (3/31/03), *available at* http://questions.cms.hhs.gov.

This would deprive the PDPs and CMS of a valuable tool for tracking important patient-specific data. Consolidated 837 claiming would facilitate the consolidation of all drugs along with the professional pharmacy "per diem" services, equipment and supplies into single claims billed for infusion therapies, easily mapped into patient services utilization data bases for analysis—whereas the possibility of billing infusion drugs separately via the retail NCPDP claim format results in loss of this consolidated data for analysis.

C. CMS should recognize that infusion coding is different from retail pharmacy drug coding.

Since 2002 the Healthcare Common Procedure Coding System (HCPCS) provides approximately 80 "S" codes for home infusion therapy services. Most codes reflect a "bundled" per diem approach in which most or all of the supplies and services provided to a home infusion patient are billed under a single code. This complete system of "S" codes for home infusion therapy services is specifically designed for use by private payers, and are available for use by government payers that adopt this widely used private sector methodology for infusion coding and payment. These codes are not used in coding of retail pharmacy drug claims and are not permitted for HIPAA-compliant use on the NCPDP transaction).

Although CMS does not have a single HIPAA coding standard for drugs, we believe that the PDPs and CMS will find requiring NDC drug coding for Part D claims will provide best opportunity for patient utilization analysis and tracking of total Part D drug costs for CMS's program administration. We believe the Part D regulations should require that all claims for drugs be coded with NDC numbers.

D. Coordination of benefits.

In addition to these reasons for infusion claiming and coding consistency, the COB portion of the Part D program is also best implemented by CMS's establishing a requirement for 837 claiming and use of the established coding systems. The majority of COB will occur with commercial payers such as the Blues and other private health plans. As the private sector has already widely adopted the established coding systems described above, it will be important for CMS to require consistent coding adoption to make COB work, ensuring that the allocation of payment for services between Part D plans and other primary or secondary plans works well.

Since the private payer sector accepts home infusion therapy claims using the HIPAA-compliant X12 N 837 format, for COB to work effectively is another reason that CMS should require PDPs to use the 837 claim format for infusion claims. Because a very large majority of private infusion payers use the HIPAA-complaint *professional* 837 (837P) claim format, to make COB work we believe that CMS's Part D regulations should require PDPs to adopt the HIPAA-compliant 837P format only, excluding both the *institutional* 837 and NCPDP transaction from use.

E. CMS should clarify the any willing provider requirements with respect to home infusion drug therapy.

CMS should clarify that this access safeguard is to be applied to any willing provider of home infusion therapy meeting the infusion-specific quality standards (see below), as distinct from retail pharmacies. Such a requirement is consistent with the statutory language.[6]

In addition, for the purpose of the any willing provider requirements, CMS should clarify that prescription drug plans should have a standard contract for home infusion pharmacies.

These recommendations for the network access standards will help safeguard enrollee access by ensuring that the Medicare Part D benefit reflects common private sector practices for home infusion drug therapy. In addition, the recommended clarifications will not impose significant burdens on PDPs.

F. CMS should recognize that OBRA 1990 standards do not represent the standard of care for infusion pharmacies.

In the preamble, CMS refers to Section 54401 of the Omnibus Reconciliation Act of 1990, stating that the regulations issued pursuant to that section in 42 CFR 456.705 "describe currently accepted standards for contemporary pharmacy practice and our intent is to require plans to continue to comply with contemporary standards." CMS seeks comments on whether these standards are industry standards and whether they are appropriate for Part D.

The OBRA 1990 standards were written for retail pharmacies. The drafters of these standards did not attempt to address the standard of care for infusion pharmacies. Infusion pharmacies that are in compliance with the infusion-specific standards established by accrediting organizations meet the OBRA 1990 standards, but the OBRA 1990 standards do not reflect "contemporary pharmacy practice" for infusion pharmacies. The community standard of care for infusion pharmacies is found in the accreditation standards that are required by virtually every private health plan, as well as numerous MA plans, to participate in their provider networks.

The quality assurance standards followed by home infusion pharmacies—and as required for accreditation--far exceed the OBRA 1990 standards. Due to advances in newly-approved drugs and technology and additional laws and regulations established in the intervening years (such as HIPAA), and development of knowledge surrounding patient safety and medication management at home, the level of patient data collection, assessment and intervention in the infusion clinical model goes far above and beyond the quality standards currently used for Medicaid. Again we respectfully direct your attention to Jared Adair's April 8, 2003 comments concerning the key differences between retail and home infusion pharmacies.

[6] Social Security Act, Section 1860D-4(b)(1)(A).

IV. Formulary Development

A. CMS should mandate that PDP and MA-PD plan sponsors maintain an open formulary for infusion drugs to ensure this population of vulnerable patients has appropriate access to necessary medications.

Much of the MMA is based on the premise that Medicare can take advantage of cost-savings techniques commonly used in the private sector and still deliver quality services to Medicare beneficiaries. CMS should note that although private health plans commonly use restricted or preferred formularies for drugs delivered orally, via patch or other non-invasive methods, private plans rarely apply these formulary restrictions to infusion drugs.

As discussed in greater detail below, there are numerous clinical and operational barriers to establishing formularies for infusion drugs. As a result, with respect to infusion drugs, formularies should remain open.

B. CMS should recognize that PDPs and pharmacy and therapeutics committees are not well situated to evaluate infusion drugs.

It will be difficult for PDPs and traditional pharmacy and therapeutics committees (P&T committees) to evaluate infusion drugs in the same manner that they evaluate orally administered drugs.

P&T committees generally evaluate the relative safety, efficacy, and effectiveness of prescription drugs within a class of prescriptions drugs and make recommendations to a health plan for the development of a formulary or preferred drug list. Frequently, P&T committees focus on the "therapeutic equivalence" of different multisource drugs (*i.e.*, whether one drug will have the same desired clinical impact as another). However, such evaluations are performed in a context where the method of administering the drug is not significant.

In contrast to oral drugs, the method of administration for an infusion drug may have separate and significant clinical and cost implications. All infusion drugs require a device of some type to deliver the drug into the body, including various catheters temporarily or semi-permanently implanted in each patient depending on the anticipated duration of therapy, potential side effects of the drug and the patient's diagnosis itself. Various methods of drug delivery also exist, from IV bags hung on poles to sophisticated external or internal infusion pumps. A patient's clinical condition may determine not only what device is selected for delivery, but also what drug should be used. For instance, many patients receiving infusion therapy are at high risk of infection or complications from infection. Consequently, a physician may need to choose a medication that can be prepared in advance in a pharmacy clean room and administered once a day to reduce the risk of infection from preparation in the home or multiple intravenous access device manipulations.

Similarly, in selecting a medication for a patient, a physician often needs to consider administration access type and what delivery technology will be best suited for use in a particular patient's home. If the patient is capable of managing a portable infusion pump, drugs requiring longer infusion times may become more clinically appropriate. If other technologies are used, such as IV bags hung on poles, the patient may require more frequent nursing visits to monitor the risk of infection.

The typical P&T Committee would usually not have the experience to evaluate the administration technology or professional support requirements, such as nursing visits, in reviewing infusion drugs. Furthermore, such committees do not typically make decisions considering all available treatment options throughout the continuum. Drugs considered ideal in an inpatient setting are often not desirable in the home setting and visa versa, especially where the first dose of the drug is concerned. Examples include Taxol® for ovarian cancer, Lovenox® for deep vein thromboses and certain immune globulins.

In addition, most infusion drugs must be compounded by the pharmacy. Once compounded, these drugs lose stability over time or be impacted by changes in temperature. For oral drugs, the frequency of administration or stability issues usually do not pose challenges for a P&T Committees as they try to determine therapeutic equivalence.

Ultimately, the infrastructure for protecting patient interests in formulary decisions—the traditional P&T Committee—does not have the ability to evaluate the extra-pharmacological considerations that must be taken into account for infusion treatment, including the administration device, drug stability, proximity to a compounding pharmacy, available administration access site and infection risk. Typically, these factors would be addressed by a physician or pharmacist knowledgeable about an individual's patient's circumstances and history when selecting a drug and delivery device.

C. CMS should recognize home infusion patients as a particularly vulnerable population that requires additional protection.

Patients receiving home infusion therapy are one of the truly vulnerable populations of the Medicare population, and as CMS acknowledged in the Proposed Rule,[7] the medical needs of such populations necessitate that they receive special protection under Medicare Part D. Infusion drugs are used to treat some of the most severe illnesses, including cancer, severe infections, pain and loss of gastrointestinal integrity.

Although the Medicare Part D regulations do create an appeals process for patients if their physician's choice of medication is not on formulary, patients with these compromising illnesses are the least capable of exercising an appeals right. If a patient does not have a family member or physician willing to take on the burden of being an advocate, then the patient's care could be compromised.

[7] 69 Fed. Reg. at 46661.

* * * *

We commend CMS for its initial efforts to understand and accurately define home infusion drug therapy under Medicare Part D. There is an important opportunity for the program to replicate the successes achieved by private health plans and Medicare managed care plans. There is also a risk that in the absence of sufficient direction from CMS and some targeted safeguards, the benefits of home infusion drug therapy will be lost for both beneficiaries and the overall Medicare program.

We would be pleased to provide additional assistance regarding these important issues. Please contact Lisa Getson, Apria's executive vice president, at 949-639- 2021 if you have any questions or comments.

Sincerely,

Lawrence M. Higby
President and Chief Executive Officer

CC: Herb Kuhn
Leslie Norwalk

Submitter : Ms. Janet Schalansky **Date & Time:** 10/04/2004 08:10:44

Organization : Dept. Of Social and Rehabilitation Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-4068-P-1234-Attach-1.pdf

K A N S A S

JANET SCHALANSKY, SECRETARY

SOCIAL AND REHABILITATION SERVICES

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Dear Sir or Madam:

The Kansas Department of Social and Rehabilitation Services respectfully submits the following comments regarding the proposed rule on the Medicare Prescription Drug Benefit published Tuesday, August 3, 2004. Comments are grouped under section identifiers as requested in the proposed rule.

One general comment needs to be made. Because of the statutory and regulatory requirements regarding states' responsibilities in implementing and administering activities related to Part D, it is absolutely critical that access to federal data be provided in a timely and thorough manner. Specifically Kansas requests access to online real time entitlement and enrollment information for not only Part D and subsidy eligibility but also Part A and B. This should occur through access to the Common Working File.

Subpart B - Eligibility & Enrollment

Section 423.34 - <u>Enrollment Process</u>

Because of the level of information required for the auto enrollment process and the resources needed to carry it out, the State would recommend that the Centers for Medicare & Medicaid Services (CMS) take the lead for this process. Information will need to be obtained in order to better guarantee that the person is enrolled in an appropriate plan taking into consideration their living arrangement, specific drug needs, and available participating pharmacies. CMS is in the best position to accomplish this task with information provided from the states and SSA.

Section 423.36 - <u>Initial Enrollment Period</u>

The State is concerned regarding the impact of the initial enrollment period for persons who are fully dually eligible at the time of this enrollment process. Per section 423.906, a person who is eligible for Part D and also is a full benefit dual eligible, medical assistance under Medicaid is not available for drugs that could be covered under Part D. It appears that in order to protect drug coverage from lapsing as of January 1, 2006 for current Medicaid eligibles, the individual would need to enroll by the

end of December 2005. If this is correct, the period of time to accomplish such enrollment (November 15 through December 31) is not sufficient for the number of beneficiaries who will be impacted. The State strongly recommends that an additional period of 90 days or more following January 1 be provided for Medicaid to continue paying drug claims for consumers who have not yet been able to complete the Part D enrollment process.

This same approach will likely be necessary for consumers who newly apply for full Medicaid coverage during this initial enrollment period for Part D. For example, a person who has not yet enrolled for Part D applies for Medicaid on December 20, 2005 and would qualify as a fully dual eligible. If the Medicaid application is not processed until January 15 but Part D enrollment does not take effect until February, the person would again appear to be left without drug coverage for the month of January.

On an ongoing basis, this additional Medicaid coverage period may need to be applied in certain instances involving the individual's own initial enrollment period for Part D. Persons may apply and qualify for full Medicaid coverage and be not only currently eligible but also eligible for Medicaid coverage in the three prior months. If not enrolled in Part D during this period, again the person would be left without drug coverage until that enrollment is completed.

Lastly such an extended Medicaid coverage period may need to be applied in situations where retroactive Medicare entitlement is established. Per section 423.4, a Part D eligible is defined as a person who is entitled to or enrolled in Part A and/or Part B. There will be instances in which an individual is retroactively enrolled in Parts A or B because of a delayed approval for disability benefits. Such persons may have received Medicaid during this time and had their drug costs covered. Once approved for retroactive enrollment in Parts A or B, the person would now become a retroactive full dual eligible. As the person was not enrolled in Part D during this time, any retroactive drug coverage would potentially be in violation of these regulations. The regulations would appear to require the State to fully reimburse CMS for the coverage provided, yet do not allow the beneficiary to enroll in Part D retroactively.

Because of these and similar instances, the State strongly encourages CMS to provide for either retroactive Part D enrollment and coverage or permit an interim period of Medicaid drug coverage to account for such situations.

Subpart C - Benefits & Beneficiary Protections

Section 423.100 - <u>Definitions</u>

Prescription drug coverage under Part D has been limited for institutionalized consumers so that only

those residing in skilled nursing facilities are eligible. The State disagrees with this limitation and believes that all institutional settings including ICF-MR's should be included. In addition, persons accessing long term care services through home and community based services waivers should also be included. Individuals in these living arrangements should be assured access to coverage of all drugs through Part D.

Subpart P - Premiums & Cost Sharing Subsidies for Low Income Individuals

Section 423.772 - Definitions

The definition of full benefit dual eligibles includes persons who meet a medically needy spenddown in a month. Such definition is extremely problematic as the person will go in and out of full benefit classification on an ongoing basis making continuity of drug coverage next to impossible. There is also an issue with persons who meet spenddown in a prior period but who are back in spenddown status in the current month of application. The State proposes that medically needy individuals who meet spenddown be viewed as meeting the full benefit dual definition for a continuous period of up to 12 months even though going back into spenddown status during this time.

Section 423.773 - Requirements for Eligibility

The State strongly concurs with the inclusion of QMB, SLMB, and QI 1's as full subsidy eligible without the requirement for a separate determination.

Section 423.774 - Eligibility Determinations, Redeterminations, and Applications

The regulations provide for a duplicative application and determination process in which persons may apply for low income subsidies with either the State or Social Security Administration. As the subsidy is directly tied to Medicare coverage, this process is best handled as an SSA function. However, it is understood that many low income subsidy applicants may qualify for the Medicaid Savings Programs (QMB, SLMB, QI1) and thus automatically qualify for a subsidy. The State recommends that where an application is filed with the State and the person does not qualify for a Medicaid category that would result in automatic qualification for a subsidy, the information be provided to Social Security for a determination of subsidy eligibility. This can best be done by permitting SSA to use the State's application to make the subsidy determination. This would prevent the State from expending substantial funds and resources on modifying eligibility systems to handle the subsidy determination. That determination uses income and resource rules as well as family size definitions that differ substantially from Medicaid rules applied is in most states. SSA should also handle the redetermination and appeal process for all subsidy-only consumers. Information systems also need to be developed to better share information gathered between the two entities.

There do not appear to be any provisions regarding treatment of individuals who lose subsidy eligibility, particularly those who are deemed eligible by virtue of Medicaid eligibility. Processes need to be put into place for SSA to redetermine subsidy eligibility before the subsidy is eliminated. This may occur in instances where the individual has failed to return a Medical redetermination form or in which they have moved to another state and not contacted the new state agency for continued

Medicaid coverage. Proper and timely notification is critical before the subsidy is withdrawn.

Subpart S - Special Rules for States

Section 423.910 - <u>Requirements</u>

The baseline for determining the state's contribution doesn't take into consideration deductions for recoveries received as a result of such activities as estate recovery, medical subrogation, consumer overpayment recoveries, and third party collections. The State requests such activities be included in the baseline calculation.

We appreciate the opportunity to provide comments regarding these regulations.

Sincerely,

Janet Schalansky
Secretary

JS:BM:DZP:jmm

CMS-4068-P-1235

Submitter : Ms. M. J. Terrebonne **Date & Time:** 10/04/2004 08:10:37

Organization : Department of Health and Hospitals

Category : State Government

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

With the use of formularies, Medicaid recipients who are currently stable on medication therapies may not have continuity of care should they be switched to MA-PD or PDP preferred drug therapies.
A Medicare Part D beneficiary who is a Medicaid dual eligible should not be disenrolled from a MA-PD or PDP plan for any reason. This group of individuals in most cases do not have an alternative drug plan.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Part B drug claims which are denied covergae due to therapeutic inappropriateness, drug-disease contraindication, incorrect drug dosage, duration of drug treatment or for similar reasons related to meidal necessity should not be considered a Part D drug. Consideration should be given for coverage of drugs which are denied coverage under Part B as there may be clinical reasons for the coverage of these products.

Also, while there is much interface between drug coverage under Part B and Part D, use of the NDC number should be require in Part B billing to ensure rebate collections from drug manufacturers on federal and state supplemental rebates. Continuing the use of HCPCS codes makes it difficult to invoice drug manufacturers accurately for all drugs.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Should the auto-enrollment of dual eligibles end prior to 1/1/06? The dual eligibles should have an opportunity to choose the MA-PD or PDP plan prior to an auto-enrollment period.

Submitter : Ms. Linda Hanold **Date & Time:** 10/04/2004 08:10:47

Organization : NCC MERP

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

By Electronic Mail October 4, 2004

Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014

File Code: CMS-4068-P

Dear Dr. McClellan:

On behalf of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), I would like to take this opportunity to respond to the proposed rule for Title 1 of the Medicare Prescription Drug, Improvement and Modernization Act under Section 423.153(c) that requires providers of qualified prescription drug coverage to implement a quality assurance program. This includes quality assurance measures and systems for reducing medication errors, reducing adverse drug reactions, and improving medication use.

At its September 24, 2004, meeting, the Council had the opportunity to carefully review and discuss these sections of the proposed rule and offers the following comments:

? The Council supports the inclusion of drug utilization review, patient counseling, and patient information record-keeping as part of the quality assurance program.

? The Council supports inclusion of the proposed elements for quality assurance systems including electronic prescribing, clinical decision support systems, educational interventions, use of barcodes, adverse event reporting systems, and provider/patient education.

? The Council strongly cautions the Agency against the inclusion of error rates or the comparison of error rates in future quality reporting systems. In June 2002, the Council issued a statement against the use of medication error rates as a basis for comparing health care organizations noting that medication error rates for this purpose are of no value because of differences in culture, interpretation of error definition, differences in patient populations, and methods of reporting and detection. This document may be found in Attachment A. The Council suggests that there is

more value in encouraging the reporting of errors to a central location (e.g., national databases such as USP MEDMARX SM and FDA MedWatch). When errors are reported to an objective third party, these data can be broadly disseminated to help avoid recurrence. It is the Council?s contention that using these data for comparisons is a step backward that will resurrect the punitive ?culture of blame? identified by IOM as a major obstacle to safer patient care. Such comparisons also foster under-reporting and less than full disclosure about events which prevent the understanding of the causes of error.

Finally, the Council would like to point out that the definition of medication error that is quoted in the proposal was originally developed by the Council (see Attachment B) and later adopted by the Food and Drug Administration. It is important to note, however, that medication errors are preventable adverse events; but not all adverse events are preventable. All drugs have intrinsic toxicities that are unavoidable in some patients. Also, some patients have unanticipated allergic or idiosyncratic reactions to drugs that cannot be prevented.

A roster of NCC MERP member organizations and individuals is included as Attachment C. These comments reflect the collective opinion of the Council, but not necessarily of its individual members.

Thank you for this opportunity to provide input on this important issue. If you require additional information, please do not hesitate to contact me at 630-792-5916 or lhanold@jcaho.org.

Sincerely,

Linda S. Hanold
Chair, NCC MERP, c/o USP, 12601 Twinbrook Parkway, Rockivlle, MD 20852

CMS-4068-P-1236-Attach-1.doc

CMS-4068-P-1236-Attach-3.doc

CMS-4068-P-1236-Attach-2.doc

Submitter : Karla Fultz McHenry **Date & Time:** 10/04/2004 08:10:00

Organization : Iowa Medical Society

Category : Physician

Issue Areas/Comments

Issues 11-20

SPECIAL RULES FOR STATES

The MMA clawback provisions and eligibility determination requirements for dual eligibles under Part D have the potential to impact State Medicaid budgets significantly.

CMS-4068-P-1238

Submitter : Mr. Randy DeFrehn **Date & Time:** 10/04/2004 08:10:33

Organization : NCCMP

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find the comments filed by the NCCMP

CMS-4068-P-1238-Attach-2.doc

CMS-4068-P-1238-Attach-1.doc

VIA ELECTRONIC DELIVERY

October 4, 2004

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014
http://www.cms.hhs.gov/regulations/ecomments

Dear Sirs/Madams:

These comments are filed by the National Coordinating Committee for Multiemployer Plans (NCCMP) in response to the request for public comments by the Centers for Medicare and Medicaid Services (CMS) on the proposed rule to implement the new Medicare Prescription Drug Benefit authorized in section 101 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). This proposed rule was published in the Federal Register of August 3, 2004 (69 Fed. Reg. 46632).

The NCCMP is the only national organization devoted exclusively to protecting the interests of the approximately ten million workers, retirees, and their families who rely on multiemployer plans for retirement, health and other benefits. Our purpose is to assure an environment in which multiemployer plans can continue their vital role in providing benefits to working men and women. The NCCMP is a nonprofit organization, with members, plans and plan sponsors in every major segment of the multiemployer plan universe, including in the building and construction, retail food and service, and entertainment industries.

Most multiemployer plans today provide for retiree health benefits and many of those plans include some type of coverage for prescription drugs. As is well documented, the number of retirees covered by employer-sponsored health benefit plans today and in the future has continued to shrink, primarily because of the combination of accounting rule changes that force private sector employers to recognize the long-term liability of the retiree medical benefits and the rapidly escalating cost of providing that retiree health coverage.

Although facing the same marketplace cost pressures as other plan sponsors, employers and unions who have come together through collective bargaining to establish multiemployer plans have been less likely to drastically reduce or eliminate retiree coverage, in part because active workers in those industries where multiemployer plan coverage is prevalent have been willing to forgo some portion of their compensation to continue to subsidize the health benefits of their brothers and sisters who have retired. Even so, some multiemployer plans have been forced to alter the way benefits are financed in order to remain fiscally solvent. For some multiemployer plans, the rapidly escalating costs, the demographic trends, and the contraction of

the unionized workforce have required them to seriously rethink plan design and financing issues and to take steps to reduce or eliminate retiree benefits in ways that would have been unthinkable just a few years ago.

During the legislative process surrounding the passage of the MMA, the NCCMP urged Congress to consider carefully the structure of the new prescription drug program so as to avoid creating additional burdens on employer-sponsored plans and further incentives for them to reduce or drop prescription drug coverage for Medicare-eligible retirees. Although Congress incorporated an employer subsidy provision in the final legislation for plans that provided prescription drug benefits that were at least actuarially equivalent to the standard Part D drug benefit to encourage employers to continue providing retiree drug coverage, the overall structure of the new Medicare Part D benefit seriously disadvantages retirees with employer-sponsored coverage. This is particularly true with respect to the ability of retirees to meet the out-of-pocket limits that would trigger Medicare's catastrophic coverage. We recognize that CMS cannot through regulation remedy such a serious structural flaw in the statutory framework of the MMA, but we urge CMS to use its interpretive authority to ameliorate wherever possible the disadvantageous treatment of retirees with employer-sponsored coverage.

The statutory provisions of the MMA relating to employer-sponsored retiree prescription drug coverage are largely fashioned with a corporate health plan model in mind. Under this model, the plan sponsor is the employer who controls both plan design and financing decisions with little or no input from employees, unions or retirees. As you know, the world of multiemployer plans is quite different. Under applicable labor law, these collectively bargained plans are administered by a Board of Trustees consisting of equal numbers of representatives of labor and management. Under the Employee Retirement Income Security Act of 1974 (ERISA), the Board functions as both plan sponsor and the named fiduciary of the plan (and often the plan administrator as well) and therefore no individual employer can influence the operation or design of the plan because those decisions are reserved for the Board.

We appreciate the obvious effort that CMS has made in crafting its proposed rule to recognize that not all employer-sponsored plans are the same. We share your goals of maximizing the number of retirees retaining existing drug coverage, avoiding windfalls in which retirees receive a smaller subsidy from plan sponsors than Medicare would pay on their behalf, minimizing administrative burdens on beneficiaries, employers, unions, and plans, minimizing costs to the government of providing retiree drug subsidies and staying within the budget estimates. However, we believe that some of the rules that are being considered, particularly those directed at avoiding employer windfalls, may not be as relevant to multiemployer plans as they might be in a corporate plan setting, since it is the joint Board of Trustees that controls the design and financing of the retiree health plan, not any individual employer. This provides a degree of protection against potential manipulation that may be missing in other circumstances.

We have focused our comments on a handful of key issues raised in Subpart R of the proposed rule but we hope to open a dialogue with CMS staff on these and other issues of concern. Our detailed comments follow.

Comments Related to Subpart R – Payments to Sponsors of Retiree Prescription Drug Plans:

Section 423.882 Definitions

"Group health plan"

We support the use of the same definition of group health plan as found in section 607(1) of ERISA, 29 U.S.C. 1167(1). To further clarify the ability of multiemployer plans to qualify for the subsidy, we suggest also incorporating the definition of "multiemployer plan" found in section 3(37) of ERISA, 29 U.S.C. 1002(3)(37).

"Sponsor"

Although the proposed rule refers back to the definition of plan sponsor found in section 3(16)(B) of ERISA, we suggest that CMS confirm that in the case of a multiemployer plan (i.e., a plan established or maintained jointly by more than one employer and one or more employee associations), the plan sponsor is the board of trustees.

It would also be helpful for CMS to confirm how the employer subsidy provisions for prescription drug coverage operate in the context of a multiemployer health plan.

As we understand the statutory structure and legislative history of MMA regarding the employer subsidy for retiree prescription drug coverage, Congress intended for the Board of Trustees of the multiemployer plan to be the recipient of the employer subsidy since it is the plan that finances the retiree drug benefits (i.e., employer contributions and retiree contributions are placed in trust and those amounts, together with interest accumulated in the trust, are used to pay retiree prescription drug benefits). Therefore, as the entity claiming the subsidy, the multiemployer plan, not each contributing employer, will be responsible for meeting the procedural requirements to claim the subsidy, including providing the required disclosures to the Secretary and all eligible individuals (e.g., the notice of creditable coverage). The plan will apply for the subsidy (including furnishing the actuarial attestation and the list of qualified retirees covered under the multiemployer retiree prescription drug plan who are not enrolled in Medicare Part D). Once CMS has processed the application and verified the status of qualified retirees of all contributing employers, the subsidy would be paid to the multiemployer retiree prescription drug plan and these amounts would be credited toward future contributions to prescription drug coverage, by providing funds to cover costs that would otherwise have to be met through additional contributions. This approach eases burdens on CMS and individual contributing employers, while allowing the entity that pays the retiree prescription drug benefits (the multiemployer plan) to receive the subsidy and use it to cover retiree drug costs without incurring necessary administrative costs.

We would be happy to review with you the way that multiemployer plans operate and to furnish further detail why it is essential that the plan be treated as the plan sponsor for purposes of the subsidy, rather than individual contributing employers.

Section 423.884 Requirements for qualified retiree prescription drug plans

(a) Actuarial Attestation

Under the proposed rule, plan sponsors seeking to claim a subsidy for their prescription drug coverage must annually apply for the subsidy, no later than 90 days before the beginning of the calendar or plan year for which the subsidy is sought.

Although the proposed rule requires an actuarial attestation that the prescription drug benefits provided under the retiree prescription drug plan is at least actuarial equivalent to the standard Medicare Part D benefit, little guidance is given regarding the content of this attestation. CMS should consider developing a model form for this attestation, in which the plan's actuary could describe in simple terms how the determination of actuarial equivalency was made and what assumptions were used. A useful example of this type of standardized actuarial reporting for CMS to consider is the Schedule B to the Form 5500, the annual financial report that certain ERISA-covered pension plans must file with the U.S. Department of Labor. Of course, if CMS decides to promulgate a model form, its use should be considered a safe harbor for satisfaction of the attestation requirement and plan sponsors should be free to submit their own attestations in any other format as long as the required information has been included.

We think that CMS's proposal to require that an additional attestation must be filed with CMS no later than 90 days before a material change to the drug coverage that impacts the actuarial value of the coverage is generally reasonable, but we are concerned that the 90-day requirement may not be feasible in all situations.

The question of whether the 90-day deadline is feasible is interrelated with the issue of whether this deadline ought to be related to a calendar year or the plan year. CMS has indicated that it is leaning toward the use of a calendar year approach. Although most plan sponsors use a calendar year as the plan year, many do not. Clearly there are persuasive arguments favoring the use of a calendar year which can be made, however, we believe to reduce administrative burdens on plan sponsors, CMS should adopt a plan year approach.

Establishing actuarial equivalency

Under the MMA, the federal government will pay a cash subsidy to employers and other plan sponsors (including multiemployer plans) that provide retiree prescription drug coverage that is at least equal in value to the new Medicare Part D prescription drug coverage. The subsidy would be 28 percent of a retiree's total covered drug costs between $250 and $5,000 per year, which translates to a maximum subsidy payment to a plan sponsor of $1,330 per retiree. The subsidy would be payable for each retiree covered under the employer-sponsored plan who is not enrolled in Medicare Part D.

Although the cost of providing the new drug coverage under Medicare is partially financed by the Federal government, retirees enrolled in the new Medicare Part D benefit program will still be paying a substantial amount themselves for the coverage.

The standard Medicare Part D benefit design which will be offered through stand-alone prescription drug plans (PDPs) is as follows:

- Retirees will pay a monthly premium set by the PDP (estimated to be $35 per month in 2006 when the program begins, but expected to increase as costs increase);
- The PDP decides which prescription drugs to cover, as long as the PDP's formulary meets certain statutory requirements;
- Retirees must pay the first $250 in covered drug costs out of their own pocket (the standard deductible);
- Retirees pay 25% of covered drug costs between $250 and $2,250 during the year;
- Retirees pay 100% of covered drug costs between $2,225 and $5,100 during the year;
- Retirees pay no more than 5% of covered drug costs to the extent that those costs exceed $5,100. But to be eligible for this "catastrophic" coverage, an individual retiree must pay $3,600 (in 2006) in covered drug costs. Costs covered by a third-party, such as insurance or a group health plan, would not count toward this so-called "true out-of-pocket" amount (TrOOP).

To qualify for the 28% Federal subsidy, coverage provided by the employer-sponsored retiree medical plan does not have to be identical to the standard Part D drug benefit described above; it must be at least equal in value on an actuarial basis to the Part D coverage.

The MMA defines this measurement and comparison of the values of the two benefit design "actuarial equivalence." This test makes it possible to compare the value of different benefit designs. Actuarial equivalence looks at the expected cost of a benefit for a typical person, not how much it will actually cost for any given individual. This is important because a person who has greater health care needs obviously will cost more than one who is healthier.

The term "actuarial equivalence" is not defined in the proposed rule itself. CMS will have to create a standard for determining whether an employer retiree drug benefit is actuarially equivalent to the standard Part D benefit. However, in the preamble to the proposed rule, CMS has suggested a variety of differing approaches or tests to determine whether the employer-sponsored retiree drug plan is actuarially equivalent to the standard Medicare Part D prescription drug plan. CMS has asked for public comments on which, if any, of these standards is the right one and which may not be suitable. The standard CMS ultimately chooses will determine how generous a benefit employers have to offer retirees and how big a share of the benefit employers can require retirees to pay and still qualify for the federal subsidy.

Below is a brief description of each of the standards for which CMS seeks public comment:

- Single Prong Test: Under this test, also known as the "gross value test," an employer's benefit is good enough to qualify for a federal subsidy if, on average, the total value of

the benefit is at least equal to the total value of the standard Part D benefit. It does not matter what share of the benefit, if any, the employer pays. Under this test, the employer could contribute nothing and require the retiree to pay the full cost of the plan, yet the employer would still be paid the federal subsidy.

- Single Prong/No Windfall Test: As with the test above, an employer's benefit is good enough for a subsidy if on average the total value of the benefit is at least equal to the total value of the standard Part D benefit. However, the dollar amount of the subsidy paid to the employer cannot be greater than the dollar amount the employer pays toward the retiree coverage. The employer could design the plan so that it pays nothing towards retiree drug coverage after taking the federal subsidies into account.

- Two-Prong Test: This test begins with the single prong test but applies a second test (or "prong") in which the employer would also have to show it is paying for at least a specific minimum share of the total benefit. CMS offers several examples of the level at which it could set the minimum share or amount the employer must pay under the Two-Prong Test. These include:
    - The average per person amount Medicare would expect to pay as a subsidy to employers during the year, estimated by CMS to be $611 in 2006 when the program begins.
    - The expected amount of paid claims under the standard Part D prescription drug plan minus the monthly part D premiums paid by the retiree, estimated by the Congressional Budget Office to be approximately $1,200 in 2006.
    - The after-tax value of the average per person amount Medicare would expect to pay as a subsidy to employers during the year. For employers subject to the federal corporate income tax, this would be higher than the $611 estimated subsidy payment and will vary depending on the employer's tax rate.

One of Congress's policy goals under MMA is to ensure that the subsidy is used to preserve retiree benefits and not used simply to improve the employer's bottom line or for other non-health care uses. The preamble to the proposed regulation endorses the principle that the subsidy should be passed through to the retirees to pay for retiree prescription drug benefits. In particular, the proposed regulation states:

> "The intent of the MMA retiree prescription drug subsidy provisions is to slow the decline in employer-sponsored retiree insurance. By providing a special subsidy payment to sponsors of qualifying plans, the MMA provides employers with extra incentives and flexibility to maintain prescription drug coverage for their retirees. Our intention is to make these subsidy payments as reasonably available to plan sponsors as possible. We wish to take into account as much as possible the needs and concerns of plan sponsors, consistent with necessary assurances that Federal payments are accurate and in accordance with statutory requirements, that the interests of retiree-beneficiaries are protected, and that employers do not receive ''windfalls'' consisting of subsidy payments that are not passed on to beneficiaries."[1]

[1] 69 Fed. Reg. 46737 (August 3, 2004).

The structure of multiemployer plans assures that this policy goal is met.

After carefully considering each of the proposed standards, we have the following recommendations regarding the actuarial equivalence test that we believe are consistent with CMS's goals.

- CMS should adopt the Two-Prong Test for actuarial equivalence, which requires the portion of the prescription drug plan financed by the employer to be at least equal to the portion of the Part D benefit that is financed by Medicare. Only this test is consistent with the letter and intent of the MMA to provide for alternative drug coverage that is actuarially equivalent to the standard Part D benefit. In considering the portion of the plan that is financed by the employer, earnings on employer contributions held in trust as plan assets should be included. The comparison of the employer plan to the Part D benefit should be based on the benefits provided, not the cost.

- All of the other standards described by CMS in the preamble to the proposed rules could penalize retirees covered under a retiree drug plan and should be rejected. The Single Prong Test, the Single Prong/No Windfall Test, and the two versions of the Two-Prong Test that permit the employer to limit its contribution to the average subsidy amount it would expect to be paid from Medicare could all require a retiree to pay more for drug coverage than the retiree would if he or she were covered under a Medicare Part D prescription drug plan.

- Other tests being considered by CMS would allow for even greater windfalls to an employer. The Single Prong (or Gross Value) Test would allow for enormous windfalls to employers since it would permit an employer to pay nothing toward the drug benefit and still collect federal subsidies. This option has been roundly criticized in the press, is inconsistent with the intent of Congress, and would undermine the integrity of the Medicare drug program and therefore endanger the future of the program.

- In those cases in which a plan sponsor would be prohibited from claiming the largest possible retiree drug subsidy payable under the law due to the anti-windfall protections, CMS should provide a mechanism permitting the plan sponsor to claim the larger subsidy, so long as it passes through the value of the subsidy exceeding the windfall protections to the retirees. This is very important from a multiemployer perspective.

- Where a plan is fully insured, the regulations should require the insurance carrier to provide to the plan sponsor the information necessary to apply for the subsidy.

What is a "plan"?

As CMS acknowledges, many plan sponsors provide different levels and packages of benefits to different groups of retirees. In determining whether the coverage meets the actuarial equivalency test, one must first determine what the plan is that is being compared to the standard Medicare Part D prescription drug coverage. In its proposed rule, CMS indicates that it intends

to adopt a definition of "plan" that mirrors the current approach found in the Treasury regulations regarding the health insurance continuation requirements of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). Under those regulations, all health benefits provided by the plan sponsor are presumed to be under a single plan unless plan documents indicate otherwise.

As a result, actuarial equivalence would be determined by evaluating the plan as a whole, not on a benefit structure by benefit structure basis, and if, on average the actuarial value of the drug coverage equals or exceeds the value of the standard Part D coverage, the plan would satisfy the actuarial equivalency test.

We support the use of such an approach because it is one that is already familiar to plan sponsors and it provides flexibility without sacrificing retiree protections.

(b) Sponsor application for the subsidy payment

In general we support the approach taken by CMS that requires the plan sponsor to apply for the subsidy annually. As previously noted above, in the case of a multiemployer prescription drug plan, it is the plan itself, not each contributing employer that will file the application for the subsidy payment.

Under the proposed rule, plan sponsors must submit their subsidy applications no later than 90 days prior to the beginning of the calendar year for which the subsidy is requested. In order to receive the subsidy for 2006, applications with accompanying documentations must be submitted by September 30, 2005. For plans that begin coverage in the middle of a year, the plan sponsor must submit an actuarial attestation no later than 90 days prior to the date that coverage begins. For new plans that begin prescription drug coverage after September 30, 2005, the plan sponsor must submit an actuarial attestation no later than 150 days prior to the start of the program.

CMS also proposes to require that a plan sponsor submit a new actuarial attestation no later than 90 days before the implementation of a material change to the plan's drug coverage that impacts the actuarial value of the plan. A material change is defined as "any change that potentially causes the plan to no longer meet the actuarial equivalence test."

Although we generally support the proposed structure, we have concerns about the need to apply for a subsidy in the first year of the program by September 30, 2005. We are not sure whether the Boards of Trustees of multiemployer plans or other plan sponsors will be able to determine with certainty what alternatives there may be for retiree coverage other than simply continuing to provide benefits in the same way as in the past. For instance, some multiemployer plans may want to contract with qualified prescription drug plans (PDPs) to offer a coordinated or supplemental benefit. There is no guarantee that all the PDPs that might ultimately be offered in the region will be up and running by September 30, 2005. CMS should consider allowing plan sponsors who think they will be claiming the subsidy to file their application by September

30, 2005, but allow some flexibility in revising that application during a somewhat more extended period.

In addition, as previously noted in our comments on actuarial attestations generally, we think that CMS's proposal to require an additional attestation must be filed with CMS no later than 90 days before a material change to the drug coverage that impacts the actuarial value of the coverage is generally reasonable, but we are concerned that the 90-day requirement may not be feasible in all situations.

The question of whether the 90-day deadline is feasible is interrelated with the issue of whether this deadline ought to be related to a calendar year or the plan year. CMS has indicated that it is leaning toward the use of a calendar year approach. Although most plan sponsors use a calendar year as the plan year, many do not. Clearly there are persuasive arguments favoring the use of a calendar year which can be made, however, we believe to reduce administrative burdens on plan sponsors, CMS should adopt a plan year approach.

(c) Disclosure of creditable coverage

The proposed rule requires plan sponsors to disclose to retirees (and their Medicare-eligible spouses and dependents) whether the retiree prescription drug plan is actuarially equivalent to the standard Medicare Part D drug plan and therefore whether their coverage under the employer plan is creditable coverage. CMS has asked for input on a number of issues related to this requirement.

We encourage CMS to develop a model disclosure form that plan sponsors might use. We agree with CMS that it would be useful to consider as a model the approach taken by CMS, the Department of Labor and the Department of Treasury in their joint regulations regarding notices of creditable coverage under the Health Insurance Portability and Accountability Act of 1996, although the notice must be provided in a more timely fashion that would enable retirees to enroll in Part D if their plan is not actuarially equivalent.

CMS has also asked for comments regarding whether this disclosure could be incorporated into existing disclosures made to retirees in the normal course of plan operation or whether a separate notice should be required. In particular, CMS notes:

> We are soliciting comments regarding the types of materials that could provide an appropriate vehicle for this purpose, as well as ways to ensure that the notice is conspicuous and readily identified by recipients, particularly in those instances where the coverage is not creditable. 69 Fed. Reg. 46744.

Although we normally would oppose additional separate notices as unduly burdensome and would typically encourage CMS to allow plan sponsors to incorporate disclosure into existing types of dissemination, given the importance of the choice facing retirees, the need for timely disclosure of whether or not the plan's drug coverage is actuarially equivalent, and the

potential late enrollment penalties that retirees will face if they do not enroll in Part D when they are first eligible, we support requiring a separate notice regarding creditable coverage, unless the retiree prescription drug plan finds an alternative method of incorporating the notice with existing mailings or other forms of disclosure that assures that the notice will be conspicuous and readily identified by the recipients as important.

(d) HSAs, FSAs, HRAs, and MSAs

In the Preamble to the proposed rule, CMS requests input on whether the amounts used for prescription drug expenses under health savings accounts (HSAs) and other types of individual savings arrangements, including flexible spending accounts (FSAs), health reimbursement arrangements (HRAs) and medical savings accounts (MSAs) should be treated as group health payments for purposes of counting as incurred costs for purposes of meeting the Part D out-of-pocket threshold. 69 Fed. Reg. 46650. The general rule under Section 1860D-2(b)(4)(C)(ii) of the MMA is that any costs for which the individual is reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement do not count toward incurred costs.

CMS indicates that its "strong preference" is to treat HSA amounts differently so as to allow amounts reimbursed through an HSA to count towards incurred costs. Under this interpretation, a Medicare beneficiary could withdraw funds from his or her HSA, pay Part D drug expenses, and allow these expenses to count toward the beneficiary's out-of-pocket payments. Medicare catastrophic coverage would consequently begin sooner than if these payments were not counted toward TrOOP.

We strongly oppose creating a special exception for these payments. Although the Department of Labor has established a regulatory safe harbor for certain HSAs so that they may not be treated as group health plans under the Employee Retirement Income Security Act of 1974 (ERISA),[2] not all HSAs will fall into that safe harbor and some may, in fact, be group health plans. Even under the Department's guidance this question is ultimately decided by the individual facts and circumstances of each case. There is no statutory authority for CMS to create a special rule for HSAs and it would be both illegal and inappropriate to do so. Moreover, if HHS were to create a special exception from TrOOP only for those HSAs that were not employer plans would create an enforcement problem and an administrative nightmare. Who would determine whether the HSA in question was an ERISA plan? The Department of Labor? HHS? The plan sponsor? The individual who established the HSA himself or herself? The structure of the MMA and the proposed rule places a great deal of confidence in the plan sponsor to self-police compliance. Determining whether or not an arrangement constitutes an ERISA plan has always been the purview of the Department of Labor or, ultimately, the courts through actions brought under ERISA section 502. This would create a level of complexity and administrative burden that seems unjustified and unsupportable, given CMS' goals of

[2] Department of Labor Field Assistance Bulletin 2004-1 (April 7, 2004). This can be found at: http://www.dol.gov/ebsa/regs/fab_2004-1.html.

minimizing administrative burdens on employers, unions, plans and beneficiaries and minimizing costs to the government of providing retiree prescription drug coverage.

We believe that HSA amounts should be treated as other tax-favored forms of health coverage and excluded from incurred costs. They are not "essentially analogous to a beneficiary's bank account" because individuals who establish these accounts have been given extraordinarily generous tax preferences to use this form of tax-favored savings. Individuals can deduct amounts placed in HSAs when the contributions are made "above-the-line," contributions can be made by others on behalf of an individual and deducted by the individual, even though he or she didn't make the contribution, and withdrawals from HSAs for qualified medical expenses (including prescription drug costs) are tax free. In contrast, individuals who place money in a bank account are given no special tax preferences.

CMS' desire to give HSAs special treatment is simply another example of discrimination against retirees with employer-sponsored prescription drug coverage, since HSAs can be set up by individuals without any employer involvement, although employer contributions to HSAs on behalf of employees are permitted. HSAs should be treated as all other tax-favored savings mechanisms – whether individual or employer-sponsored (including FSAs, HRAs and MSAs). In other words, payments from all four of these vehicles should be excluded from incurred costs. To do otherwise would create a substantial windfall and an unjustified double taxpayer subsidy for individuals who establish HSAs. Not only would they receive a tax subsidy for establishing such an arrangement, they would be treated more favorably than individuals who pay prescription drug expenses through salary reduction programs that are employer-sponsored. To allow HSA amounts to count toward incurred costs while barring other forms of subsidized employer coverage from doing so is just another example of the bias against retiree drug coverage provided under employer-sponsored plans that is an integral part of the structure of the MMA, notwithstanding Congress' attempt to ameliorate that bias somewhat through the offering of an employer subsidy for continuing to provide coverage.

Waivers for Plan Sponsors to contract with or become Part D Prescription Drug Plans (PDPs) or Medicare Advantage (MA-PD) plans

Plan sponsors that do not choose to provide coverage that qualifies for the subsidy or provide coverage that supplements or wraps around the Part D benefit can instead contract with or become a PDP or Medicare Advantage (MA) plan. CMS indicates that an MA-PD plan or a PDP plan may request, in writing from CMS, a waiver or modification of the Medicare Advantage or Part D requirements that hinder the design of, the offering of, or the enrollment in Medicare Advantage plans by employees or former employees receiving benefits from plans sponsored by employers, labor organizations, or multiemployer plans. MA and PDP plans that receive a waiver may restrict the enrollment to participants and beneficiaries in an employer-sponsored plan. Waivers might include restricting enrollment to the plan sponsor's retirees and offer a benefit that resembles existing active coverage. A waiver might also include authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group.

A waiver process should be established for employers and other plan sponsors to contract with or otherwise create Medicare Part D PDPs and MA-PD plans that serve employment-based populations. Waivers should be published and made easily available online. Existing waivers that were made available to Medicare+Choice plans should be catalogued and placed online so that plan sponsors can determine what requirements have already been considered for waiver.

CMS recognizes that one option available to employers under the MMA is to provide retiree prescription coverage that supplements coverage offered under a PDP or MA-PD plan. For this option to work smoothly for plan sponsors, particularly those with retirees living across the PDP and MA-PD regions to be established, CMS should take appropriate steps to encourage the development of supplemental plans by PDP and MA-PD providers. If both the Part D plan and the supplemental plan are offered a single provider, it may be easier to coordinate benefits.

In addition, a number of multiemployer plans have joined together to establish purchasing coalitions to improve their purchasing leverage for prescription drugs with pharmacy benefit managers (PBMs). We strongly urge CMS to extend waiver authority to purchasing coalitions involved with employer-sponsored plans. It is quite likely that these purchasing coalitions may be potential PDP plan sponsors, so CMS should not preclude waivers for such entities.

Conclusion

Again we appreciate your willingness to seek input from the plan sponsor community and other stakeholders in the fight to preserve employer-sponsored retiree health programs. We are especially grateful for your willingness to consider the special administrative problems of multiemployer plans because of their structural differences from plans sponsored by individual employers. Please feel free to contact me for further information. We would be pleased to meet with you to discuss these comments and any other issues on which you are seeking input. We look forward to working with you in the future.

Yours truly,

Randy DeFrehn
Executive Director

VIA ELECTRONIC DELIVERY

October 4, 2004

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014
http://www.cms.hhs.gov/regulations/ecomments

Dear Sirs/Madams:

These comments are filed by the National Coordinating Committee for Multiemployer Plans (NCCMP) in response to the request for public comments by the Centers for Medicare and Medicaid Services (CMS) on the proposed rule to implement the new Medicare Prescription Drug Benefit authorized in section 101 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). This proposed rule was published in the Federal Register of August 3, 2004 (69 Fed. Reg. 46632).

The NCCMP is the only national organization devoted exclusively to protecting the interests of the approximately ten million workers, retirees, and their families who rely on multiemployer plans for retirement, health and other benefits. Our purpose is to assure an environment in which multiemployer plans can continue their vital role in providing benefits to working men and women. The NCCMP is a nonprofit organization, with members, plans and plan sponsors in every major segment of the multiemployer plan universe, including in the building and construction, retail food and service, and entertainment industries.

Most multiemployer plans today provide for retiree health benefits and many of those plans include some type of coverage for prescription drugs. As is well documented, the number of retirees covered by employer-sponsored health benefit plans today and in the future has continued to shrink, primarily because of the combination of accounting rule changes that force private sector employers to recognize the long-term liability of the retiree medical benefits and the rapidly escalating cost of providing that retiree health coverage.

Although facing the same marketplace cost pressures as other plan sponsors, employers and unions who have come together through collective bargaining to establish multiemployer plans have been less likely to drastically reduce or eliminate retiree coverage, in part because active workers in those industries where multiemployer plan coverage is prevalent have been willing to forgo some portion of their compensation to continue to subsidize the health benefits of their brothers and sisters who have retired. Even so, some multiemployer plans have been forced to alter the way benefits are financed in order to remain fiscally solvent. For some multiemployer plans, the rapidly escalating costs, the demographic trends, and the contraction of

the unionized workforce have required them to seriously rethink plan design and financing issues and to take steps to reduce or eliminate retiree benefits in ways that would have been unthinkable just a few years ago.

During the legislative process surrounding the passage of the MMA, the NCCMP urged Congress to consider carefully the structure of the new prescription drug program so as to avoid creating additional burdens on employer-sponsored plans and further incentives for them to reduce or drop prescription drug coverage for Medicare-eligible retirees. Although Congress incorporated an employer subsidy provision in the final legislation for plans that provided prescription drug benefits that were at least actuarially equivalent to the standard Part D drug benefit to encourage employers to continue providing retiree drug coverage, the overall structure of the new Medicare Part D benefit seriously disadvantages retirees with employer-sponsored coverage. This is particularly true with respect to the ability of retirees to meet the out-of-pocket limits that would trigger Medicare's catastrophic coverage. We recognize that CMS cannot through regulation remedy such a serious structural flaw in the statutory framework of the MMA, but we urge CMS to use its interpretive authority to ameliorate wherever possible the disadvantageous treatment of retirees with employer-sponsored coverage.

The statutory provisions of the MMA relating to employer-sponsored retiree prescription drug coverage are largely fashioned with a corporate health plan model in mind. Under this model, the plan sponsor is the employer who controls both plan design and financing decisions with little or no input from employees, unions or retirees. As you know, the world of multiemployer plans is quite different. Under applicable labor law, these collectively bargained plans are administered by a Board of Trustees consisting of equal numbers of representatives of labor and management. Under the Employee Retirement Income Security Act of 1974 (ERISA), the Board functions as both plan sponsor and the named fiduciary of the plan (and often the plan administrator as well) and therefore no individual employer can influence the operation or design of the plan because those decisions are reserved for the Board.

We appreciate the obvious effort that CMS has made in crafting its proposed rule to recognize that not all employer-sponsored plans are the same. We share your goals of maximizing the number of retirees retaining existing drug coverage, avoiding windfalls in which retirees receive a smaller subsidy from plan sponsors than Medicare would pay on their behalf, minimizing administrative burdens on beneficiaries, employers, unions, and plans, minimizing costs to the government of providing retiree drug subsidies and staying within the budget estimates. However, we believe that some of the rules that are being considered, particularly those directed at avoiding employer windfalls, may not be as relevant to multiemployer plans as they might be in a corporate plan setting, since it is the joint Board of Trustees that controls the design and financing of the retiree health plan, not any individual employer. This provides a degree of protection against potential manipulation that may be missing in other circumstances.

We have focused our comments on a handful of key issues raised in Subpart R of the proposed rule but we hope to open a dialogue with CMS staff on these and other issues of concern. Our detailed comments follow.

Comments Related to Subpart R – Payments to Sponsors of Retiree Prescription Drug Plans:

Section 423.882 Definitions

"Group health plan"

We support the use of the same definition of group health plan as found in section 607(1) of ERISA, 29 U.S.C. 1167(1). To further clarify the ability of multiemployer plans to qualify for the subsidy, we suggest also incorporating the definition of "multiemployer plan" found in section 3(37) of ERISA, 29 U.S.C. 1002(3)(37).

"Sponsor"

Although the proposed rule refers back to the definition of plan sponsor found in section 3(16)(B) of ERISA, we suggest that CMS confirm that in the case of a multiemployer plan (i.e., a plan established or maintained jointly by more than one employer and one or more employee associations), the plan sponsor is the board of trustees.

It would also be helpful for CMS to confirm how the employer subsidy provisions for prescription drug coverage operate in the context of a multiemployer health plan.

As we understand the statutory structure and legislative history of MMA regarding the employer subsidy for retiree prescription drug coverage, Congress intended for the Board of Trustees of the multiemployer plan to be the recipient of the employer subsidy since it is the plan that finances the retiree drug benefits (i.e., employer contributions and retiree contributions are placed in trust and those amounts, together with interest accumulated in the trust, are used to pay retiree prescription drug benefits). Therefore, as the entity claiming the subsidy, the multiemployer plan, not each contributing employer, will be responsible for meeting the procedural requirements to claim the subsidy, including providing the required disclosures to the Secretary and all eligible individuals (e.g., the notice of creditable coverage). The plan will apply for the subsidy (including furnishing the actuarial attestation and the list of qualified retirees covered under the multiemployer retiree prescription drug plan who are not enrolled in Medicare Part D). Once CMS has processed the application and verified the status of qualified retirees of all contributing employers, the subsidy would be paid to the multiemployer retiree prescription drug plan and these amounts would be credited toward future contributions to prescription drug coverage, by providing funds to cover costs that would otherwise have to be met through additional contributions. This approach eases burdens on CMS and individual contributing employers, while allowing the entity that pays the retiree prescription drug benefits (the multiemployer plan) to receive the subsidy and use it to cover retiree drug costs without incurring necessary administrative costs.

We would be happy to review with you the way that multiemployer plans operate and to furnish further detail why it is essential that the plan be treated as the plan sponsor for purposes of the subsidy, rather than individual contributing employers.

Section 423.884 Requirements for qualified retiree prescription drug plans

(a) Actuarial Attestation

Under the proposed rule, plan sponsors seeking to claim a subsidy for their prescription drug coverage must annually apply for the subsidy, no later than 90 days before the beginning of the calendar or plan year for which the subsidy is sought.

Although the proposed rule requires an actuarial attestation that the prescription drug benefits provided under the retiree prescription drug plan is at least actuarial equivalent to the standard Medicare Part D benefit, little guidance is given regarding the content of this attestation. CMS should consider developing a model form for this attestation, in which the plan's actuary could describe in simple terms how the determination of actuarial equivalency was made and what assumptions were used. A useful example of this type of standardized actuarial reporting for CMS to consider is the Schedule B to the Form 5500, the annual financial report that certain ERISA-covered pension plans must file with the U.S. Department of Labor. Of course, if CMS decides to promulgate a model form, its use should be considered a safe harbor for satisfaction of the attestation requirement and plan sponsors should be free to submit their own attestations in any other format as long as the required information has been included.

We think that CMS's proposal to require that an additional attestation must be filed with CMS no later than 90 days before a material change to the drug coverage that impacts the actuarial value of the coverage is generally reasonable, but we are concerned that the 90-day requirement may not be feasible in all situations.

The question of whether the 90-day deadline is feasible is interrelated with the issue of whether this deadline ought to be related to a calendar year or the plan year. CMS has indicated that it is leaning toward the use of a calendar year approach. Although most plan sponsors use a calendar year as the plan year, many do not. Clearly there are persuasive arguments favoring the use of a calendar year which can be made, however, we believe to reduce administrative burdens on plan sponsors, CMS should adopt a plan year approach.

Establishing actuarial equivalency

Under the MMA, the federal government will pay a cash subsidy to employers and other plan sponsors (including multiemployer plans) that provide retiree prescription drug coverage that is at least equal in value to the new Medicare Part D prescription drug coverage. The subsidy would be 28 percent of a retiree's total covered drug costs between $250 and $5,000 per year, which translates to a maximum subsidy payment to a plan sponsor of $1,330 per retiree. The subsidy would be payable for each retiree covered under the employer-sponsored plan who is not enrolled in Medicare Part D.

Although the cost of providing the new drug coverage under Medicare is partially financed by the Federal government, retirees enrolled in the new Medicare Part D benefit program will still be paying a substantial amount themselves for the coverage.

The standard Medicare Part D benefit design which will be offered through stand-alone prescription drug plans (PDPs) is as follows:

- Retirees will pay a monthly premium set by the PDP (estimated to be $35 per month in 2006 when the program begins, but expected to increase as costs increase);
- The PDP decides which prescription drugs to cover, as long as the PDP's formulary meets certain statutory requirements;
- Retirees must pay the first $250 in covered drug costs out of their own pocket (the standard deductible);
- Retirees pay 25% of covered drug costs between $250 and $2,250 during the year;
- Retirees pay 100% of covered drug costs between $2,225 and $5,100 during the year;
- Retirees pay no more than 5% of covered drug costs to the extent that those costs exceed $5,100. But to be eligible for this "catastrophic" coverage, an individual retiree must pay $3,600 (in 2006) in covered drug costs. Costs covered by a third-party, such as insurance or a group health plan, would not count toward this so-called "true out-of-pocket" amount (TrOOP).

To qualify for the 28% Federal subsidy, coverage provided by the employer-sponsored retiree medical plan does not have to be identical to the standard Part D drug benefit described above; it must be at least equal in value on an actuarial basis to the Part D coverage.

The MMA defines this measurement and comparison of the values of the two benefit design "actuarial equivalence." This test makes it possible to compare the value of different benefit designs. Actuarial equivalence looks at the expected cost of a benefit for a typical person, not how much it will actually cost for any given individual. This is important because a person who has greater health care needs obviously will cost more than one who is healthier.

The term "actuarial equivalence" is not defined in the proposed rule itself. CMS will have to create a standard for determining whether an employer retiree drug benefit is actuarially equivalent to the standard Part D benefit. However, in the preamble to the proposed rule, CMS has suggested a variety of differing approaches or tests to determine whether the employer-sponsored retiree drug plan is actuarially equivalent to the standard Medicare Part D prescription drug plan. CMS has asked for public comments on which, if any, of these standards is the right one and which may not be suitable. The standard CMS ultimately chooses will determine how generous a benefit employers have to offer retirees and how big a share of the benefit employers can require retirees to pay and still qualify for the federal subsidy.

Below is a brief description of each of the standards for which CMS seeks public comment:

- Single Prong Test: Under this test, also known as the "gross value test," an employer's benefit is good enough to qualify for a federal subsidy if, on average, the total value of

the benefit is at least equal to the total value of the standard Part D benefit. It does not matter what share of the benefit, if any, the employer pays. Under this test, the employer could contribute nothing and require the retiree to pay the full cost of the plan, yet the employer would still be paid the federal subsidy.

- Single Prong/No Windfall Test: As with the test above, an employer's benefit is good enough for a subsidy if on average the total value of the benefit is at least equal to the total value of the standard Part D benefit. However, the dollar amount of the subsidy paid to the employer cannot be greater than the dollar amount the employer pays toward the retiree coverage. The employer could design the plan so that it pays nothing towards retiree drug coverage after taking the federal subsidies into account.

- Two-Prong Test: This test begins with the single prong test but applies a second test (or "prong") in which the employer would also have to show it is paying for at least a specific minimum share of the total benefit. CMS offers several examples of the level at which it could set the minimum share or amount the employer must pay under the Two-Prong Test. These include:
    - The average per person amount Medicare would expect to pay as a subsidy to employers during the year, estimated by CMS to be $611 in 2006 when the program begins.
    - The expected amount of paid claims under the standard Part D prescription drug plan minus the monthly part D premiums paid by the retiree, estimated by the Congressional Budget Office to be approximately $1,200 in 2006.
    - The after-tax value of the average per person amount Medicare would expect to pay as a subsidy to employers during the year. For employers subject to the federal corporate income tax, this would be higher than the $611 estimated subsidy payment and will vary depending on the employer's tax rate.

One of Congress's policy goals under MMA is to ensure that the subsidy is used to preserve retiree benefits and not used simply to improve the employer's bottom line or for other non-health care uses. The preamble to the proposed regulation endorses the principle that the subsidy should be passed through to the retirees to pay for retiree prescription drug benefits. In particular, the proposed regulation states:

> "The intent of the MMA retiree prescription drug subsidy provisions is to slow the decline in employer-sponsored retiree insurance. By providing a special subsidy payment to sponsors of qualifying plans, the MMA provides employers with extra incentives and flexibility to maintain prescription drug coverage for their retirees. Our intention is to make these subsidy payments as reasonably available to plan sponsors as possible. We wish to take into account as much as possible the needs and concerns of plan sponsors, consistent with necessary assurances that Federal payments are accurate and in accordance with statutory requirements, that the interests of retiree-beneficiaries are protected, and that employers do not receive ''windfalls'' consisting of subsidy payments that are not passed on to beneficiaries."[1]

[1] 69 Fed. Reg. 46737 (August 3, 2004).

The structure of multiemployer plans assures that this policy goal is met.

After carefully considering each of the proposed standards, we have the following recommendations regarding the actuarial equivalence test that we believe are consistent with CMS's goals.

- CMS should adopt the Two-Prong Test for actuarial equivalence, which requires the portion of the prescription drug plan financed by the employer to be at least equal to the portion of the Part D benefit that is financed by Medicare. Only this test is consistent with the letter and intent of the MMA to provide for alternative drug coverage that is actuarially equivalent to the standard Part D benefit. In considering the portion of the plan that is financed by the employer, earnings on employer contributions held in trust as plan assets should be included. The comparison of the employer plan to the Part D benefit should be based on the benefits provided, not the cost.

- All of the other standards described by CMS in the preamble to the proposed rules could penalize retirees covered under a retiree drug plan and should be rejected. The Single Prong Test, the Single Prong/No Windfall Test, and the two versions of the Two-Prong Test that permit the employer to limit its contribution to the average subsidy amount it would expect to be paid from Medicare could all require a retiree to pay more for drug coverage than the retiree would if he or she were covered under a Medicare Part D prescription drug plan.

- Other tests being considered by CMS would allow for even greater windfalls to an employer. The Single Prong (or Gross Value) Test would allow for enormous windfalls to employers since it would permit an employer to pay nothing toward the drug benefit and still collect federal subsidies. This option has been roundly criticized in the press, is inconsistent with the intent of Congress, and would undermine the integrity of the Medicare drug program and therefore endanger the future of the program.

- In those cases in which a plan sponsor would be prohibited from claiming the largest possible retiree drug subsidy payable under the law due to the anti-windfall protections, CMS should provide a mechanism permitting the plan sponsor to claim the larger subsidy, so long as it passes through the value of the subsidy exceeding the windfall protections to the retirees. This is very important from a multiemployer perspective.

- Where a plan is fully insured, the regulations should require the insurance carrier to provide to the plan sponsor the information necessary to apply for the subsidy.

What is a "plan"?

As CMS acknowledges, many plan sponsors provide different levels and packages of benefits to different groups of retirees. In determining whether the coverage meets the actuarial equivalency test, one must first determine what the plan is that is being compared to the standard Medicare Part D prescription drug coverage. In its proposed rule, CMS indicates that it intends

to adopt a definition of "plan" that mirrors the current approach found in the Treasury regulations regarding the health insurance continuation requirements of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). Under those regulations, all health benefits provided by the plan sponsor are presumed to be under a single plan unless plan documents indicate otherwise.

As a result, actuarial equivalence would be determined by evaluating the plan as a whole, not on a benefit structure by benefit structure basis, and if, on average the actuarial value of the drug coverage equals or exceeds the value of the standard Part D coverage, the plan would satisfy the actuarial equivalency test.

We support the use of such an approach because it is one that is already familiar to plan sponsors and it provides flexibility without sacrificing retiree protections.

(b) Sponsor application for the subsidy payment

In general we support the approach taken by CMS that requires the plan sponsor to apply for the subsidy annually. As previously noted above, in the case of a multiemployer prescription drug plan, it is the plan itself, not each contributing employer that will file the application for the subsidy payment.

Under the proposed rule, plan sponsors must submit their subsidy applications no later than 90 days prior to the beginning of the calendar year for which the subsidy is requested. In order to receive the subsidy for 2006, applications with accompanying documentations must be submitted by September 30, 2005. For plans that begin coverage in the middle of a year, the plan sponsor must submit an actuarial attestation no later than 90 days prior to the date that coverage begins. For new plans that begin prescription drug coverage after September 30, 2005, the plan sponsor must submit an actuarial attestation no later than 150 days prior to the start of the program.

CMS also proposes to require that a plan sponsor submit a new actuarial attestation no later than 90 days before the implementation of a material change to the plan's drug coverage that impacts the actuarial value of the plan. A material change is defined as "any change that potentially causes the plan to no longer meet the actuarial equivalence test."

Although we generally support the proposed structure, we have concerns about the need to apply for a subsidy in the first year of the program by September 30, 2005. We are not sure whether the Boards of Trustees of multiemployer plans or other plan sponsors will be able to determine with certainty what alternatives there may be for retiree coverage other than simply continuing to provide benefits in the same way as in the past. For instance, some multiemployer plans may want to contract with qualified prescription drug plans (PDPs) to offer a coordinated or supplemental benefit. There is no guarantee that all the PDPs that might ultimately be offered in the region will be up and running by September 30, 2005. CMS should consider allowing plan sponsors who think they will be claiming the subsidy to file their application by September

30, 2005, but allow some flexibility in revising that application during a somewhat more extended period.

In addition, as previously noted in our comments on actuarial attestations generally, we think that CMS's proposal to require an additional attestation must be filed with CMS no later than 90 days before a material change to the drug coverage that impacts the actuarial value of the coverage is generally reasonable, but we are concerned that the 90-day requirement may not be feasible in all situations.

The question of whether the 90-day deadline is feasible is interrelated with the issue of whether this deadline ought to be related to a calendar year or the plan year. CMS has indicated that it is leaning toward the use of a calendar year approach. Although most plan sponsors use a calendar year as the plan year, many do not. Clearly there are persuasive arguments favoring the use of a calendar year which can be made, however, we believe to reduce administrative burdens on plan sponsors, CMS should adopt a plan year approach.

(c) Disclosure of creditable coverage

The proposed rule requires plan sponsors to disclose to retirees (and their Medicare-eligible spouses and dependents) whether the retiree prescription drug plan is actuarially equivalent to the standard Medicare Part D drug plan and therefore whether their coverage under the employer plan is creditable coverage. CMS has asked for input on a number of issues related to this requirement.

We encourage CMS to develop a model disclosure form that plan sponsors might use. We agree with CMS that it would be useful to consider as a model the approach taken by CMS, the Department of Labor and the Department of Treasury in their joint regulations regarding notices of creditable coverage under the Health Insurance Portability and Accountability Act of 1996, although the notice must be provided in a more timely fashion that would enable retirees to enroll in Part D if their plan is not actuarially equivalent.

CMS has also asked for comments regarding whether this disclosure could be incorporated into existing disclosures made to retirees in the normal course of plan operation or whether a separate notice should be required. In particular, CMS notes:

> We are soliciting comments regarding the types of materials that could provide an appropriate vehicle for this purpose, as well as ways to ensure that the notice is conspicuous and readily identified by recipients, particularly in those instances where the coverage is not creditable. 69 Fed. Reg. 46744.

Although we normally would oppose additional separate notices as unduly burdensome and would typically encourage CMS to allow plan sponsors to incorporate disclosure into existing types of dissemination, given the importance of the choice facing retirees, the need for timely disclosure of whether or not the plan's drug coverage is actuarially equivalent, and the

potential late enrollment penalties that retirees will face if they do not enroll in Part D when they are first eligible, we support requiring a separate notice regarding creditable coverage, unless the retiree prescription drug plan finds an alternative method of incorporating the notice with existing mailings or other forms of disclosure that assures that the notice will be conspicuous and readily identified by the recipients as important.

(d) HSAs, FSAs, HRAs, and MSAs

In the Preamble to the proposed rule, CMS requests input on whether the amounts used for prescription drug expenses under health savings accounts (HSAs) and other types of individual savings arrangements, including flexible spending accounts (FSAs), health reimbursement arrangements (HRAs) and medical savings accounts (MSAs) should be treated as group health payments for purposes of counting as incurred costs for purposes of meeting the Part D out-of-pocket threshold. 69 Fed. Reg. 46650. The general rule under Section 1860D-2(b)(4)(C)(ii) of the MMA is that any costs for which the individual is reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement do not count toward incurred costs.

CMS indicates that its "strong preference" is to treat HSA amounts differently so as to allow amounts reimbursed through an HSA to count towards incurred costs. Under this interpretation, a Medicare beneficiary could withdraw funds from his or her HSA, pay Part D drug expenses, and allow these expenses to count toward the beneficiary's out-of-pocket payments. Medicare catastrophic coverage would consequently begin sooner than if these payments were not counted toward TrOOP.

We strongly oppose creating a special exception for these payments. Although the Department of Labor has established a regulatory safe harbor for certain HSAs so that they may not be treated as group health plans under the Employee Retirement Income Security Act of 1974 (ERISA),[2] not all HSAs will fall into that safe harbor and some may, in fact, be group health plans. Even under the Department's guidance this question is ultimately decided by the individual facts and circumstances of each case. There is no statutory authority for CMS to create a special rule for HSAs and it would be both illegal and inappropriate to do so. Moreover, if HHS were to create a special exception from TrOOP only for those HSAs that were not employer plans would create an enforcement problem and an administrative nightmare. Who would determine whether the HSA in question was an ERISA plan? The Department of Labor? HHS? The plan sponsor? The individual who established the HSA himself or herself? The structure of the MMA and the proposed rule places a great deal of confidence in the plan sponsor to self-police compliance. Determining whether or not an arrangement constitutes an ERISA plan has always been the purview of the Department of Labor or, ultimately, the courts through actions brought under ERISA section 502. This would create a level of complexity and administrative burden that seems unjustified and unsupportable, given CMS' goals of

[2] Department of Labor Field Assistance Bulletin 2004-1 (April 7, 2004). This can be found at: http://www.dol.gov/ebsa/regs/fab_2004-1.html.

minimizing administrative burdens on employers, unions, plans and beneficiaries and minimizing costs to the government of providing retiree prescription drug coverage.

We believe that HSA amounts should be treated as other tax-favored forms of health coverage and excluded from incurred costs. They are not "essentially analogous to a beneficiary's bank account" because individuals who establish these accounts have been given extraordinarily generous tax preferences to use this form of tax-favored savings. Individuals can deduct amounts placed in HSAs when the contributions are made "above-the-line," contributions can be made by others on behalf of an individual and deducted by the individual, even though he or she didn't make the contribution, and withdrawals from HSAs for qualified medical expenses (including prescription drug costs) are tax free. In contrast, individuals who place money in a bank account are given no special tax preferences.

CMS' desire to give HSAs special treatment is simply another example of discrimination against retirees with employer-sponsored prescription drug coverage, since HSAs can be set up by individuals without any employer involvement, although employer contributions to HSAs on behalf of employees are permitted. HSAs should be treated as all other tax-favored savings mechanisms – whether individual or employer-sponsored (including FSAs, HRAs and MSAs). In other words, payments from all four of these vehicles should be excluded from incurred costs. To do otherwise would create a substantial windfall and an unjustified double taxpayer subsidy for individuals who establish HSAs. Not only would they receive a tax subsidy for establishing such an arrangement, they would be treated more favorably than individuals who pay prescription drug expenses through salary reduction programs that are employer-sponsored. To allow HSA amounts to count toward incurred costs while barring other forms of subsidized employer coverage from doing so is just another example of the bias against retiree drug coverage provided under employer-sponsored plans that is an integral part of the structure of the MMA, notwithstanding Congress' attempt to ameliorate that bias somewhat through the offering of an employer subsidy for continuing to provide coverage.

Waivers for Plan Sponsors to contract with or become Part D Prescription Drug Plans (PDPs) or Medicare Advantage (MA-PD) plans

Plan sponsors that do not choose to provide coverage that qualifies for the subsidy or provide coverage that supplements or wraps around the Part D benefit can instead contract with or become a PDP or Medicare Advantage (MA) plan. CMS indicates that an MA-PD plan or a PDP plan may request, in writing from CMS, a waiver or modification of the Medicare Advantage or Part D requirements that hinder the design of, the offering of, or the enrollment in Medicare Advantage plans by employees or former employees receiving benefits from plans sponsored by employers, labor organizations, or multiemployer plans. MA and PDP plans that receive a waiver may restrict the enrollment to participants and beneficiaries in an employer-sponsored plan. Waivers might include restricting enrollment to the plan sponsor's retirees and offer a benefit that resembles existing active coverage. A waiver might also include authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group.

A waiver process should be established for employers and other plan sponsors to contract with or otherwise create Medicare Part D PDPs and MA-PD plans that serve employment-based populations. Waivers should be published and made easily available online. Existing waivers that were made available to Medicare+Choice plans should be catalogued and placed online so that plan sponsors can determine what requirements have already been considered for waiver.

CMS recognizes that one option available to employers under the MMA is to provide retiree prescription coverage that supplements coverage offered under a PDP or MA-PD plan. For this option to work smoothly for plan sponsors, particularly those with retirees living across the PDP and MA-PD regions to be established, CMS should take appropriate steps to encourage the development of supplemental plans by PDP and MA-PD providers. If both the Part D plan and the supplemental plan are offered a single provider, it may be easier to coordinate benefits.

In addition, a number of multiemployer plans have joined together to establish purchasing coalitions to improve their purchasing leverage for prescription drugs with pharmacy benefit managers (PBMs). We strongly urge CMS to extend waiver authority to purchasing coalitions involved with employer-sponsored plans. It is quite likely that these purchasing coalitions may be potential PDP plan sponsors, so CMS should not preclude waivers for such entities.

Conclusion

Again we appreciate your willingness to seek input from the plan sponsor community and other stakeholders in the fight to preserve employer-sponsored retiree health programs. We are especially grateful for your willingness to consider the special administrative problems of multiemployer plans because of their structural differences from plans sponsored by individual employers. Please feel free to contact me for further information. We would be pleased to meet with you to discuss these comments and any other issues on which you are seeking input. We look forward to working with you in the future.

Yours truly,

Randy DeFrehn
Executive Director

CMS-4068-P-1239

Submitter : Mr. Carlos Ortiz **Date & Time:** 10/04/2004 08:10:02

Organization : CVS/pharmacy

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

Please accept these comments on behalf of CVS/pharmacy regarding the proposed rule addressing Medicare Program: Medicare Prescription Drug Benefit, CMS 4068-P, RON-0938-AN08.

CMS-4068-P-1239-Attach-1.doc

CARLOS R. ORTIZ, R.Ph.
Vice President of Government Affairs

September 30, 2004

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Subject: Medicare Program: Medicare Prescription Drug Benefit, CMS 4068-P, RIN-0938-AN08

To Whom It May Concern:

CVS/Pharmacy is providing comments with regard to the proposed rule published August 3, 2004. This rule would implement Title I of the Medicare Modernization Act of 2003 that establishes the voluntary Medicare Part D prescription drug benefit.

CVS operates over 5,300 pharmacies in 36 states and the District of Columbia. CVS is the largest provider of out-patient prescription drugs in the United States. As such, our expectation is that CVS will be a major provider of pharmacy services to Medicare recipients under the Part D program.

Section 423.30-423.50 – Issues Relating to Eligibility and Enrollment (Subpart A)

The confusion that has surrounded the Medicare discount card demonstrates the need for clear and understandable materials for Medicare recipients. CVS would also encourage CMS to recognize the role of the pharmacist in helping recipients to understand this benefit. Some of the components of these materials would include:

- The network status of a pharmacy and whether the pharmacy is a preferred or non-preferred pharmacy.
- The eligibility status of the recipient, whether they have met their front end deductible, and whether they have reached a gap in coverage (ie. the donut hole).
- This information must be provided to the pharmacist via an on-line real time basis.
- The experience with Medicare recipients, who were eligible for the $600 Transitional Assistance and failed to enroll, shows a definite need for special attention to be directed to the Medicare/Medicaid dual eligible. CVS would encourage CMS to allow for a transitional period for these dual eligible beneficiaries. We would also encourage an automatic enrollment process for these individuals.

Section 423.100 – Definition of Covered Part D Drugs

Options for Dispensing Fees – 69 Federal Register 46647-48

Most Medicare recipients will receive their Part D benefits from private insurers or prescription benefit managers (PBMs). CVS is concerned that these entities will attempt to utilize dispensing fees usually reserved for private insurers for this program. The complexity of providing services to this population, because of issues such as coordination of benefits, gaps in coverage, determination of front end deductibles, product and patient eligibility, etc. makes this program considerably more difficult. Recent studies, including the newly enacted California Medicaid dispensing fee, showing that the dispensing fee has to be in excess of $7 to adequately reimburse pharmacies for providing these services.

Section 423.104 – Requirements relating to Qualified Precription Drug Coverage

Access to negotiated prices

Subsection(h) of this section requires pharmacies to pass through negotiated prices during coverage gaps and for non-covered formulary drugs. This requirement amounts to nothing less than price controls on retail pharmacies. While this burden is extended to retail pharmacies, no such burdens are required of pharmaceutical manufacturers, or plan sponsors. Plan sponsors should not be able to keep any "pharmacy spreads" on prescriptions. Thus, they should not be able to reimburse pharmacies at a lower rate than they are charging the plan for filling the prescription.

Section 423.120 – Access to Covered Part D Drugs

Section 423.120(a)(1)-(5) – Issues relating to access to pharmacies

The legislative history demonstrates that it was the intent of Congress to require plans to comply, at a minimum, with the Department of Defense TriCare access standards. These standards require that 90% of Medicare beneficiaries must live within 2 miles of a participating pharmacy in an urban area, 90% of recipients in a suburban area must live within a 5 mile radius of a participating pharmacy, and 70% of recipients living in rural areas they must live within a 15 mile radius of a participating pharmacy. The proposed rule should also clearly define whether these distances are geographic or driving distances.

Averaging Access Standards

The proposed rules allow plans to meet these standards by averaging. CVS believes that each plan must meet these standards in each state and in region in which they operate. Allowing them to average the access standards could create areas where Medicare recipients lack adequate accessibility to a participating pharmacy. For

example, in Pennsylvania, averaging could result in a situation where Philadelphia is more than adequately served while Pittsburgh is not.

Creating "Preferred Pharmacy" Network

The proposed rule also allows plans to use this averaging methodology when creating networks of "preferred pharmacies" and "non-preferred pharmacies". By utilizing this method, the plan could create a higher cost non-preferred network that meets the TriCare access standards and at the same time create a lower cost preferred network that does not meet the standard. The proposed rule should be changed to require that all networks meet the TriCare access standard.

Section 423.120(a)(4) – Contracting Terms with Pharmacies and Prohibition of Transferring Insurance Risk

This section and Congress clearly prohibited plans from requiring pharmacies to accept insurance risk as a condition of participation. The proposed rule defines insurance risk as "risk that is commonly assumed by insured licensed by a state". It further states that it should not include payment variations due to performance based measures. Although these performance based incentives are common in the market place, they are usually in addition to the basic reimbursement. They represent additional payments for meeting certain objectives and there are no deductions from the basic payment, if these objectives are not met.

The final rule should prohibit plans from utilizing a variation of the system detailed above to require pharmacies to accept any contractual terms that would require them to accept lower payment rates if a plan experiences cost over runs. The plans should also cleanly identify to the pharmacy the pricing source that they will use for payment.

Section 423.120(a)(6) – Level playing field between mail order and network pharmacies

The Legislative Record shows that it was the intent of Congress to allow community pharmacies to provide a 90-day supply with no artificial cost sharing that would "coerce" recipients to obtain their maintenance medication from a mail order entity. Thus, the only additional cost to the recipient should be the difference in the negotiated price for the covered drug at the network pharmacy and the mail order pharmacy. With this in mind, the definition of "negotiated price" should reflect the price to the plan net any rebates, discounts or other price concessions paid to the plan for a similar drug quantity obtained from either the retail pharmacy or the mail order pharmacy. These price concessions should be applied directly to reducing the cost of the prescription. The plan should not be allowed to use the price concessions to artificially lower the cost of mail order prescriptions.

Section 423.153(b)) – Quality Assurance Programs

The preamble of the proposed rule contains extensive discussion of quality assurance programs the plans should incorporate. CVS fully supports the incorporation of quality assurance programs. However, rather than requiring the prescription drug plans to establish their own quality assurance programs, the role of the plans should be to develop a system that ensures that the provider has established a quality assurance program and measures the value of such programs. The preamble also states that future reporting of error rates may be required to allow recipients to compare the quality of service in choosing a plan. All studies involved in accessing quality assurance plans have shown that the most effective quality assurance programs allow for an anonymous and confidential reporting structure with legal protection from discovery.

Section 423.851-.875 – Subpart Q – Guaranteeing Access to Choice of Coverage (fall back plans)

These sections contain the requirements that the government establish a fall back plan in the event there is a region where there are not two choices of either a risk bearing PDP or MA-PD. The final rule should make clear that these fall back plans must comply with all the access and quality standards that PDP and MA-PD must adhere to. Additionally, the fall back plan should also be required to adequately reimburse pharmacies with regard to a dispensing fee and an appropriate product cost reimbursement.

In conclusion, CVS appreciates this opportunity to comment with regard to the proposed regulations regarding the Medicare Part D portion of the Medicare Modernization Act. We would urge CMS to use its discretionary power to amend the proposed rule to address our concerns with regard to adequate reimbursement for pharmacies, access standards, quality assurance issues, and education of recipients and pharmacies.

Sincerely,

Carlos R. Ortiz, R.Ph
Vice President of Government Affairs

CO:bab

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CMS-4068-P-1240

Submitter : Mr. Robert McKay **Date & Time:** 10/04/2004 08:10:14

Organization : PharmaCare

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

This is PharmaCare's response to Medicare Drug Benefit; Comments to
The Proposed Rule.

CMS-4068-P-1240-Attach-1.rtf

Medicare Drug Benefit; Comments to The Proposed Rule

Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)

Contents

Background, Intent and Acknowledgement

Founded in 1994, PharmaCare is a wholly owned subsidiary of CVS Corporation, the nations largest operator of retail pharmacies with annual sales in excess of $33 billion. PharmaCare has more than 3,000 employees and is the most diversified pharmaceutical care management company in the country. PharmaCare holds leading positions in pharmacy benefit management services, mail-service pharmacy, specialty drug pharmacy and clinic pharmacy services. PharmaCare is also a Medicare approved national drug discount card sponsor. By the conclusion of 2004, over 140,000 Medicare beneficiaries will have enrolled in ***myPharmaCare***.

Through this document PharmaCare offers comment to the proposed rule (42 CFR Parts 403, 411, 417 and 423; Medicare program; Medicare Drug Benefit). The creation of Prescription Drug Plans (PDP's), Limited Risk Plans and Fallback Plans through the Act are of potential interest to PharmaCare. However, some aspects of the proposed rule, which we address herein, raise concerns that should be addressed by CMS. These concerns are not unique to PharmaCare as they are, in many respects, shared by our competitors. We are sure that should CMS publish a final rule that satisfactorily addresses these issues that all Medicare beneficiaries will be better served.

Finally, PharmaCare appreciates the opportunity to make comment to this proposed rule. Today PBM's are providing millions of Medicare beneficiaries drug benefits through employer sponsored plans and Medicare Choice contractor plans. Consultation between PBM's and CMS is the right course of action. Accordingly, PharmaCare offers our services freely to CMS now, and throughout the process ahead that will conclude with the successful implementation of Medicare Part-D in 2006.

The Proposed PDP Regions

Introduction. PharmaCare attended the open forum held in Chicago, IL (Rosemont) regarding the formation of regions for MA-PD and PDP's. The presentations made indicated that serious study and analysis had been given to each option under consideration. In the broader context the issue of fewer versus many regions clearly dominates the debate at hand.

Discussion. PharmaCare offers the following comments.

Comments About Fewer Regions. Of the two options being considered (10 regions or 11) we believe that the option for 11 regions has greater merit. It is our view that this option represents a better distribution of markets, or concentrations of beneficiaries, over the 10-region option. However, while fewer regions create larger pools of beneficiaries for PDP's to market to, they also offer unique barriers that also inhibit the scale value of such large multi-state regions. State insurance regulations are the most noteworthy barrier. State licensure and oversight would will prove burdensome for PDP's. As the proposed rule offers PDP's no safe-harbor in this regard, PDP's will not freely enjoy the scale inherent in multi-state regions, but will instead be forced to operate as multiple state based entities within a region. This will increase cost and hamper the ability of PDP's to effectively capitalize on the larger pools of beneficiaries offered through multi-state regions.

Comments About Many Regions. Of the four regions being considered (32, 34, 37 and 50) we believe that the option of 50 regions is most appealing and the option for 37 regions has merit as well. In summary the 50-region option simplifies many regulatory and operational considerations by equating region with state. Of the remaining regional considerations, we believe the option for 37 regions does the better job of joining several states to form the few multi-state regions. In these cases the 37 region option does the best job of preserving the

integrity of traditional regional markets; e.g. Northern New England, Pacific Northwest, etc. While not by any means uniform, insurance considerations should vary less among the states joined to form these few multi-state regions.

Recommendation. For the reasons discussed above, PharmaCare recommends many regions versus few, with 50 regions being recommended above all other considerations. We appreciate the goals and intent of CMS through the concept of larger multi-state regions. However, given the pace of this program, the challenges posed by such an approach would be too numerous and prove a barrier to program implementation. The issue of multi-state regions is always a consideration CMS could revisit in the future.

Issues Related to TROOP

Introduction. PharmaCare has studied the proposed rule regarding TROOP (True Out Of Pocket) and has participated in CMS special open door forums regarding TROOP as well. Of all of the topics worthy of comment, TROOP represents a topic in need of serious comment by industry and re-consideration by CMS.

Discussion. At the heart of the issue with TROOP is the requirement to coordinate benefits with the beneficiary's Other Health Insurance (OHI) on a real time basis. While there are several issues that make TROOP coordination problematic, it is the issue of real time coordination that is most serious.

Under the proposed rule PDP's would be required to assure TROOP through coordination with OHI as self-identified by the beneficiary upon their application. While the intent of TROOP can easily be appreciated, the practicality of coordinating OHI on a real time basis for pharmacy benefits is very problematic. In summary, with respect to pharmacy claims, the activity of claims adjudication corresponds to the actual time of service; a process that takes less than 5 seconds. This differs significantly from the process used for medical billing. Under medical claims management, claims adjudication is not associated real time with the performance of service, but instead occurs days, weeks even months later, and this lag time makes OHI coordination possible under a medical claims approach. The rule, as written, approaches TROOP coordination in the context of a medical claims management model, not the existing pharmacy model. And, it assumes this model is transferable to pharmacy, when it is not. The approach to TROOP in the proposed rule is inconsistent with pharmacy claims management standards and practice, and should be changed in the final rule. We offer amplification below to support this recommendation.

Are pharmacies the answer? Pharmacies are not the solution to accomplish TROOP. Pharmacies do not and cannot split claims. The point of sale (POS) systems used universally by pharmacies direct each claim to a designated single payor; not multiple payors. The transaction is processed in 2 to 3 seconds with a response as either paid or denied, but only from the one payor. With respect to the relationship between the patient and the pharmacy, the pharmacy is only a provider. It has no way of knowing what the beneficiary disclosed regarding OHI when the beneficiary made their application to the PDP. The pharmacy will only know to submit a beneficiaries claim to a PDP when beneficiary presents a prescription and their PDP program card.

Are PBM's the answer? Given that pharmacies are not the solution for TROOP, the question is rightfully directed to PBM systems for consideration. As the PBM system receives claims from pharmacy systems, is it possible that that the PBM system can coordinate TROOP on a real time basis? The answer is, no. The adjudication process is bi-directional only: e.g. between the pharmacy, where the claim is originated, and the PBM. PBM systems do not systematically redirect claims to other health insurance providers in real time before responding to the claims originator, the pharmacy. Coordination of benefits is most often accomplished by PBM systems by denying claims for plan members where the plan sponsor has indicated the existence of other health insurance through the eligibility file. Under these conditions a beneficiary would be denied until the plan sponsor indicated they were satisfied that the member's OHI had been exhausted. Such a determination would occur directly between the beneficiary and the plan sponsor, and outside of the claims adjudication process.

The PBM's role in coordinating TROOP is further complicated by other considerations. Today, PBM's contract almost entirely with group payers (e.g. self-insured employer plans, managed care plans, etc.), and not individuals. Should a group payer have just one source of OHI, it ***may*** be possible for the PBM to coordinate with that singular source in real-time under unique conditions;

(e.g. the PBM already had a contractual relationship with the other health insurance payer). However, as Part-D is not a group product, enrolling beneficiaries may have OHI from any number of sources (e.g. an employer wrap-plan; a Med-Sup plan; a drug manufacturer plan; etc.). As written, the proposed rule would require that TROOP be coordinated real-time with each and every OHI source identified by the beneficiary. This would require the PBM to establish contracts and real-time electronic claims processing procedures with an open-ended number of OHI sources. This is unrealistic. First, as discussed previously, PBM systems are not configured to redirect claims to OHI providers in real-time. Second, assuming the first problem could be overcome, it is unrealistic to assume that a PBM could successfully conclude contract terms and on-line claims transaction coordination with every source of OHI. Many of these sources would not even be capable of on-line claims transactions. In conclusion, PBM's and their systems are not the solution for assuring accurate coordination of TROOP.

Recommendation. PharmaCare recommends that CMS confer with the National Council for Prescription Drug Programs (NCPDP). NCPDP serves an important role for all industries associated with pharmacy programs. Most importantly they establish the electronic claims standards necessary to accomplish prescription drug program management. Together, NCPDP and CMS can coordinate a workable solution for TROOP.

Also, CMS should give serious consideration to allowing PDP's to simply deny acceptance for any applicant who indicates they have OHI. The approach to TROOP under the proposed rule is a source of unacceptable risk to potential PDP's in terms of investment and accountability. As PDP's are risk based providers they should be asked to only assume risk for beneficiaries where accurate risk accountability can be assured. Beneficiaries with OHI are perfectly suited for Limited Risk Plans or Fallback Plans, and we recommend that PDP's should not be required to enroll such beneficiaries.

The Proposed Data Set

Introduction. PharmaCare participated in a CMS sponsored Open Door Forum (ODF) on September 9, 2004 regarding the Bidders' Data Set for Prescription Drug Plans. The forum's intent was for the American Academy of Actuaries Working Group to identify the high-priority data needs for bidders, to summarize their discussions with CMS on developing a bidders data set, and to present a plan for making essential data available in a timely manner. A summary of the ODF went on to describe the need for a data set as follows: *A data set including detailed information on drug utilization is an essential element in facilitating bids by insurers to provide prescription drug coverage.*

Discussion. PharmaCare concurs that an accurate and comprehensive data set is an essential element to facilitate bidding. The ODF, however, pointed to significant problems with the approaches being pursued by the Academy's Working Group.

The data sources available to the Working Group are of little value as they are incomplete and dated. The Medicare Current Beneficiary Survey (MCBS) has significant limitations and shortcomings as an instrument for producing the necessary drug utilization information needed by potential PDP bidders. The 2001 FEP retirees' data does not reflect the many new drugs that have come to market since that time nor the changes in drug prices. In summary, these sources are inadequate and incomplete.

Recommendation. To gain the confidence of PDP's, CMS should endeavor to secure credible sources of data for the Academy's Working Group to analyze. Such sources are readily available. Three excellent sources are discussed below.

1. TRICARE. The TRICARE pharmacy benefit program includes a program unique to over 1.5 million retirees. CMS should coordinate the transfer of both a historical drug utilization file from the Department of Defense's TRICARE Management Activity (TMA) and update files as necessary. The TRICARE TMA subscribes to the standards established by NCPDP. The creation of file reflecting the data fields and layout standards of NCPDP is a task that can be easily accomplished by TMA or its contractor. PharmaCare recommends CMS act quickly as this approach to securing valuable and relevant data represents a low or no cost activity that can be accomplished in days.

2. Pharmacy Benefits Managers. Today PBM's administer pharmacy benefit programs for millions of Medicare beneficiaries through employer sponsored plans and Medicare Choice contractor plans. No better source of data is available than that which can be provided by PBM's. PharmaCare recommends that CMS ask PBM's to voluntarily offer the Working Group data files reflecting the utilization of Medicare age beneficiaries. The process would result in the largest, most robust data set possible and provide the Working Group the information they need to produce quality results.

3. Chain Drug Stores. The National Association of Chain Drug Stores (NACDS) is an excellent source of data. Pharmacies are stakeholders in this endeavor and desire a well-developed program. Their membership, if approached, would freely cooperate with CMS by sharing data.

Issues Related to PDP's and Risk

Introduction. It will be the PBM industry that makes administration of the Medicare Drug Benefit possible. However, their role as PDP's or in association with PDP's is questionable unless the proposed rule is modified. Since the enactment of MMA in December 2003, some in the PBM industry have made public comment to the issues of PDP's being treated as insurers and of the requirement to assume risk. These requirements are in inconsistent with commercial practices where PBM's are not insurers and do not assume risk. Consequently, we recommend that CMS appreciate that unless the final rule satisfactorily addresses these issues PBM's may not view Medicare as such an important new market opportunity, which in turn could place the implementation of the Medicare Drug Benefit in jeopardy.

Discussion. Risk posses many new considerations for PBM's. Several of these considerations are discussed below, and illustrate why some PBM's have indicated they may be required to forgo the opportunities presented by MMA unless the final rule is modified.

In the context of an insurer risk is defined as "the danger or probability of loss". Auto insurers, for example, know that not every policyholder will file a claim, making the probability of loss low among most policyholders and high only among a few at one time. It is the excess premium secured from non-claimant policyholders that pay for the excess costs of the few claimant policyholders. With respect to prescription drugs, however, the opposite is true. The probability of loss in never low because it can be assumed that most policyholders will be claimants and few will not. Even worse, in the case of the elderly it can be assumed that substantially ALL elderly beneficiaries will be claimants. And, as drug therapy is the primary form of treatment today for almost all chronic medical conditions that afflict the elderly, the possibility of radically curtailing drug use is unrealistic, especially given the overwhelming efficacy offered by most drug

therapies today. In summary the elderly are a very bad risk because there is almost certainty of loss.

The issue of adverse selection is also very problematic for PBM's. As the Medicare Drug Benefit will be voluntary, only the sickest beneficiaries can be expected migrate to the new Part-D leaving the premium payments for lower utilizing healthier beneficiaries unavailable to supplement the excess costs of the adverse membership. This is not conjecture, but reality. Medicare Choice contractors struggled under the weight of adverse selection for years resulting in withdrawal from numerous counties across the country. Adverse selection is assured for a PDP under the Medicare Drug Benefit.

And finally, PBM's are not insurers. Requiring PDP's to be insurance companies creates a significant new burden for PBM's and creates unintended business risk. In the precious little time available to prepare for this program a PBM faces many costly hurdles associated with state licensures. This is unknown territory for PBM's and States alike. One concern PBM's have that licensing actions may in fact trigger an unintended response from states whereby they attempt to bring substantially all PBM operations under state insurance authority. This would be a costly struggle to defend against. And, should the states succeed, it would prove very problematic to the PBM industry as it would add significant cost and seriously hamper the evolution of business practices, benefit design and even quality management programs.

Recommendation. PharmaCare recommends CMS publish a final rule that lowers the barriers posed by insurance and risk. The final rule should set out a safe harbor for PDP's with respect to state insurance regulations. And, in order to lower the adverse risk associated with Medicare aged beneficiaries, the government should consider adopting a final rule that limits the risk faced by PDP's. One example includes creating risk-free sources of revenue for PDP's such as separate program management fees rather than all-inclusive premiums.

In another example CMS could offer to cap the PDP's risk to a maximum loss. Changes such as these are important as they will serve to attract prospective PDP's. A final rule that does not mitigate the implications of insurance and risk may not attract PBM's to this program as PDP's.

Risk and The Issue of Any Willing Provider

Introduction. The issue of Any Willing Provider (AWP) is problematic for PDP's as risk bearing entities. Also, the proposed rule offers guidance that is impracticable to potential PDP's. PharmaCare believes the proposed rule should be modified to reposition the intended role of AWP to what we believe was intended by the authors of MMA.

Discussion. The MMA and the proposed rule make reference to both Any Willing Provider and pharmacy network access standards. In the context of commercial practices, the two are in some ways redundant. Prescription plan sponsors seeking pharmacy network services from a PBM, for example, specify access standards to ensure a PBM contracts with sufficient providers, but not all providers. In the process of assembling a network a PBM uses the leverage offered by the access standards to negotiate price knowing that more aggressive prices can be secured if there is no requirement to allow the participation of any willing provider. Under a requirement to assemble a network where any willing provider may participate, no such leverage exists and no access standard may be assured as providers participate at will.

It is the opinion of PharmaCare that the authors of the Act included access standards as a means for prospective PDP's to establish network contracting leverage while protecting the interests of beneficiaries. This is fundamentally consistent with any entity bearing risk and assures the government of the best possible basis of cost. And, the Federal Government also shares this opinion. The Federal Trade Commission has concluded that Any Willing Provider requirements are fundamentally in conflict with the ability of any network assembler to secure best price. Please refer to the FTC's web site at http://www.ftc.gov/opa/2004/04/ribills.htm for an example of a recent example of the Commission's position on AWP.

PharmaCare also believes the issue of Any Willing Provider has also been misinterpreted as presented in the proposed rule. The proposed rule infers that Any Willing Provider is a requirement of a PDP, which we believe incorrectly interprets the intent of the Act. PharmaCare believes the Act discusses Any Willing Provider in the context of a right of the beneficiary, not a requirement of a plan sponsor or PDP. It is common for States to extend the privilege of pharmacy Freedom of Choice (FOC) to the membership of health insurance carriers; the terms Freedom of Choice and Any Willing Provider are often used interchangeably in the context of a member or beneficiary. But this privilege offered by States to members does not necessarily flow by extesnion to health insurers as a requirement. In summary, such laws are intended to reinforce and support the freedom of individuals to secure service from providers of their choice, but not by extension require health insurers to contract with them.

Recommendation. PharmaCare recommends that the final rule clarify the intent of the Act by specifying that the law protects the right of each beneficiary to choose their own provider, but does not require the PDP to include any willing provider in their network. And, it is not sufficient enough for CMS to allow PDP's to designate such providers as "non-preferred" or "out of network" if it still requires they contract with them. In-network providers will not negotiate best price if they know other providers can participate through circuitous means. The rule should clearly state that while beneficiaries may use providers of their choice, benefits will not be payable unless they use a contracted in-network provider of the PDP. The final rule should also clarify that the access standards set out in the Act are the principle methodology for assuring adequate access and drop any reference to AWP with respect to the establishment of networks.

Medication Therapy Management (MTM)

Introduction. The final rule should make clarification with respect to Medication Therapy Management (MTM) and the role of PDP's and providers. The proposed rule raises concerns that PDP's may be required to fund MTM by themselves.

Discussion. Considerable attention has been paid to the topic of MTM. However, the proposed rule should make clarifications in several regards. First, the proposed rule leaves questions unanswered as to the source of funding for MTM services. One could interpret the proposed rule as inferring that MTM services will be paid for by PDP's. This raises concerns. Assume a provider (e.g. a pharmacy) performs an MTM service. If the obligation to pay for that service falls on the PDP then where will those funds come from? If the answer is, from the fixed premium's paid by the beneficiary and Medicare, then this poses significant risk to PDP's. Such services would represent an open checkbook to providers who could perform them at will and make payment demands on a PDP, who in turn must pay from a fixed pool of premium revenue. Even worse the MTM activity could actually cause increased drug use, which is in conflict with a fixed price risk-based program.

The proposed rule should also clarify the MTM is an activity that can be performed by the PDP itself and is not the exclusive domain of others like pharmacists, nurses and physicians. PDP's will be in the best position to perform MTM themselves as they will have all available utilization data available. The final rule should clarify that MTM is a service that may be performed by providers as exclusively determined by the PDP. Otherwise the PDP will lose control of where and how these services are performed.

And, finally, the final rule should make it clear that MTM is not an exercise or activity that is exclusively performed in person between a health care provider

and the beneficiary, but may also be performed remotely by phone, internet and by paper. These recommended approaches are very cost effective and can reach more beneficiaries than in-person approaches. And, many quality programs already exist that employ these approaches.

Recommendation. The final rule must clarify the issue of MTM. MTM cannot be an at will activity of any willing provider. PDP's must hold the authority to establish who may provide MTM to their program membership. The final rule must also clarify from what source of funds the services of MTM will be paid. PharmaCare recommends that CMS pay for MTM separately and not include MTM funding as part of an inclusive premium calculation. MTM payments should also not be subject to risk as the activity of MTM will, in many cases, cause increases in drug use (e.g. under-utilization, therapy initiation, etc.).

Beneficiary Late Enrollment Penalty

Introduction. The formula for imposing beneficiary late enrollment fees, as discussed in the proposed rule, is not aggressive enough to promote rapid beneficiary enrollment in PDP's.

Discussion. Underlying the intent of the MMA is the belief that the government's best interest is served when industry participates on a risk basis to share the financial management challenge posed by Medicare beneficiaries. To attract the most qualified entities to serve as PDP's CMS should make every effort to ensure fast and rapid adoption of Medicare Part-D through PDP's. To this end, the proposed late enrollment fee is insufficient. PharmaCare does not believe $0.36 per month is enough of a fee to motivate beneficiaries to rapidly adopt Medicare Part-D.

Recommendation. PharmaCare recommends that CMS consider a black-out period where enrollment is not authorized rather than a late penalty. For example, offering beneficiaries the right to enroll only in November and December of each year for proceeding calendar year, with January through October being closed to enrollment (e.g. the black-out). Such an approach would create a sense of urgency among beneficiaries. The late enrollment penalty, as proposed, will only promote a "wait and see" attitude. If CMS is to attract prospective PDP's, then the final rule should include an approach that creates a sense of urgency for beneficiaries to enroll in Medicare Part-D through a PDP.

Conclusive Comments & Contact Information

PharmaCare again extends our thanks to CMS for the opportunity to make comment to this proposed rule. The Medicare Drug Benefit can only be viewed as a sea change event. As such PharmaCare very much desires to take part in this exciting program. We recognize that CMS has precious little time to implement this program, however, if prospective PDP's are to value the opportunity created by the Act then CMS should give serious consideration to our recommended modifications of the proposed rule. The modifications recommended by PharmaCare are, in our opinion, modest yet essential to assuring a workable program. PharmaCare offers our service freely to CMS for the purpose of concluding a final rule.

Should CMS desire to contact PharmaCare regarding these topics, all inquiries may be made to the following individual:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
DEPARTMENT FOR REGULATIONS & DEVELOPMENT

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CMS-4068-P-1241

Submitter : James Finley **Date & Time:** 10/04/2004 08:10:09

Organization : National Association of Social Workers

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

See attached comments

CMS-4068-P-1241-Attach-2.doc

CMS-4068-P-1241-Attach-1.doc

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

The National Association of Social Workers (NASW) welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. NASW is the largest professional social work organization with more than 153,000 members nationwide. NASW promotes, develops, and protects the practice of social work and social workers, while enhancing the well being of individuals, families, and communities through its work, service, and advocacy. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

Coverage of Dual Eligibles (§ 423.34)

Of grave concern is the impact of the new Medicare drug benefit on those beneficiaries who currently have drug coverage through their state Medicaid programs, i.e. the dual eligibles. CMS must ensure that these very vulnerable beneficiaries receive coverage for the medications they need under the new drug benefit and are not harmed or made worse off when their drug coverage is switched from Medicaid to Medicare.

Based on social workers experience with this group of beneficiaries, we are gravely concerned that the proposed regulations would cause harmful disruption in care and inadequate drug coverage for dual eligibles. In particular, the proposed regulations do not address how access to needed medications by dual eligibles will be maintained when their drug coverage is switched from Medicaid to Medicare.

We urge CMS to take account of the unique circumstances and needs of this population, and delay transfer of drug coverage from Medicaid to Medicare for the dual eligibles for at least six months to allow adequate time to educate and enroll these vulnerable and often hard-to-reach individuals and to ensure they receive the drug coverage to which they are entitled.

CMS must also address the real threat of adverse health outcomes facing dual eligibles. Under the proposed rule, dual eligibles would effectively be forced to enroll in the lowest cost plans in their areas because the low-income subsidy they will receive will only cover the premium for these plans (and automatic enrollment would require placement in a low-cost plan). While it is critical that the transfer from Medicaid to Medicare drug coverage maintain continuity of care, the proposed regulations provide no such protection. To the contrary, the formularies for these low-cost drug plans will not be as comprehensive as the drug coverage these individuals currently have through Medicaid. Without access to the coverage they need, dual eligibles would have no real choice but to switch medications. Yet changing medications is for those with complex conditions is both very difficult and potentially dangerous. For example, abrupt changes in psychiatric medications bring the risk of serious adverse drug reactions and interactions and the potential for a severe loss of functioning.

With respect to beneficiaries with mental illness, these regulations must give meaningful effect to the concern Congress itself voiced, stating in the conference report on the Act that: "[i]f a plan chooses not to offer or restrict access to a particular medication to treat the mentally ill, the disabled will have the freedom to choose a plan that has appropriate access to the medicine needed. The Conferees believe this is critical as the severely mentally ill are a unique population with unique prescription drug needs as individual responses to mental health medications are different." [Report No. 108-391, pp. 769-770] Unfortunately, the proposed rule does not adequately provide the protection for people with mental illness that Congress called for. We urge that the regulations be revised to provide for "grandfathering" coverage of psychiatric medications for dual eligibles into the new Part D benefit, as a number of states have done in implementing preferred drug lists for their Medicaid programs.

Lastly, for the dual eligibles in particular, CMS must fund collaborative partnerships with organizations representing people with disabilities and other vulnerable populations. Such partnerships will be critical to an effective outreach and enrollment process. Targeted and hands-on outreach to vulnerable Medicare beneficiaries, especially those with low-incomes, is vitally important in the enrollment process. We strongly urge CMS to develop a specific plan for facilitating enrollment of beneficiaries with disabilities and complex medical conditions in each region that incorporates collaborative partnerships with the state and local agencies and advocacy organizations that serve them.

Alternative, Flexible Formularies for Beneficiaries for Vulnerable Populations (§ 423.120(b))

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing deteriorating health, unnecessary hospitalizations and even death, on the other. Often, people with disabilities and complex medical conditions need access to the newest medications, because they have fewer side effects and may represent a better treatment option than older less expensive drugs. Many individuals have multiple disabilities and health conditions making drug

interactions a common problem. Frequently, extended release versions of medications are needed to effectively manage these conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects making it more important for the doctor to be able to prescribe the best medication for the individual. Often that pharmacological process takes time since many people with significant disabilities must try multiple medications and only after much experimentation find the medication that is most effective for their circumstance. The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury or debilitating side effects, even hospitalization or other types of costly medical interventions.

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs, and the enormous potential for serious harm (including death) if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations who:

- are dually eligible for Medicare and Medicaid;
- live in nursing homes, ICF-MRs and other residential facilities;
- have life threatening conditions; or
- have pharmacologically complex condition such as mental illness, Alzheimer's disease, multiple sclerosis, HIV/AIDS, and epilepsy.

Furthermore, new limits on cost management tools must be imposed for these vulnerable populations. We urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications that are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

Involuntary Disenrollment for Disruptive Behavior (§ 423.44)

The proposed regulation raises grave concerns in allowing Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" (§ 423.44(d)(2)). These provisions create enormous

opportunities for discrimination against individuals with mental illness and cognitive impairments. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and as a result they could also be subject to a late enrollment penalty increasing their premiums for the rest of their lives. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage.

As a matter of principle, for a critical safety net program such as Medicare prescription drugs for dual eligibles, NASW cannot support automatic disenrollment of this population under any circumstances. We are therefore alarmed that CMS has proposed an expedited disenrollment process that would undermine the minimal standards and protections included in the proposed rule. This expedited process proposal must not be included in the final rule. In addition, CMS must provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and must waive the late enrollment penalty for these individuals as well. The final rule must include the following protections:

- drug plans must be prohibited from disenrolling a beneficiary because he/she exercises the option to make treatment decisions with which the plan disagrees, including the option of no treatment and/or no diagnostic testing;
- drug plans may not disenroll a beneficiary because he/she chooses not to comply with any treatment regimen developed by the plan or any health care professionals associated with the plan;
- documentation provided to CMS arguing for approval of a plan's proposal to involuntarily disenroll an individual must include:
  - documentation of the plan's effort to provide reasonable accommodations for individuals with disabilities in accordance with the Americans with Disabilities Act; and
  - documentation that the plan provided the beneficiary with appropriate written notice of the consequences of continued disruptive behavior or written notice of its intent to request involuntary disenrollment; and
- drug plans must provide beneficiaries subject to involuntary disenrollment with the following notices:
  - advance notice to inform the individual that the consequences of continued disruptive behavior will be disenrollment;
  - notice of intent to request CMS' permission to disenroll the individual; and
  - A planned action notice advising that CMS has approved the plan's request for approval of involuntary disenrollment.

Appeals Procedures (§§ 423.562-423.604)

The appeals processes outlined in the proposed regulations are overly complex, drawn-out, and inaccessible to beneficiaries. Under these proposed rules, there are too many levels of internal appeal that a beneficiary must request from the drug plan before receiving a truly independent review by an administrative law judge (ALJ) and the

timeframes for plan decisions are unreasonably long. In order to qualify for a hearing by an ALJ, beneficiaries must first request a coverage determination or exception from a tiered cost-sharing scheme or formulary which can take between 14 and 30 days, unless a plan honors a beneficiary's request that the determination or exception be expedited in which case it could still take up to 14 days. To appeal adverse determinations or exception decisions, beneficiaries must request plans to review their decision again and make a redetermination within 30 days unless the beneficiary paid out-of-pocket for the medication at issue, in which case the plan has 60 days to decide. Even if a plan honors a request to expedite a redetermination, the deadline for plans to make a decision could be as long as 14 days. Following a redetermination, beneficiaries may appeal to a so-called independent review entity for a reconsideration of their case, but these entities will not be authorized to review or question the criteria plans use to evaluate exceptions requests. The proposed rules do not even set deadlines for reconsideration decisions. After receiving a reconsideration decision, beneficiaries are only allowed to appeal to an administrative law judge if the amount in controversy meets a threshold level of $100 and it is unclear how CMS will calculate whether a beneficiary has met this threshold.

In addition to imposing unreasonable delays and burdens on beneficiaries, these appeal processes are far from transparent. Drug plans would be authorized to establish their own criteria for reviewing determination, exceptions, and redetermination requests and these criteria will vary from plan to plan. Plans would also be authorized to establish varying degrees of paperwork requirements for beneficiaries and their prescribing physicians who wish to request exceptions from tiered cost-sharing schemes or formularies. Far from ensuring that beneficiaries' rights are protected, which should be their primary function, these procedures would actually impede the right of beneficiaries to a fair hearing.

Beneficiaries with disabilities and complex health needs often have an extremely limited capacity to navigate grievance and appeals procedures. To accommodate the special needs of these beneficiaries and others who are vulnerable or with low income, CMS must establish a simpler process that puts a priority on ensuring ease of access and rapid results for beneficiaries and their doctors and includes a truly expedited exceptions process for individuals with immediate needs, including individuals facing health care crises, which should be modeled after the federal Medicaid requirement that states respond to prior authorization requests within 24 hours.

We also urge CMS to require plans to dispense a temporary supply of drugs in emergencies. The proposed system does not ensure that beneficiaries' rights are protected and does not guarantee beneficiaries have access to needed medications. For many individuals with disabilities such as epilepsy, mental illness or HIV, treatment interruptions can lead to serious short-term and long-term consequences. For this reasons the final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

Outreach and Enrollment (§ 423.34)

The proposed regulations do not adequately address the need for collaboration with state and local agencies and community-based organizations on outreach and enrollment of beneficiaries with disabilities and complex health conditions. In the conference report for the Medicare Modernization Act, Congress directed that "the Administrator of the Center for Medicare Choices [sic] shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriated [sic] access to pharmaceutical treatments for mental illness" (Report No. 108-391, pp. 769-770).

To respond to Congress's concern with ensuring enrollment and comprehensive coverage for beneficiaries, CMS must partner with community-based organizations focused on addressing the needs of vulnerable beneficiaries and the state and local agencies that coordinate benefits for them. Beneficiaries with special needs will most likely turn to organizations that they know and trust with questions and concerns regarding the new Part D drug benefit. Making information and educational materials available at these sites will help inform beneficiaries with mental illness about the new benefit, but providing community-based organizations with pamphlets and brochures alone is not adequate. To answer the many difficult, detailed, and time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be needed. Social workers and community-based organizations can provide the kind of detailed help needed, but they will need additional resources.

CMS must develop a specific plan for facilitating enrollment of beneficiaries with special needs, in each region that incorporates collaborative partnerships with and additional funding for state and local public and nonprofit agencies and organizations focused on these needs. In addition, in their bids, drug plans should include specific plans for encouraging enrollment of often hard-to-reach populations.

NASW strongly urges that the concerns discussed above be addressed in order to ensure access to psychiatric medications under the Part D drug benefit for the many Medicare beneficiaries who need them.

Thank you for your consideration of our comments.

Sincerely,

Toby Weismiller, ASCW
Director, Professional Development and Advocacy

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

The National Association of Social Workers (NASW) welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. NASW is the largest professional social work organization with more than 153,000 members nationwide. NASW promotes, develops, and protects the practice of social work and social workers, while enhancing the well being of individuals, families, and communities through its work, service, and advocacy. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

Coverage of Dual Eligibles (§ 423.34)

Of grave concern is the impact of the new Medicare drug benefit on those beneficiaries who currently have drug coverage through their state Medicaid programs, i.e. the dual eligibles. CMS must ensure that these very vulnerable beneficiaries receive coverage for the medications they need under the new drug benefit and are not harmed or made worse off when their drug coverage is switched from Medicaid to Medicare.

Based on social workers experience with this group of beneficiaries, we are gravely concerned that the proposed regulations would cause harmful disruption in care and inadequate drug coverage for dual eligibles. In particular, the proposed regulations do not address how access to needed medications by dual eligibles will be maintained when their drug coverage is switched from Medicaid to Medicare.

We urge CMS to take account of the unique circumstances and needs of this population, and delay transfer of drug coverage from Medicaid to Medicare for the dual eligibles for at least six months to allow adequate time to educate and enroll these vulnerable and often hard-to-reach individuals and to ensure they receive the drug coverage to which they are entitled.

CMS must also address the real threat of adverse health outcomes facing dual eligibles. Under the proposed rule, dual eligibles would effectively be forced to enroll in the lowest cost plans in their areas because the low-income subsidy they will receive will only cover the premium for these plans (and automatic enrollment would require placement in a low-cost plan). While it is critical that the transfer from Medicaid to Medicare drug coverage maintain continuity of care, the proposed regulations provide no such protection. To the contrary, the formularies for these low-cost drug plans will not be as comprehensive as the drug coverage these individuals currently have through Medicaid. Without access to the coverage they need, dual eligibles would have no real choice but to switch medications. Yet changing medications is for those with complex conditions is both very difficult and potentially dangerous. For example, abrupt changes in psychiatric medications bring the risk of serious adverse drug reactions and interactions and the potential for a severe loss of functioning.

With respect to beneficiaries with mental illness, these regulations must give meaningful effect to the concern Congress itself voiced, stating in the conference report on the Act that: "[i]f a plan chooses not to offer or restrict access to a particular medication to treat the mentally ill, the disabled will have the freedom to choose a plan that has appropriate access to the medicine needed. The Conferees believe this is critical as the severely mentally ill are a unique population with unique prescription drug needs as individual responses to mental health medications are different." [Report No. 108-391, pp. 769-770] Unfortunately, the proposed rule does not adequately provide the protection for people with mental illness that Congress called for. We urge that the regulations be revised to provide for "grandfathering" coverage of psychiatric medications for dual eligibles into the new Part D benefit, as a number of states have done in implementing preferred drug lists for their Medicaid programs.

Lastly, for the dual eligibles in particular, CMS must fund collaborative partnerships with organizations representing people with disabilities and other vulnerable populations. Such partnerships will be critical to an effective outreach and enrollment process. Targeted and hands-on outreach to vulnerable Medicare beneficiaries, especially those with low-incomes, is vitally important in the enrollment process. We strongly urge CMS to develop a specific plan for facilitating enrollment of beneficiaries with disabilities and complex medical conditions in each region that incorporates collaborative partnerships with the state and local agencies and advocacy organizations that serve them.

Alternative, Flexible Formularies for Beneficiaries for Vulnerable Populations (§ 423.120(b))

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing deteriorating health, unnecessary hospitalizations and even death, on the other. Often, people with disabilities and complex medical conditions need access to the newest medications, because they have fewer side effects and may represent a better treatment option than older less expensive drugs. Many individuals have multiple disabilities and health conditions making drug

interactions a common problem. Frequently, extended release versions of medications are needed to effectively manage these conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects making it more important for the doctor to be able to prescribe the best medication for the individual. Often that pharmacological process takes time since many people with significant disabilities must try multiple medications and only after much experimentation find the medication that is most effective for their circumstance. The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury or debilitating side effects, even hospitalization or other types of costly medical interventions.

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs, and the enormous potential for serious harm (including death) if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations who:

- are dually eligible for Medicare and Medicaid;
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- have pharmacologically complex condition such as mental illness, Alzheimer's disease, multiple sclerosis, HIV/AIDS, and epilepsy.

Furthermore, new limits on cost management tools must be imposed for these vulnerable populations. We urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications that are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

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As a matter of principle, for a critical safety net program such as Medicare prescription drugs for dual eligibles, NASW cannot support automatic disenrollment of this population under any circumstances. We are therefore alarmed that CMS has proposed an expedited disenrollment process that would undermine the minimal standards and protections included in the proposed rule. This expedited process proposal must not be included in the final rule. In addition, CMS must provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and must waive the late enrollment penalty for these individuals as well. The final rule must include the following protections:

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- documentation provided to CMS arguing for approval of a plan's proposal to involuntarily disenroll an individual must include:
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timeframes for plan decisions are unreasonably long. In order to qualify for a hearing by an ALJ, beneficiaries must first request a coverage determination or exception from a tiered cost-sharing scheme or formulary which can take between 14 and 30 days, unless a plan honors a beneficiary's request that the determination or exception be expedited in which case it could still take up to 14 days. To appeal adverse determinations or exception decisions, beneficiaries must request plans to review their decision again and make a redetermination within 30 days unless the beneficiary paid out-of-pocket for the medication at issue, in which case the plan has 60 days to decide. Even if a plan honors a request to expedite a redetermination, the deadline for plans to make a decision could be as long as 14 days. Following a redetermination, beneficiaries may appeal to a so-called independent review entity for a reconsideration of their case, but these entities will not be authorized to review or question the criteria plans use to evaluate exceptions requests. The proposed rules do not even set deadlines for reconsideration decisions. After receiving a reconsideration decision, beneficiaries are only allowed to appeal to an administrative law judge if the amount in controversy meets a threshold level of $100 and it is unclear how CMS will calculate whether a beneficiary has met this threshold.

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Beneficiaries with disabilities and complex health needs often have an extremely limited capacity to navigate grievance and appeals procedures. To accommodate the special needs of these beneficiaries and others who are vulnerable or with low income, CMS must establish a simpler process that puts a priority on ensuring ease of access and rapid results for beneficiaries and their doctors and includes a truly expedited exceptions process for individuals with immediate needs, including individuals facing health care crises, which should be modeled after the federal Medicaid requirement that states respond to prior authorization requests within 24 hours.

We also urge CMS to require plans to dispense a temporary supply of drugs in emergencies. The proposed system does not ensure that beneficiaries' rights are protected and does not guarantee beneficiaries have access to needed medications. For many individuals with disabilities such as epilepsy, mental illness or HIV, treatment interruptions can lead to serious short-term and long-term consequences. For this reasons the final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

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To respond to Congress's concern with ensuring enrollment and comprehensive coverage for beneficiaries, CMS must partner with community-based organizations focused on addressing the needs of vulnerable beneficiaries and the state and local agencies that coordinate benefits for them. Beneficiaries with special needs will most likely turn to organizations that they know and trust with questions and concerns regarding the new Part D drug benefit. Making information and educational materials available at these sites will help inform beneficiaries with mental illness about the new benefit, but providing community-based organizations with pamphlets and brochures alone is not adequate. To answer the many difficult, detailed, and time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be needed. Social workers and community-based organizations can provide the kind of detailed help needed, but they will need additional resources.

CMS must develop a specific plan for facilitating enrollment of beneficiaries with special needs, in each region that incorporates collaborative partnerships with and additional funding for state and local public and nonprofit agencies and organizations focused on these needs. In addition, in their bids, drug plans should include specific plans for encouraging enrollment of often hard-to-reach populations.

NASW strongly urges that the concerns discussed above be addressed in order to ensure access to psychiatric medications under the Part D drug benefit for the many Medicare beneficiaries who need them.

Thank you for your consideration of our comments.

Sincerely,

Toby Weismiller, ASCW
Director, Professional Development and Advocacy

CMS-4068-P-1242

Submitter : Ms. Marcie Roth **Date & Time:** 10/04/2004 08:10:08

Organization : The National Spinal Cord Injury Association

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

see attached document

CMS-4068-P-1242-Attach-1.doc

National Spinal Cord Injury Association

6701 Democracy Boulevard • Suite 300-9 • Bethesda, Maryland • 20817

Telephone: (301) 588-6959 • Fax: (301) 588-9414 • Email: info@spinalcord.org • Web: www.spinalcord.org

September 30, 2004

Department of Health and Human Services
Centers for Medicare and Medicaid Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

To Whom It May Concern:

The National Spinal Cord Injury Association is pleased to submit comments on the proposed rule "Medicare Program;
Medicare Prescription Drug Benefit," 69 FR 46632. The National Spinal Cord Injury Association (NSCIA), founded in 1948, is the nation's oldest and largest civilian organization dedicated to improving the quality of life for hundreds of thousands of Americans living with the results of spinal cord injury and disease (SCI/D) and their families. This number grows by thirty newly-injured people each day.

Tens of thousands of individuals with spinal cord injury or disease (sci/d) are Medicare beneficiaries. NSCIA has grave concerns because the proposed rule does not provide critical protections for people with sci/d and almost 13 million other Medicare beneficiaries with disabilities and chronic health conditions. We offer the following essential recommendations:

DESIGNATE SPECIAL POPULATIONS WHO WILL RECEIVE AFFORDABLE ACCESS TO AN ALTERNATIVE, FLEXIBLE FORMULARY:

Individuals who have sci/d or other with serious and complex health issues must have access to the right medications. Such medications are critical to leading healthy, functioning, productive lives in the community as opposed to being institutionalized in nursing homes. Not having access to the correct medications can cause expensive hospital stays and life threatening events. People with sci/d and other disabilities may need the latest medications because they have fewer side effects.
Denying the suitable medication for an individual with a disability or chronic health condition can cause serious side effects, create unnecessary health problems, and lead to costly medical interventions. We strongly support the suggestion in the proposed rule that people with disabilities and other chronic conditions require special treatment due to unique medical needs, and the enormous potential for serious harm or death if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program.

We recommend the following groups be among those included in these exempt populations:

- people who are dually eligible for Medicare and Medicaid
- people with sci/
- people who live in nursing homes and other residential facilities
- people who have life threatening conditions
- people who have pharmacologically complex conditions

POSTPONE THE IMPLEMENTATION OF THE PART D PROGRAM FOR DUAL ELIGIBLES:

Dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. Among these are many with sci/d. They rely extensively on prescription drug coverage to sustain their basic health. Because of low income, they are the most vulnerable beneficiaries. NSCIA believes there is not enough time allowed to address how drug coverage for these health and fiscally exposed beneficiaries will be transferred to Medicare on Jan. 1, 2006.

CMS and the private Part D plans giving drug coverage do not have enough time to implement a prescription drug benefit staring on January 1, 2006. These time constraints may well lead to plans that jeopardize the lives of people with sci/d and

other disabilities who fall into the dual eligible population. It is highly improbable that 6.4 million dual-eligibles could be identified, educated, and enrolled in six weeks (from November 15th the beginning of the enrollment period to January 1, 2006),

Therefore, **NSCIA urges that transfer of drug coverage from Medicaid to Medicare be delayed a minimum of six months even if legislative mandate is required.**
We further urge CMS to actively support such legislation in the current session of Congress.

FUND COLLABORATIVE PARTNERSHIPS WITH ORGANIZATIONS REPRESENTING PEOPLE WITH DISABILITIES THAT ARE CRITICAL TO AN EFFECTIVE OUTREACH AND ENROLLMENT PROCESS:

Organizations representing people with disabilities and other targeted populations of Medicare beneficiaries should be funded to collaborate with CMS in the outreach and enrollment process. These advocacy and service groups are one of the most effective inroads to disseminate outreach and enrollment information. **NSCIA strongly recommends that CMS develop national and regional partnerships with disability service and advocacy groups and local and state agencies.**

COST MANAGEMENT LIMITS AND CONSUMER PROTECTION:

NSCIA recommends that CMS make major enhancement to its provisions for consumer protection. One key example is not allowing any plan to require 100% cost sharing for any medication. These and other proposed cost burdens on the consumer could threaten and adversely effect people with sci/d and other disabilities. In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We oppose any regulations that allow cost containment practices that would limit a physician from prescribing the best medication for an individual. This elimination of said cost containment practices is especially critical for the lives of people with sci/d and other disabilities.

ENHANCE AND STRENGTHEN INADEQUATE EXCEPTIONS AND APPEALS PROCESSES:

NSCIA believes the appeals processes in the proposed rule are not accessible, too complex and will have a major adverse and deleterious impact on beneficiaries with disabilities. We
urge that CMS develop an understandable process that allows simplicity of access and fast results for beneficiaries and their doctors. NSCIA also urges an expedited appeals process. Along with many other disability organizations, NSCIA believes that the proposed rule **fails to meet Constitutional due process requirements and fails to satisfy the requirements of the statute**. The proposed rule has so many levels of cumbersome internal appeals to the drug plan that it makes unbiased appeal nearly impossible. The appeals process itself could preclude critical medications over a duration of time so as to be life threatening to people with disabilities.

The parts of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) that call for design and implementation of an exception process are vital consumer protections that must include regulations that are enforced. Such procedures could assure that individuals with sci/d and other disabilities would receive timely coverage determination for on and off formulary medications in a manner unique to their complex needs.

NSCIA joins other disability organizations in asking that CMS revamp the exceptions process to: establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

REQUIRE PLANS TO DISPENSE A TEMPORARY SUPPLY OF DRUGS IN EMERGENCIES:

Persons with sci/d, other disabilities, and chronic health conditions must have access to prescribed medications at all times. The proposed system does not ensure beneficiary
access to needed medications. Said drugs are vital to the continued, productive functioning of persons with sci/d and other disabilities. Interruption of medication regimes can cause serious health complications and may even be life threatening. Consequently, the final rule must ensure that an emergency supply of drugs be made available for dispensing while pending the resolution of an exception request or an appeal.

NSCIA appreciates your consideration of these public comments.

CMS-4068-P-1243

Submitter : Dr. John C. Lewin **Date & Time:** 10/04/2004 08:10:29

Organization : California Medical Association

Category : Physician

Issue Areas/Comments

Issues 1-10

BACKGROUND

Comments Attached.

CMS-4068-P-1243-Attach-1.doc

CMS-4068-P-1243-Attach-2.doc

California Medical Association
Physicians dedicated to the health of Californians

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014
E-mail: http://www.cms.gov/regulations/ecomments

Re: CMS-4068-P Comments on Part D, Medicare, Proposed Outpatient Drug Program Rules

Dear Dr. McClellan:

On behalf of the California Medical Association, we wish to join the American Medical Association in seeking further clarification regarding a range of patient safeguards that should be more explicitly addressed in your proposed rules. We believe it is imperative that these regulations clearly prohibit manipulations of a physician's prescribing authority that could subsequently result in disruptions in both the quality and continuity of medical care.

We strongly agree with your comments recently in the Wall Street Journal that "the choice of drugs should reflect current medical practice." In that spirit, we respectfully urge that CMS consider the following:

Benefit Design: As noted in AMA's testimony, we are concerned by 'serious deficiencies' in the USP's proposed model classification system. We find numerous circumstances whereby entire classes of vital drugs could be excluded by an HMO, PBM or other plan administrator. While some may believe this could help produce short term savings in the drug benefit program, it is inevitable that such limitations on coverage will shift the ensuing costs resulting from therapeutic failure to other parts of the Medicare program.

P&T Committee Coverage Decisions: We join the AMA in expressing our concern that absent further clarification, P&T Committees may be allowed to meet in secret, limit clinical and public input, and be stacked to favor the plan administrator's drug class preferences. It is not clear that the scope of the P&T Committees would include other coverage restriction strategies, such as prior authorization procedures or tiered/step formularies, nor if the committee's decisions would be binding on the PDP. We feel very strongly that the rule should be modified to make it clear that P&T committees must be responsible for the development of all coverage policies, and that their decisions should be made and explained openly through a transparent process that allows for public input.

Patient Protections: We are also very concerned that the plans could change formularies with only 30 days notice. You are aware that the Medicare population in general, and the dual eligible population in particular, commonly have multiple chronic conditions that require multiple ongoing drug therapies. In a majority of these patients their conditions are medically fragile and the dosages and drug products have been carefully titrated. Other than adding drug products, we believe formularies should only be modified, with adequate notice and P&T Committee approval, between plan years/contracts.

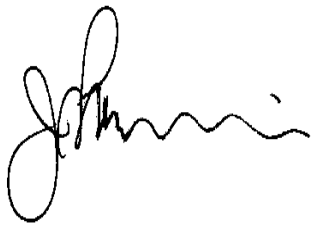
Drug Switching, Federal Preemption of State Pharmacy and Patient Protection Laws. While the preamble states that drug switching should require explicit approval by the treating physician, the rules themselves fail to expressly preserve this vital principle. Similarly, nowhere in the rule is the likely effect of the MMA on state pharmacy laws – which currently regulate the practice of therapeutic interchange – or drug switching – discussed. Switching prescriptions without the consent of the treating physician is the practice of medicine by non-physicians. Health plan or PBM employees who have virtually no history or contact with affected patients should not be permitted to override the treating physician's expert judgment. Again, Medicare is essentially a closed system—short-term savings which result in higher costs overall do not serve Medicare patients or the public well. To ensure that the final rules are not interpreted as permitting drug switching without the explicit consent of the treating physician, we urge you make it clear in the text of the regulations that state laws regulating therapeutic interchange must continue to be respected.

Office-Based Injectible Drugs for Oncology and Other Specialties: The MMA will drastically reduce the payment amount for drugs and drug administration services compared to the 2004 amounts. In addition, it appears likely that the payment methodology for drugs (106% of the manufacturer's average sales price) will result in payment amounts for many drugs that are lower than the prices at which physicians can purchase them, yet there is no mechanism in the MMA for adjustments in such circumstances. These changes have the potential to create substantial impairment of patient access to cancer and other essential treatments. Therefore, Congress should create exceptions under which CMS would be required to ensure that the payment amounts for in 2005 and later years are sufficient to cover the cost that physicians incur in purchasing the drugs. In addition, Congress should revise the MMA's transitional adjustment payment for drug administration services to an amount that will maintain the net revenue available to physicians from drugs and drug administration services in 2005 and 2006 at the same level as in 2004.

We readily acknowledge the daunting, complex nature of this new and promising program. And we applaud your efforts to implement it in a fair and responsible fashion. As you work to refine the implementing rules, we ask that the agency anticipate the consequences of arbitrarily limiting access to medically necessary drug products and work diligently to ensure that the standards and requirements that you ultimately set out for the program first and foremost do no harm.

Thank you for your consideration of these important medical principles and our mutual support of the patients we all serve.

Sincerely,



John C. Lewin, M.D.
Chief Executive Officer
California Medical Association

California Medical Association
Physicians dedicated to the health of Californians

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014
E-mail: http://www.cms.gov/regulations/ecomments

Re: CMS-4068-P Comments on Part D, Medicare, Proposed Outpatient Drug Program Rules

Dear Dr. McClellan:

On behalf of the California Medical Association, we wish to join the American Medical Association in seeking further clarification regarding a range of patient safeguards that should be more explicitly addressed in your proposed rules. We believe it is imperative that these regulations clearly prohibit manipulations of a physician's prescribing authority that could subsequently result in disruptions in both the quality and continuity of medical care.

We strongly agree with your comments recently in the Wall Street Journal that "the choice of drugs should reflect current medical practice." In that spirit, we respectfully urge that CMS consider the following:

Benefit Design: As noted in AMA's testimony, we are concerned by 'serious deficiencies' in the USP's proposed model classification system. We find numerous circumstances whereby entire classes of vital drugs could be excluded by an HMO, PBM or other plan administrator. While some may believe this could help produce short term savings in the drug benefit program, it is inevitable that such limitations on coverage will shift the ensuing costs resulting from therapeutic failure to other parts of the Medicare program.

P&T Committee Coverage Decisions: We join the AMA in expressing our concern that absent further clarification, P&T Committees may be allowed to meet in secret, limit clinical and public input, and be stacked to favor the plan administrator's drug class preferences. It is not clear that the scope of the P&T Committees would include other coverage restriction strategies, such as prior authorization procedures or tiered/step formularies, nor if the committee's decisions would be binding on the PDP. We feel very strongly that the rule should be modified to make it clear that P&T committees must be responsible for the development of all coverage policies, and that their decisions should be made and explained openly through a transparent process that allows for public input.

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Thank you for your consideration of these important medical principles and our mutual support of the patients we all serve.

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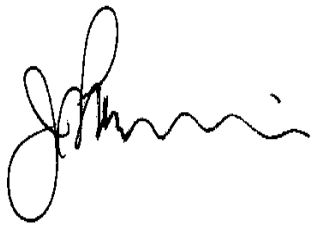


John C. Lewin, M.D.
Chief Executive Officer
California Medical Association

Submitter : Daniel Hilferty **Date & Time:** 10/04/2004 08:10:59

Organization : AmeriHealth Mercy Health Plan

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Comments from AmeriHealth Mercy Health Plan

CMS-4068-P-1244-Attach-1.doc

October 4, 2004

Mark B. McClelland, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Dr. McClellan:

AmeriHealth Mercy Health Plan is pleased to have the opportunity to submit comments in response to the notice of proposed rulemaking by the Centers for Medicare & Medicaid Services (CMS) to establish the program for the Medicare Prescription Drug Benefit under Part D. AmeriHealth Mercy Health Plan is submitting separate comments to the Medicare Advantage (MA) regulations that relate to some of the same issues discussed here.

Background

AmeriHealth Mercy Health Plan is a subsidiary jointly owned by Independence Blue Cross and Mercy Health System. AmeriHealth Mercy Health Plan is a leading provider of Medicaid managed care programs and services. Together with its affiliate Keystone Mercy Health Plan and *PerformRx*, its pharmacy benefits management division, AmeriHealth Mercy Health Plan touches the lives of more than one million Medicaid members in seven states. AmeriHealth Mercy Health Plan and its affiliates (collectively, AmeriHealth Mercy Health Plan) are very interested in the opportunities provided by the Medicare Modernization Act (MMA) to participate both in the MA program through the offering of specialized MA plans for dual eligibles and in the offering of pharmacy benefit services on behalf of specialized MA plans serving dual eligibles.

The need to effectively manage prescription drug benefits for our large mandatory enrollment Medicaid populations led AmeriHealth Mercy Health Plan to develop *Perform Rx,* a Medicaid pharmacy care management program that meets financial objectives while improving the quality of health care for members. *PerformRx* manages drug benefits and services for almost 900,000 Medicaid beneficiaries in six states.

As further background, AmeriHealth Mercy has significant experience in serving dual eligible populations. AmeriHealth Mercy Health Plan furnishes services to about 50,000 full benefit dual eligibles in the following three health plans:

- Keystone Mercy Health Plan, Southeastern Pennsylvania's largest Medicaid managed care health plan serving more than 280,000 Medical Assistance recipients, including 31,000 dual eligibles, in Bucks, Chester, Delaware, Montgomery and Philadelphia counties**.** Keystone Mercy Health Plan operates this plan under a license held by Vista Health Plan, a subsidiary of Independence Blue Cross.
- AmeriHealth Mercy Health Plan serves about 76,000 Medical Assistance recipients, including about 6, 000 dual eligibles, in fifteen counties in Central and Northeastern Pennsylvania. AmeriHealth Mercy Health Plan operates this plan under a license held by Vista Health Plan, a subsidiary of Independence Blue Cross.
- Passport Health Plan[1] is a Medicaid managed care plan that serves over 130,000 members in Louisville and 15 surrounding counties in Kentucky. Its membership includes 12,000 dual eligibles. Passport was formed in 1997 by a group of safety net Medicaid providers. AmeriHealth Mercy provides complete health plan management and administrative support services under the governance of the Passport Health Plan board. Passport Health Plan is currently in the process of completing an application to participate in the Medicare Advantage program as a specialized MA plan for dual eligibles.

Discussion

1. Introduction

As an overall comment, AmeriHealth Mercy's experience in managing comprehensive prescription drug benefits for high risk Medicaid populations is that the management of the prescription drug benefit and medical benefits (hospital, physician, ancillary, etc.) are inherently interrelated because the quality outcomes and total costs are interdependent. Good disease management programs incorporate prescription drug data and management as integral components to clinical quality improvement and utilization/cost management efforts. Successful disease and case management programs serving high risk, low income populations focus on removing barriers to services. While total medical costs can be stabilized/reduced, an individual's prescription drug utilization may actually increase with appropriate use and adherence to medication plans. Thus, from the perspective of an MA-PD plan that is managing medical and pharmaceutical services, the sponsoring MA organization has strong motivation to ensure that the Part D drug benefit is designed and administered in a manner that serves the best interests of its enrollees. Over the years, health plans have developed effective programs to appropriately manage their drug benefits. AmeriHealth Mercy Health Plan urges CMS to develop the Part D regulations in a manner that gives health plans the discretion to continue these programs.

2. Subpart B – Eligibility and Enrollment

[1] Passport Health Plan is the trade name for University Health Care, a section 501(c)(3) tax exempt organization.

In this section of our letter, we provide our rationale for requesting that CMS adopt a policy that would allow the auto-assignment of full benefit dual eligibles into an MA-PD that is offered by a health plan in which the full benefit dual eligibles are enrolled or a health plan under common ownership and control of the health plan in which the full benefit dual eligibles are enrolled. Because of the importance of these comments, AmeriHealth Mercy Health Plan has repeated these recommendations in its comments to the MA proposed rule.

The MMA establishes a mechanism for full benefit dual eligibles who will be losing their outpatient drug coverage under Medicaid to select enrollment in an MA-PD plan or a PDP. The statute allows for default enrollment into a PDP in the event that a full benefit dual eligible fails to select a PDP or an MA-PDP Plan. Based on information provided at an open door forum, our understanding is that CMS intends to have this default enrollment occur effective January 1, 2006.

In the preamble to the PDP proposed rule (page 46638), CMS explains that there are conflicting statutory provisions related to default enrollments. To address these conflicts, CMS is proposing to default full benefit dual eligibles into an MA-PD if the full benefit dual eligible was enrolled in the MA organization previously. In the preamble, CMS articulates its policy justification for this decision as follows:

> To the extent that the MA-only portion of the MA-PD plan parallels the coverage under a full benefit dual eligible individual's MA plan, enrolling the individual in the MA-PD plan would be similar to permitting the individual to remain enrolled in the MA plan while simultaneously enrolling the individual in a PDP. In other words, enrolling the individual in a MA-PD plan offered by the same MA organization is, in effect, simply adding qualified prescription drug coverage to the individual's MA benefits. For this reason, we believe the reference to ``prescription drug plans'' in section 1860D-1(b)(1)(C) of the Act should be interpreted as requiring enrollment of a full benefit dual-eligible into a plan that will provide the individual with Part D drug benefits in addition to any other benefits the individual receives under Medicare, whether through Medicare Part A and/or Part B, or through enrollment in the Medicare Advantage program under Part C. We believe this interpretation promotes the policies underlying sections 1860D-1(b)(1)(C) and 1860D-1(a)(1)(B)(ii) of the Act, giving full effect to both statutory provisions.

AmeriHealth Mercy Health Plan fully supports CMS proposed policy, but requests that CMS expand this policy to allow for default enrollments in two additional, related circumstances illustrated below. First, Passport Health Plan currently enrolls 12,000 dual eligibles and is in the process of applying for an MA-SNP to serve dual eligibles. AmeriHealth Mercy Health Plan is recommending that CMS expand its policy to allow for the current full benefit dual eligible enrollees of Passport Health Plan's Medicaid MCO who do not otherwise select an MA-PD or PDP to default into Passport Health Plan's MA-PD. Because virtually all Medicare services are covered under Medicaid, allowing such a default enrollment would permit these full benefit enrollees to continue to receive the full range of A/B services and drug benefits from the same

health plan. Moreover, AmeriHealth Mercy Health Plan believes that allowing dual eligibles to retain their prescription drug providers and the existing pharmacy management structure is fully consistent with the objectives stated above.

AmeriHealth Mercy Health Plan believes there is legal precedence to support our interpretation that would permit members of another health plan offered by the same organization to be viewed as members of the Medicare managed care organization. Section 1851(a)(3)(B) includes the provision that prohibits beneficiaries with end-stage renal disease (ESRD) to enroll in an MA plan. This paragraph includes an exception that permits the enrollment of "an individual who develops end-stage renal disease while enrolled in an MA plan may continue to be enrolled in that plan." As part of the BBA regulations, CMS was confronted with the issue of whether a Medicare beneficiary who was enrolled in a non-Medicare+Choice plan and who developed ESRD could enroll in a Medicare+Choice plan offered by the same organization. In answering this question, CMS appropriately asserted its authority to depart from the literal reading of the statute and took the following position:

> For purposes of this provision only we are considering individuals who are enrolled in a private health plan offered by the M+C organization to have been enrollees of the M+C plan when they developed ESRD. (63 FR 34976, June 26, 1998)

While this ESRD enrollment issue is in a different context from the default enrollment issue under the MMA, it illustrates the clear willingness of CMS to depart from the literal reading of the statute to reach an important and desirable policy result. In this case, that departure entailed treating a non-MA enrollee of an organization as an MA enrollee of that same organization for purposes of enrollment into an MA plan. Consistent with CMS' willingness to extend a reference to M+C organizations to a non-Medicare health plan offered by the same entity, we believe that CMS has the corresponding legal authority to make an analogous legal interpretation. AmeriHealth Mercy Health Plan believes that strong policy reasons also support this result because this interpretation would allow a single organization to coordinate the services and be responsible for the full range of Medicare and Medicaid benefits for the full benefit dual eligibles. In making this recommendation, we emphasize that these full benefit dual eligibles would have the right to disenroll from the MA-SNP, if they want.

We also believe our recommendation has policy support under the statutory provision in Section 1851(c)(3)(a)(II), which address seamless continuation of coverage. Under that provision, CMS has the authority to establish procedures under which an individual who is enrolled in a health plan (other than an MA plan) offered by an MA organization at the time of the initial election period and who fails to elect to receive coverage other than through the organization is deemed to have elected the MA plan offered by the organization. While this provision applies to initial election period when a person is first eligible for Medicare coverage, the provision demonstrates Congressional support for arrangements that facilitate enrollment into an MA plan of an enrollee covered by a non-MA plan sponsored by the same organization. In addition, this provision offers clear authority for CMS to provide for this default enrollment in the future when an

enrollee of a Medicaid MCO first becomes eligible for Medicare and the same entity also offers an MA plan.

Our second policy recommendation related to how CMS interprets the default enrollment provision is an extension of our initial request and relates to the two Pennsylvania Medicaid managed care plans: Keystone Mercy Health Plan in Southeastern Pennsylvania, and AmeriHealth Mercy Health Plan in Central and Northeastern Pennsylvania. As noted above, AmeriHealth Mercy Health Plan and its affiliate, Keystone Mercy Health Plan, are owned by Independence Blue Cross and Mercy Health System. Both of these Medicaid plans are operated under an HMO license held by Vista Health Plan, a wholly owned subsidiary of Independence Blue Cross.

Independence Blue Cross itself and through its subsidiaries has three separate MA contracts. One contract is a PPO sponsored by Independence Blue Cross itself. The second contract is held by a wholly owned subsidiary of Independence Blue Cross, Keystone Health Plan East, Inc., and is offered in Southeastern Pennsylvania. The third contract is held by AmeriHealth HMO, Inc. AmeriHealth Mercy Health Plan is requesting that CMS adopt a policy that would allow the full benefit dual eligible enrollees of AmeriHealth Mercy Health Plan and Keystone Mercy Health Plan and who do not otherwise select another MA-PD or PDP to default on January 1, 2006, into the MA-SNP sponsored by AmeriHealth HMO, Inc, and Keystone Health Plan East, Inc., respectively. In making this request, we want to be clear that substantial efforts will be made in advance of the default date to have these Medicaid enrollees either select a MA-PD plan or a drug plan. Keystone Health Plan East and AmeriHealth HMO, Inc. will be actively marketing the dual eligibles enrolled in their affiliated Medicaid managed care organizations in a manner consistent with CMS rules. However, as CMS is aware from its experience in the drug discount card program and the challenges associated with enrolling dual eligibles in the Medicare savings programs, many dual eligibles will take no action prior to January 1, 2006. AmeriHealth Mercy Health Plan strongly believes it is in the best interests of their enrollees and the Medicare program to default these enrollees into Keystone Health Plan East's MA-SNP.

AmeriHealth Mercy Health Plan also believes there is a legal precedent for allowing affiliates of organizations to avail themselves of statutory rights under the Medicare or Medicaid program. Prior to enactment of the BBA, Medicaid MCOs were prohibited from having more than 75 percent of their enrollment comprised of persons eligible for Medicare and Medicaid. Certain community health centers, migrant health centers, and Appalachian health centers were exempt from this requirement. When CMS implemented this statutory provision, CMS departed from the literal reading of the statute and extended this exemption to HMOs owned by these health centers. CMS discussed this issue in the following manner:

> As noted in the previous section, we are proposing to amend the regulations to recognize the statutory exemption from the composition of enrollment standard for certain Community, Migrant, and Appalachian Health Centers. It has come to our attention that some of these exempt centers have joined to form larger organization in order to operate an HMO of adequate size. Under simple arrangements, several community health centers have established an HMO that

> enrolls members who are then provided primary care services through the same community health centers. The HMO serves simply as the corporate vehicle allowing the centers to combine their efforts. In this circumstance, we believe that, consistent with Congressional intent, the HMO formed by centers that are exempt from the composition of enrollment standard should itself be exempt from the standard. (53 FR 746, January 12, 1988)

This discussion illustrates CMS willingness to extend statutory rights from an organization to an affiliate of that organization in appropriate circumstances. In the context of the issues being raised to CMS here, it is important to note that the complexity arising from these different organizational structures derives both from the limitations that Independence Blue Cross has to use the Blue Cross mark outside of its designated area and Medicaid managed care program requirements. Notwithstanding this complexity, it is clear that all of the entities that hold the MA contracts and Medicaid contracts with the Pennsylvania Department of Public Welfare are wholly owned subsidiaries of Independence Blue Cross. Therefore, for purposes of developing public policy interpreting the default enrollment provisions, we believe it is reasonable and appropriate for CMS to treat these affiliated companies as a single entity.

AmeriHealth Mercy Health Plan recognizes that CMS' consideration of AmeriHealth Mercy Health Plan's requests needs to be considered in the context of a broader policy that is consistent with the objectives of the MMA and serves the best interests of full benefit dual eligibles. To achieve this end, AmeriHealth Mercy Health Plan recommends that CMS adopt the following policy:

> That CMS approve default enrollment of a full benefit dual eligible who has not otherwise selected an MA-PD or PDP into an MA-PD that is administered by an MA organization (1) that operates the Medicaid MCO in which the dual eligible is enrolled or (2) that is affiliated by common ownership or control with an organization that operates the Medicaid MCO in which the dual eligible is enrolled. As a condition of CMS approving this policy, the MA organization would be obligated to meet the following conditions:
>
> 1. The MA organization would have to assure that the full benefit dual eligibles are given notice of the default enrollment and their opportunity to select other options in advance of the default enrollment as well as their continued ability to disenroll from the specialized MA-PD plan following their enrollment.
>
> 2. The bid for A/B benefits would not include beneficiary premiums or cost sharing that would be paid by the full benefit dual eligible enrollees. If the Part D premium is determined to be in excess of the low income premium subsidy, the MA-PD plan would reallocate rebate dollars to the amount of the low income premium subsidy (if permitted by CMS).
>
> 3. The MA organization must represent that substantially all of the Medicaid providers currently furnishing services to the full benefit dual eligibles are either

part of the MA-SNP's delivery system or would have the opportunity to participate in that delivery system provided that the MA organization's credentialing requirements could be met.

4. The same pharmacy benefits manager that will administer the Part D benefit on behalf of the MA-SNP must also have previously managed the pharmacy benefit for the dual eligible enrollees of the Medicaid MCO.

AmeriHealth Mercy Health Plan would welcome the opportunity to discuss with CMS its proposal. As implicitly reflected in the above conditions, AmeriHealth Mercy Health Plan is recommending that CMS allow default enrollments into an MA-PD even if the Part D premium exceeds the low income premium subsidy. We believe the enrollees' best interests will be met by enrolling them in the MA plan under the above conditions rather than forcing them into a PDP.

3. Subpart C – Benefits and Beneficiary Protections

a. USP Classification structure

AmeriHealth Mercy Health Plan supports the proposed USP classification structure. We believe that the skeletal structure does exactly what it was primarily intended to do -- prevent enrollee discrimination through non-inclusion of certain medication types and categories. This skeletal structure provides a good basis from which to create a workable formulary that will ultimately be reviewed by CMS for appropriateness. AmeriHealth Mercy Health Plan reiterates its earlier point that it is very important for CMS to give MA organizations the flexibility to administer their drug benefit in a manner that serves the best interest of their beneficiaries. AmeriHealth Mercy Health Plan has substantial experience developing and managing formularies under Medicaid programs in a number of states. These formularies make available to enrollees in a cost effective manner the pharmaceuticals they need. AmeriHealth Mercy Health Plan urges CMS not to develop requirements that impair the ability of health plans like AmeriHealth Mercy Health Plan to continue the effective pharmaceutical programs that they currently offer to their enrollees.

b. Formulary development

AmeriHealth Mercy Health Plan supports the formulary development requirements and believes that the statutory and proposed regulatory requirements are generally consistent with industry practices in the development of formularies. Under the proposed rule, the majority of members comprising the P&T committee would be required to be practicing physicians and/or practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician member would have to be an expert in the care of elderly and disabled individuals and free of conflict with respect to the PDP sponsor and PDP or MA organization and MA-PD. AmeriHealth Mercy Health Plan believes this standard, in general, is reasonable and consistent with standard industry practice. However, AmeriHealth Mercy Health Plan has one concern with regard to how CMS is

interpreting "independent." In the preamble discussion, it appears that CMS would preclude a pharmacist from being viewed as "independent" if the pharmacist was part of the pharmacy network of the MA-PD plan. AmeriHealth Mercy Health Plan believes that many health plans attempt to create their P & T Committees composed of the "best and brightest" physicians within their geographic area. They also have this same goal for their provider networks. As a result, we have concerns that it may not be possible to obtain a physician or pharmacist who meets the requisite qualifications but is not part of the health plan's network. The health plan would be forced to find a pharmacist or physician who is located outside their service area to participate on their P & T Committee. Consequently, the selected P & T Committee member would lack a good understanding of local health care issues and concerns.

c. Use of rebates to reduce cost sharing

Under §423.100 in the definition of "required prescription drug coverage" an MA-PD plan may offer enhanced alternative coverage if there is no supplementary beneficiary premium as a result of the use of rebate dollars from A/B savings. In the preamble, CMS notes that an MA-SNP may use rebate dollars to reduce the nominal copayments that apply to low-income subsidy individuals who have incomes below 135 percent of FPL. We are seeking CMS confirmation on an issue related to this position. These dual eligibles may have copayments of $1/$3 or $2/$5. Our understanding is that an MA organization offering an MA-SNP for dual eligibles may use rebate dollars to remove both levels of copayments. AmeriHealth Mercy Health Plan is requesting that CMS confirm this interpretation in the preamble to the final regulation.

d. Drugs covered under Part B and Part D

CMS sets forth a lengthy discussion in the preamble concerning issues arising from drugs that may be provided under Part B and Part D. Based on our experience in the Medicaid program, AmeriHealth Mercy Health Plan has found that enormous issues can arise regarding the appropriate classification of drugs when the classifications dictate different financial obligations. AmeriHealth Mercy Health Plan urges CMS to the fullest extent possible to provide clear guidance regarding which drugs fall under Part B and those that fall under Part D. This guidance should also explain the rules determining treatment of newly approved drugs. This guidance should also delineate clearly the circumstances in which a drug may fall under either Part B or Part D depending on the manner in which it is administered.

4. Subpart D – Cost Control and Quality Improvement

As proposed under §423.153(b), CMS is requiring MA-PD plans and PDPs to have a cost-effective drug utilization management program. This program must:

(1) Include incentives to reduce costs when medically appropriate; and
(2) Maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications.

AmeriHealth Mercy Health Plan believes an effective drug utilization program is integral to the success of the Part D program. To this end, AmeriHealth Mercy Health Plan urges CMS to convey in the preamble its support for current practices that are commonly used by health plans and pharmacy benefit managers to manage utilization and control costs.

While unfortunate, the reality in today's health care environment is that a significant amount of beneficiary fraud and abuse occurs. This type of activity occurs in spite of significant efforts on the part of both pharmacists and the majority of practicing physicians to prevent this type of behavior. AmeriHealth Mercy Health Plan asks CMS to consider providing options, policies and processes that would allow health care payers/providers to investigate potential beneficiary fraud and misuse, and when verifiable, to attempt to control the activity in question. A large number of States already have beneficiary fraud and misuse programs in place for their Medicaid programs, and, in our opinion, these programs can be extremely successful in reducing the unwanted behavior.

AmeriHealth Mercy Health Plan, through its working relationship with the Commonwealth of Pennsylvania, has designed, developed, and implemented a program that attempts to eliminate/reduce fraud and misuse of drug products within our specific member population. Our particular program is referred to as "Recipient Restriction."

The pharmacy services department for the health plan constantly monitors drug claim data, looking for potential fraud and misuse. There are a number of algorithms that exist or could be developed by CMS to give guidance on what would, or would not, be considered fraud and/or misuse. The focus of these programs is typically on drugs and drug products that have "street" or "abuse" potential, with the primary products being the therapeutic class – opiate/narcotic pain medications. A number of other products have been included and are monitored as research and practice dictate.

The current process requires that once the health plan identifies a member misusing either products or services, a request to "restrict" that member is submitted to the Commonwealth's Department of Public Welfare "Recipient Restriction" oversight committee for a review and final determination. If the committee feels that there is enough data/information to support the restriction, based on the restriction criteria that has been approved and is in place, the member is restricted to using a single provider or group of providers and/or a single retail pharmacy vendor for a period of five years. What is also important is that this restriction attaches to the recipient and follows that recipient as they move from health plan to health plan. This is an extremely important component of the program as it precludes the recipient from re-initiating the unwanted behavior simply by changing health plans.

There appears to be little comment given in the MMA to programs/processes geared toward beneficiary fraud and misuse, the ability of MA-PD plans PDPs to initiate these types of programs, or CMS's willingness/ability to support this type of program.

AmeriHealth Mercy Health Plan's experience with this type of restriction program has been very positive. Once identified and "restricted," our research shows a significant decrease in the detrimental practices and behavior of the restricted recipients.

AmeriHealth Mercy Health Plan would encourage CMS to address and clarify the types of programs and support for these programs that might be forthcoming. The ability of a health plan to take limited action against a recipient that is misusing the system, with only the slightest impact of that recipient's access to the health care system, is an extremely valuable tool to improve appropriate utilization of medications and reduce unnecessary financial expenditures. While it may not be possible to establish a program under Medicare that parallels exactly the Medicaid programs, AmeriHealth Mercy Health Plan urges CMS to consider these issues and convey in the preamble to the final rule or the rule itself the manner in which these programs may be administered as well as alternative practices that may be followed by PDPs and MA-PD plans to accomplish the same objectives.

AmeriHealth Mercy Health Plan is also seeking confirmation from CMS with regard to the ability of MA-PDs and PDPs to require that certain drugs receive prior approval before a prescription is filled. Prior approval is a common practice and CMS repeats a number of times in the preamble the ability of health plans to continue their existing programs to manage costs. We also note that the Federal Medicaid law expressly provides:

> A State may subject to prior authorization *any* covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5)." § 1396r- 8(d)(1)(A) (emphasis added).

Paragraph (5), entitled "Requirements of prior authorization programs," reads as follows:

> A State plan under this subchapter may require, *as a condition of coverage or payment* for a covered outpatient drug for which Federal financial participation is available in accordance with this section, ... the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval-
> (A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
> (B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

42 U.S.C. § 1396r-8(d)(5) (emphasis added)

AmeriHealth Mercy Health Plan believes the process we currently use, follows the federal Medicaid guidelines. This guideline has worked well for years in the Medicaid environment, and AmeriHealth Mercy Health Plan recommends that CMS approve a comparable policy for the Part D program.

5. Subpart F Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

In the preamble discussion, CMS is clear that it expects PDP sponsors and MA organizations to identify the additional costs that may arise as a result of supplemental benefits. CMS states that a portion of these costs will be associated with increased utilization of the Part D basic benefit. CMS expects that the costs associated with this increased utilization will be included in the component of the bid attributable to the supplemental benefits, not the basic benefits.

This position raises a number of very significant and troubling issues for AmeriHealth Mercy Health Plan. If AmeriHealth Mercy Health Plan were to offer a MA-SNP for dual eligibles, its enrollees would have substantial "supplemental" coverage through the payment by CMS of the low-income subsidies. Our actuaries estimate that the utilization associated with an MA-SNP is well above that associated with the basic plan -- potentially 20 percent higher. This increased utilization is for the same population; it does not reflect populations choosing the plan or the value of the cost sharing itself. It is in addition to any risk adjustment needed due to diagnosis or medical conditions of a given population. Of the total allowed costs due to the increased utilization, a portion is reimbursed through increased cost sharing subsidies or increased reinsurance subsidies. The remaining portion is not reimbursed through any of the Part D direct subsidy, the reinsurance subsidy, the low-income premium subsidy, or the low-income cost sharing subsidy. Most importantly, the additional costs associated with this additional utilization cannot be reallocated outside of the basic drug benefit because AmeriHealth Mercy Health Plan will not be offering supplemental benefits.

As a result, AmeriHealth Mercy Health Plan and other MA-SNPs will be placed at a significant competitive disadvantage to MA-PDs and PDPs that will not have these additional costs included in their basic bid. More importantly, this inequity increases the likelihood that the premium of an MA-SNP will be greater than the low-income premium subsidy in its region. If this should occur, full benefit dual eligibles, who might otherwise have no premium, will be forced to pay a premium to the MA-SNP. This occurrence could create an incentive for the full benefit dual eligibles of the MA-SNP to disenroll and enroll in another plan that may be less expensive, but may not offer the special services needed by the dual eligible population.

For this reason, AmeriHealth Mercy Health Plan opposes CMS' proposed decision to require the costs associated with increased Part D basic services that arise when supplemental benefits are provided to be removed from the basic bid.

6. Subpart G Payments to PDP Sponsors and MA Organizations Offering MA-PD plans for all Medicare Beneficiaries for Qualified Prescription Drug Coverage

On page 46688 of the preamble, CMS included the following discussion conveying its concerns that plans serving large portions of low-income subsidy beneficiaries may not be paid adequately under the new Part D risk adjustment system:

> Any risk adjustment methodology we adopt should adequately account for low-income subsidy (LIS) individuals (and whether such individuals incur higher or lower-than average drug costs). Our risk adjustment methodology should provide neither an incentive nor a disincentive to enrolling LIS individuals, and we request comments on this concern and suggestions on how we might address this issue.
>
> Our particular concern is that a risk adjustment methodology, coupled with the statutory limitation restricting low-income subsidy (LIS) payments for premiums to amounts at or below the average, could systematically underpay plans with many LIS enrollees (assuming LIS enrollees have higher costs than average enrollees). If the risk-adjustor fails to fully compensate for the higher costs associated with LIS recipients, an efficient plan that attracts a disproportionate share of LIS eligible individuals would experience higher costs to the extent the actual costs of the LIS beneficiaries are greater than the risk-adjustment compensation. Failing to discourage enrollment by LIS beneficiaries in 2006, the plan would experience higher than expected costs in that year and presumably be driven to reflect these higher costs (due to adverse selection, not efficiency) in its bid for 2007. In this hypothetical, plans would have a disincentive to attracting a disproportionate share of LIS beneficiaries. One possible solution would be to assure that the initial risk-adjustment system, which will be budget neutral across all Part D enrollees, does not undercompensate plans for enrolling LIS beneficiaries. In fact, to the extent that an initial risk-adjustor might at the margin tend to overcompensate for LIS beneficiaries, plans would have a strong incentive to disproportionately attract such beneficiaries. Plans could attract LIS beneficiaries both by designing features that would be attractive to such beneficiaries but also by bidding low. We would appreciate comments on this concern and suggestions on how we might address this potential problem.

AmeriHealth Mercy Health Plan shares the concern that the risk adjustment methodology could systematically underpay plans with many low-income subsidy enrollees. As noted above, of the total allowed costs due to the increased utilization, a portion is reimbursed though increased cost sharing subsidies or increased reinsurance subsidies. The remaining portion is not reimbursed through any of the Part D direct subsidy, the reinsurance subsidy, the low-income premium subsidy, or the low income cost sharing subsidy. Because these costs are not reimbursed, MA-SNPs will need to build them into member premium. As a result, MA-SNPs like AmeriHealth Mercy Health Plan will be less competitive than plans without such low-income eligibles.

To address this issue, CMS could include in the risk adjuster a component that reflects both the extra utilization the dually eligible Medicare/Medicaid population reflects due to its inherent risk (if it bought the basic Part D plan) and the extra utilization because it will effectively receive a much richer $1/$3 copay plan. AmeriHealth Mercy Health Plan believes that this incremental adjustment would be beyond that reflected in the standard (to be determined) diagnosis-based risk adjuster. We believe that this solution would protect both MA-SNPs and other PDP or MA-PD plans that happen to enroll low-income members.

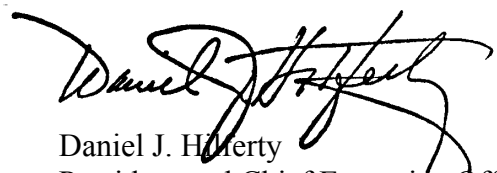
In addition to the increased costs associated with the greater utilization of services, we believe that the additional administrative expense involved in the increased utilization and the administration of the cost sharing subsidy is also unlikely to be included in:

- Standard PDP bids
- Reinsurance subsidies
- Low income premium subsidy
- Cost sharing subsidy

If so, it again would be in the member premium and put plans with LIS enrollees at a competitive disadvantage. This cost could be either a) added to a Medicaid/low income risk adjustment (as above), or b) added as a load onto the actual cost sharing reimbursement.

AmeriHealth Mercy Health Plan appreciates the opportunity to comment on these regulations. If you would like to discuss any of our comments, feel free to call me at (215) 937-8200.

Sincerely,



Daniel J. Hilferty
President and Chief Executive Officer

CMS-4068-P-1245

Submitter : Mrs. Stephanie Belling **Date & Time:** 10/04/2004 08:10:12

Organization : The Medicine Shoppe of LaCrosse, Wisconsin

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I am writing today in regards to the proposed Medicare Part D rules. As a pharmacist of the Medicine Shoppe Pharmacy located in LaCrosse, WI, I am greatly concerned about these proposed rules and the impact they will have on pharmacy services for our patients.

Please know that myself and all pharmacists want to see this Medicare Part D benefit work for all those involved. Unfortunately as past history will show, the private sector health plans have and continue to target pharmacies and pharmacy reimbursement in cost containment measures rather than teaming with pharmacy providers to enhance the quality and accessability to important health care services. We cannot continue to follow this path.

As a community pharmacist, I am concerned with three aspects of the Medicare Part D proposed rule and recommend that Centers for Medicare and Medicaid Services enable the following three policies:

1) Medicare recipients must be able to choose their own pharmacies.
It is critical that plan sponsors make every effort to include as many pharmacy providers as possible in the Part D benefit. Accessibility should be applied at a level no broader than a county to ensure all patients have ready access to the pharmacies in their community. Furthermore, plan sponsors must be required to provide pharmacy payment such that it at a minimum covers the average costs associated with dispensing prescription drugs. Private health plans often use their market force to drive down pharmacy reimbursement rates below a pharmacy's operational costs, thereby forcing pharmacy providers to shift costs to other business sectors. Medicare must now allow plan sponsors to continue this practice.

2) Implement measures to prohibit incentives designed to coerce recipients into choosing plans that exclude pharmacies.
Medicare patients should not be economically coerced into using one pharmacy over another unless the plan sponsor can justify quality reasons for a preferential pharmacy. Plan sponsors should be prohibited from providing economic incentives to recipients for using mail order pharmacies. Plan sponsors should also be prohibited from promoting pharmacies in which they have ownership interest.

3) Plan sponsors should be required to establish specified Medication Therapy Management services.
The Center for Medicare and Medicaid Services should require all plan sponsors to provide at least a specified set of medication therapy management services. Plan sponsors could provide additional MTM services, beyond the minimum required, but each must meet the CMS miminum requirements. Likewise, all plan sponsors should be directed to allow any pharmacist who receives an order for an MTM service to be able to provide that service.

All medicare eligible prescribers shoud be allowed to refer their patients in need of MTM services to a provider of such. At a minimum, each plan should be required to pay for MTM services ordered by such prescribers.

Plan sponsors should also have a plan in place to direct specifed patients, such as those with multiple chronic diseases and/or drug therapies, to MTM service providers. In turn, MTM service payment must be adequate to warrant provision of the necessary services provided by a pharmacist. As well, all pharmacists practicing within a region should be afforded the opportunity to provide MTM services.

In closing, I would like to express my appreciation for this opportunity to offer CMS my opinion of the rules being proposed for Medicare Part D benefit. I hope that my concerns and the concerns expressed by pharmacists locally and nationally are being considered.

Thank you for your time and consideration.

Sincerely,

Stephanie Belling, RPH
Wis Lic 12172
1585 Crestwood Ave
West Salem, WI 54669

CMS-4068-P-1246

Submitter : **Date & Time:** **10/04/2004 08:10:57**

Organization : **Option Care of East and Central Iowa**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

Please see comments in attached Word document.

CMS-4068-P-1246-Attach-1.doc

Option Care of East and Central Iowa is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Option Care of East and Central Iowa is a member of the national network of the Option Care home infusion companies and is located in Cedar Rapids, Iowa. We are an employee-owned company that has been specializing in this type of home care services for over 20 years. We are a member of the largest network of home infusion companies in the country. We are accredited by the Joint Commission and have earned a rather large market share in this state through clinical excellence and the resulting high patient satisfaction. We serve several hundred infusion patients on an on-going basis and have relationships with all government payers and most managed care organizations.

Option Care of East and Central Iowa appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

* Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm <http://www.nhianet.org/perdiemfinal.htm> .

* CMS should establish specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require specific standards for home infusion pharmacies under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the X12N 837 P billing format for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should mandate that prescription drug plans maintain open formularies for infusion drugs to ensure that this population of vulnerable

patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Shari Mailander, RN
Chief Operating Officer

Bryce Jackman, RPh
Director of Pharmacy

Option Care of East and Central Iowa
402 10th Street Ste 100
Cedar Rapdis, Iowa 52403

CMS-4068-P-1247

Submitter : **Date & Time:** **10/04/2004 08:10:41**

Organization : **Center on Budget and Policy Priorities**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

Please find attached our comments to the Medicare Prescription Drug Benefit proposed regulations (CMS-4068-P).

Sincerely,

Center on Budget and Policy Priorities
820 First Street, N.E., Suite 510
Washington, D.C. 20002
(202) 408-1080

CMS-4068-P-1247-Attach-1.doc

CENTER ON BUDGET AND POLICY PRIORITIES

820 First Street, NE, Suite 510, Washington, DC 20002
Tel: 202-408-1080 Fax: 202-408-1056 center@cbpp.org www.cbpp.org

October 4, 2004

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Subject: Comments on Medicare Prescription Drug Benefit Proposed Rule
(*69 Fed. Reg. 46632-46863,* August 3, 2004)

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulations that implement the new Medicare Prescription Drug Benefit enacted in last year's Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Center on Budget and Policy Priorities is a non-profit policy organization that works at the federal and state levels on fiscal policy and public programs that affect low- and moderate-income families and individuals. Our comments here focus on the new Part D benefit as it will apply to low-income Medicare beneficiaries including those who are dually eligible for both Medicare and Medicaid.

One key issue that we believe has not received appropriate attention in the proposed regulations is the historic opportunity the new drug benefit offers in improving enrollment in various public programs such as food stamps for which many low-income elderly and disabled beneficiaries are eligible. We believe that it is important that the regulation ensures that eligible beneficiaries are connected to other benefits for which they are likely to be eligible. We recognize that one agency, the Centers for Medicare & Medicaid Services (CMS) is promulgating this regulation and that the regulation relates to programs under its purview. But, in addition to Medicare, full Medicaid, and the Medicare Savings Programs for which CMS is responsible, other programs like food stamps, SSI and Social Security are the linchpins of federal support for the members of our society who are aging or experience a disability. This low-income Medicare population cannot be expected to navigate overly complicated enrollment procedures. To the extent that the government as a whole fails to coordinate these benefits, it is failing a very vulnerable population.

In addition, as noted by numerous other groups concerned with the dual eligibles and low-income Medicare beneficiaries, we find that the regulation falls short in many other areas especially in transitioning the dual eligibles from Medicaid drug coverage to the new Medicare drug benefit, ensuring that dual eligibles have access to the drugs they need, and in the processes that are envisioned for enrolling low-income beneficiaries in the low-income subsidies.

Please find below our general comments to the proposed regulations on these issues. Please note that we have also submitted more comprehensive comments along with other groups. These comments were submitted by Families USA.

Sincerely,

Robert Greenstein Executive Director	Edwin Park Senior Health Policy Analyst	Dorothy Rosenbaum Senior Policy Analyst

cc: Eric M. Bost, Under Secretary for Food, Nutrition, and Consumer Services, U.S. Department of Agriculture

Jo Anne B. Barnhart, Commissioner, Social Security Administration

I. General Comments on Improved Coordination with Other Programs Like Food Stamps

A. Background

Many Medicare beneficiaries who are eligible for a low-income subsidy under the Medicare Part D benefit will also be eligible for food stamps. The MMA and the proposed rule provide that applications for the Part D low-income subsidy may be filed with either a State's Medicaid program or with the Social Security Administration (SSA). The proposed rule has very little detail, however, about how the application process is likely to work. Because so many people who are eligible for but not participating in food stamps are likely to apply for the Part D subsidy, this application process presents an historic opportunity to connect eligible seniors and people with disabilities to the Food Stamp Program.

Many Medicare Beneficiaries Who Are Eligible for Part D Subsidies Also Are Eligible for Food Stamps

Many of the low-income Medicare beneficiaries who will be eligible for — and apply for — the new low-income drug subsidies that the prescription drug law provides are eligible for food stamps but not enrolled. A Medicare beneficiary will be eligible for some additional subsidy under Part D if his or her income, together with the income of any spouse who is present, is below 135 percent of the federal poverty level. The asset limit for the Part D low-income subsidy will be $6,000 for single beneficiaries and $9,000 for married couples. (Those with incomes below 150 percent of the poverty line with assets below $10,000 for individuals and $20,000 for couples receive a smaller low-income subsidy).

Food stamp eligibility rules are very similar — the universe of food stamp-eligible Medicare beneficiaries is a subset of the Part D-eligible population. Specifically, to be eligible for food stamps a household must have *net* income, after all available deductions are taken into account, below the federal poverty level and assets, not including a primary residence, personal items, and an automobile in most states, must be below $3,000.

Deductions play an important role in food stamp eligibility and benefit levels by taking into account certain household expenses in determining the amount of income that is available to purchase food. In practice, this means that a Medicare beneficiary could have gross income somewhat above the poverty level and still be eligible for food stamps. For the elderly and people with disabilities, the most important deductions are: a *medical expense deduction* for out-of-pocket medical expenses greater than $35 a month; a *dependent care deduction*, for expenses of up to $175 a month for adults who need care; and a *shelter deduction*, for households that have high shelter costs (including mortgage, rent, taxes, insurance, and utility expenses) in relation to their income.

The primary difference between the Part D subsidy eligibility and food stamp eligibility is the definition of who is considered in the family unit. For the Part D subsidy, only the Medicare beneficiary and his or her spouse, if present, will be considered unless there are related dependents who rely on the individual or his or her spouse for at least one-half of their financial support. For food stamps a household consists of individuals who live together and who purchase and prepare meals together. So in some instances where Medicare beneficiaries live

with others, the food stamp unit will include more people than the Part D family unit. USDA finds, however, that about half of elderly people who are eligible for food stamps but do not participate live alone, so in many cases there will be no difference.

Seniors and People With Disabilities Have Low Food Stamp Participation Rates, Despite Being Eligible for Sizable Benefits

Very low-income elderly and individuals with disabilities — those with annual incomes below about 75 percent of the poverty line (which is $6,788 for an individual and $8,554 for a couple) — are fairly well connected to the safety net; they are generally eligible for cash assistance under the Supplemental Security Income (SSI) Program and health coverage under Medicaid. The majority of these very low-income individuals do participate in food stamps.

But low-income elderly and individuals with disabilities with incomes above this level — including many such people who live below the poverty line — generally do not qualify for SSI or Medicaid, and although they are eligible for food stamps, they often are not enrolled. Overall, the program serves only about a quarter of eligible elderly people and just under half of the population of eligible adults with disabilities. In total, USDA estimates that there are over 6 million seniors and adults with disabilities who are eligible for food stamps but do not receive them.[1] Of course, Medicare beneficiaries who are not receiving SSI or Medicaid are the people who will be applying for the Part D benefit through SSA or state or local offices.

For many low-income Medicare beneficiaries, Social Security benefits bring them close to or modestly above the poverty line. For such households who do not have high expenses — for example, because they live in public housing and have no out-of-pocket medical costs — the food stamp benefit for which they qualify can be relatively low, perhaps only $10 a month. If, however, such a household has high shelter expenses, out-of-pocket medical expenses, or dependent care expenses, its monthly food stamp benefit will be significantly higher. The average Social Security recipient who has medical expenses and receives food stamps qualifies for about $50 a month in benefits. A typical household with members who are elderly or disabled and very high deductions can receive close to $90 a month or more in food stamps. Outreach messages that SSA or states use may be more useful if they explain that households with high expenses will qualify for more food stamps.

Current Responsibilities of SSA and States Make Them Appropriate to Play a Role in Enrolling Medicare Beneficiaries in Food Stamps

The states and SSA each currently have responsibilities related to the Food Stamp Program. Although food stamp benefits are 100 percent federally-funded and many of the program's eligibility and benefit rules are set by federal rules, the states have primary responsibility for virtually all aspects of the administration of the program (as they do with Medicaid), including outreach, certification and enrollment, issuance, and on-going case management. States receive a 50 percent federal match for administrative costs related to food

[1] For the Food Stamp Program an individual is considered to be elderly upon turning 60. So this figure somewhat overstates the number who would also be Medicare beneficiaries.

stamps. With only a handful of exceptions, the same local agency or local office that processes Medicaid applications also determines food stamp eligibility.

The Food Stamp Act envisions that SSA will play an important role in informing seniors and people with disabilities about food stamps. Under section 11(j)(1) of the Food Stamp Act, Social Security and SSI applicants and recipients are to be "informed of the availability of a simple application to participate in [the food stamp] program at the social security office." Section 11(j)(2) of the Food Stamp Act further requires SSA to "forward immediately" to state agencies food stamp applications from households where all members are applicants for or receive SSI. Finally, section 11(j)(2)(C) provides that the Secretary of Agriculture will reimburse the Commissioner of Social Security for any costs associated with these activities. To be clear, this means that food stamps, an entitlement with open-ended funding, can fully reimburse SSA for these food stamp-related activities without Congress needing to appropriate additional funds. (See 7 U.S.C. § 2020(j) — attached.)

Unfortunately, to our knowledge, SSA and USDA are largely out of compliance with Section 11(j)(2) of the Food Stamp Act. There is no uniform simple application currently available at social security offices for applicants or recipients to use to apply for food stamps. Not many social security offices make much effort to inform Social Security or SSI applicants about the availability of food stamps. Nationwide, the total amount that SSA received from USDA for these activities was less than $10 million in fiscal year 2003.

One promising exception is the "Combined Application Projects," or CAPs, that have been implemented in four states (Mississippi, New York, South Carolina, and Washington) in the past decade. In the CAP states, for SSI applicants who live alone, SSA provides a shortened food stamp application form with just a couple of additional questions to what the SSI application gathers. Data from the SSA application and interview are transferred to the food stamp agency, and food stamp benefits are determined without the applicant having to take any further action. (See http://www.fns.usda.gov/fsp/government/caps.pdf.) SSA has agreed to allow three additional states (Florida, Massachusetts, and Pennsylvania) to adopt this model but has declined to make the option available nationwide.

B. Comments on Subpart P Section 423.774 and Subpart S Section 423.904

The Part D enrollment process offers an historic opportunity to connect Medicare beneficiaries to food stamps and other assistance programs that might help them make ends meet. We urge you in the final regulation, and through other implementation decisions, to set up an eligibility process for the Part D low-income subsidy that allows low-income Medicare beneficiaries to be enrolled as seamlessly as possible in food stamps, as well as other state- or SSA-administered benefits for which they may qualify. This will require CMS to work collaboratively with SSA, USDA, and state agencies. Below are some specific opportunities that we see.

- **Provide information about food stamps and other major benefits for which applicants may be eligible in any outreach materials that CMS, SSA, and state Medicaid programs design and distribute.** CMS and SSA are planning

large-scale information and outreach efforts in the lead-up to the Medicare drug benefit going into effect. Mailings, on-line resources, and other materials that are made available to low-income Medicare beneficiaries and to groups that work with such beneficiaries could easily include information about the availability of food stamps and how to apply. USDA has developed an on-line prescreening tool at http://209.48.219.49/fns/.

- **Design procedures that allow applications that are filed and other information that applicants provide to be shared between SSA, state agencies, and CMS so that it is available to all agencies.** Such data sharing would allow states to target follow-up outreach to applicants who appear to be eligible for other programs, such as food stamps. For example, states could use the information that applicants provide to them or SSA for the drug benefit to automatically fill out significant sections of a food stamp application. The state could then mail the application to the elderly individual asking him or her simply to fill in the remaining questions and mail the application back, without having to come to the food stamp office.

- **Collaborate with other federal agencies, primarily USDA and SSA, on ways to enroll eligible applicants in all benefit programs.** The three agencies should seek to simplify federal program rules so that low-income Medicare beneficiaries can readily access all programs for which they qualify. A model may be the SSA Combined Application Projects that now operate in a handful of states, where SSI applicants are asked only a couple of additional questions and are certified automatically for food stamps based on their SSI applications. The standardized federal rules under these projects have allowed SSI applicants who live alone to apply for food stamps with significantly less burden than would otherwise be required.

- **Develop coordinated redetermination processes that are as simple as possible for Medicare beneficiaries.** Under the regulation, CMS seems to envision that once the Part D benefit is underway, Medicare beneficiaries will have their eligibility redetermined annually. It appears that a beneficiary who receives a Part D subsidy, is a QMB, and also receives food stamps would have to reapply separately for these three benefits at different times and would potentially have to provide virtually all of the same information to three different entities. This is an unreasonable burden for a poor senior or individual with a disability who may find it difficult and confusing to navigate three separate processes. In addition, this population tends to have relatively stable income and other circumstances. One option would be for SSA and state agencies to renew Part D eligibility based on information the beneficiary has provided for other programs, such as food stamps, if it is current. Many states have successfully used this type of “passive renewal” procedure in their Medicaid and State Children’s Health Insurance Programs (SCHIP).

- **USDA can reimburse SSA for the food stamp program's share of any costs associated with efforts to inform Social Security recipients of the availability of food stamps and other programs.** This could include, for example, outreach mailings to Medicare beneficiaries or costs associated with making computerized information available to states.

II. General Comments on Other Proposed Regulations

A. Comments on Subpart B — Eligibility and Enrollment

Enrollment of Dual Eligibles in Medicare Part D Plans

The proposed regulations fail to address adequately how responsibility for providing drug coverage for the 6.4 million Medicare beneficiaries with full Medicaid coverage (i.e., the full dual eligibles) will be appropriately transferred from Medicaid to Medicare on January 1, 2006. There are issues both of timing and of the mechanics of instituting the enrollment process. The proposed regulations do not adequately address these issues in a way that would ensure that these 6.4 million dually eligible beneficiaries avoid a potential loss of drug benefits or a gap in drug coverage, either of which could have unfortunate health consequences for these individuals.

According to the preamble, automatic enrollment of dual eligibles as required under section 423.34(d) will not begin until the end of the initial enrollment period on May 15, 2006. However, the Medicaid drug benefit for dual eligibles will no longer be available on January 1, 2006. (Federal Medicaid matching funds will no longer be available for providing outpatient drug coverage to the dual eligibles after January 1, 2006.) Given the difficulty of appropriately educating this population about Part D plan choices, it is a near certainty that a substantial number of dual eligibles will face a several month gap in coverage between the end of Medicaid's drug benefit and the scheduled automatic enrollment. This likely scenario would directly contravene Members of Congress' and the Administration's commitment that dual eligibles will be better off under Medicare Part D (or at least not be made worse off). The most appropriate solution would be to delay the cut-off of federal Medicaid matching funds to allow more adequate time to ensure an effective transition of the dual eligibles from Medicaid to the new Medicare Part D benefit. However, that would likely require statutory changes to the MMA. At the very least, CMS needs to encourage large-scale education efforts targeted to the dual eligibles by states and other organizations and allow for an earlier auto-enrollment deadline prior to January 1, 2006 to avoid gaps in coverage for the dual eligibles.

In the preamble, CMS requests comments on whether CMS or the states should perform automatic enrollment of dual eligibles. State officials are familiar with the needs of their dual eligible populations and have more data readily available on the dual eligibles in their state. They also will already be involved in the enrollment process because they are required to perform low-income subsidy enrollment; therefore, we recommend that states have the option of performing automatic enrollment. (We are concerned that under section 1860D-1(b)(1)(C) of the MMA and section 423.34(d)((2) of the proposed regulations, the auto enrollment must be conducted on a random basis, which may limit the ability of states that are conducting this auto

enrollment from moving dual eligibles to the plan that provides the greatest access to drugs. This too may require further statutory changes)

We are also extremely concerned with ensuring continuity of care for dual eligibles who have substantial drug needs. As discussed below in our comments on the need for special open formularies for the dual eligible population, for example, a disproportionate number of dual eligibles struggle with mental illness and need access to a wide variety of medications.

As outlined in the proposed regulations, dual eligibles would be forced to enroll (or be automatically enrolled) in the "benchmark" or average cost plans in their areas because, under the low-income subsidy, they will receive only a premium subsidy up to the cost of the premium for these plans. They will not receive additional premium subsidies for plans with premiums higher than the premium cost of a benchmark plan. The formularies for these plans, however, may not be as comprehensive as the drug coverage that these individuals currently have through Medicaid.

Without access to the coverage they need, dual eligibles may be forced to switch medications. In the treatment of HIV/AIDS, for example, such switches can be highly problematic and potentially deadly. We believe the same is true for a number of other illnesses and categories. Not ensuring continuity of care for prescription drugs for the dual eligibles could increase the costs of their care; dual eligibles with restricted access to drugs could end up requiring expensive services like hospitalization.

The regulations do provide a special enrollment period for full dual eligibles to use "at any time" (section 423.36). However, this provision of the regulations does not adequately address the needs of dual eligibles. There may not be adequate choice of low-cost drug plans in each region, particularly in rural areas which have not had much luck attracting Medicare managed care plans in the past. In addition, the dual eligibles are unlikely to have income or resources to pay the additional premiums (in addition to the low-income subsidy) necessary to enroll in higher cost plans that may have more comprehensive drug coverage and greater access to drugs. Moreover, the special enrollment provisions under section 423.36 do not specify that dual eligibles would not be subject to a late enrollment fee if this complex process of disenrollment and reenrollment results in a gap in coverage of more than 63 days.

In addition, full benefit dual eligibles (and their personal representatives) should receive a notice explaining their right to a special enrollment period both when they enroll in a plan and each time the prescription drug plan changes its coverage in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

In the preamble to the proposed regulations, CMS points to the exceptions process as a means of securing coverage of off-formulary medications. But the process proposed is extremely complex and will likely be impossible to navigate for people having a psychiatric crisis, facing cognitive impairments, or in the midst of aggressive chemotherapy, to list just a few examples. Moreover, the timelines established are drawn out; an expedited determination could

take as long as two weeks. Drug plans are not required to provide an emergency supply of medications until at least two weeks following a request.

Congress and the Administration have promised that dual eligible beneficiaries would be better off with this new Part D drug benefit (or at least no worse off) than they were receiving drug coverage through Medicaid. To honor this commitment, coverage of medications currently available to dual eligibles and other special populations under Medicaid must be grandfathered into the new Part D benefit just as a number of states (such as Wisconsin, Oregon, Kentucky, Texas and California) have done in implementing preferred drug lists under their Medicaid programs. For dual eligibles (and for others with life-threatening diseases such as HIV/AIDS, mental illness, cancers, and other extreme conditions), Part D plans should be required to cover their existing medications. At a minimum, this protection should be given to dual eligibles, because it is likely to be impossible for dual eligibles to enroll in more generous drug plans by paying supplemental premiums or paying for off-formulary drugs on an out-of-pocket basis.

B. Comments on Subpart C —Benefits and Beneficiary Protections

Special Formulary Protections for Dual Eligibles

Section 423.120(b) outlines the requirements on Part D prescription drug plans and on Medicare Advantage plans for their drug formularies. We strongly support the suggestion in the preamble to the proposed rule that certain populations require special treatment due to their unique medical needs. Such populations include full dual eligibles as well as institutionalized populations, persons with life-threatening conditions, and persons with pharmacologically complex conditions. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and must be protected from tiered cost-sharing that could create insurmountable access barriers. We recommend that the final rule provide for alternative, flexible formularies for special populations that include coverage for all FDA-approved covered Part D drugs with a valid prescription. Furthermore, because of the clinical importance of providing access to the specific drugs prescribed, drugs prescribed to these defined populations ought to be made available at the preferred level of cost-sharing for each drug.

In enacting the MMA, Members of Congress and the Administration committed to the principle that dual eligibles (persons eligible both for Medicare and Medicaid) would be better off (or at least not be made worse off) when their coverage for prescription drugs shifted from Medicaid to the new Medicare Part D coverage. Historically, the Medicaid prescription drug benefit has been closely tailored to the poor and generally sicker population it serves, providing beneficiaries with a range of drugs that they need with little or no co-payment. Under section 1927 of the Social Security Act, states that elect to provide prescription drug coverage under their Medicaid programs must cover all FDA-approved drugs from every manufacturer that has entered into an agreement with the Secretary of Health and Human Services to pay rebates to states for the products that the states cover. All drug manufacturers currently participate in the Medicaid rebate program.

Dual eligibles are the most vulnerable Medicare beneficiaries. Dual eligibles are people with disabilities and other serious conditions who tend to need a wide variety of prescription drugs. They are more than twice as likely to be in fair or poor health as other Medicare beneficiaries; they are three times more likely to have problems with Activities of Daily Living (ADLs) as other beneficiaries; and they are ten times more likely to be in a long-term care facility than other beneficiaries. In serving dual eligibles, Medicare prescription drug plans must be able to respond to a range of disabilities and conditions, such as physical impairments and limitations like blindness and spinal cord injury, debilitating psychiatric conditions, and other serious and disabling conditions such as Parkinson's disease and HIV/AIDS. If dual eligibles are not to be worse off when Part D prescription drug coverage begins, then they must have continued access to an alternative and flexible formulary that permits treating physicians to prescribe the full range of FDA-approved medications.

This will particularly be the case for many of the dual eligibles who reside in nursing facilities and other residential facilities. Such institutionalized beneficiaries require access to flexible formularies on the basis of their complex and multiple prescription drug needs.

Moreover, although we recommend that any alternative formulary include access to all FDA-approved medications, if the final rule permits a more restrictive alternative formulary, it should ensure that all drugs included on the formulary of participating Long-Term Care (LTC) pharmacies are included in the plan's formulary, and drugs that are preferred by the LTC pharmacies' formularies should be treated by the plan as a preferred drug. Institutionalized individuals also have little or no capacity to pay cost-sharing for non-preferred drugs or to purchase drugs for which coverage has been denied. It is imperative that any alternative formulary provide strong protections that prevent such individuals from being charged cost-sharing. For dual eligibles who reside in institutions, a condition of eligibility requires them to pledge all but a nominal personal needs allowance, usually $30 per month, to the cost of the institutional care. (We note that individuals who require an institutional level of care but live in the community under home- and community-based Medicaid waivers should have the same special protections as institutionalized beneficiaries because of their similar substantial need for prescription drugs. Otherwise, providing greater access to drugs for institutionalized individuals than to those living in the community would have the adverse effect of reversing the continued progress states have made in moving people from nursing homes to the community setting.)

C. Comments on Subpart P — Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Automatic Eligibility and Enrollment of Dual Eligibles for Low-Income Subsidy

Section 423.773 of the proposed regulations states that both full benefit dual eligibles (as well as Medicare Savings Program beneficiaries, as discussed below) are *eligible* for the additional low income subsidies, but it does not explicitly state that these beneficiaries are to be automatically *enrolled* in the subsidy program. The regulations should clarify that an individual treated as a full subsidy individual (such as a dual eligible or a MSP beneficiary) does not have to take any further action with respect to the subsidy (i.e., to make application or in any other to way verify their status), except to the extent that they need to enroll in a Part D plan. This will

help smooth the transition from Medicaid drug coverage for dual eligibles and should improve participation for others.

Treatment of Resources

Under section 423.772, we support the proposed regulation's limitation of countable resources to liquid assets only. However, the definitions of liquid assets and what it means for an asset to be able to be converted into cash in 20 days need to be clarified. The final rule should enumerate the list of countable resources that constitute liquid assets to promote clarity for states and beneficiaries. The scope of countable liquid assets should be construed narrowly, as experience under the MSP programs shows that assets tests tend to discourage enrollment and raise administrative costs for states. Experience among the states with MSPs has shown that when states waive the assets test or make it more reasonable by excluding, for example, burial plots, burial funds and life insurance from the list of countable assets, enrollment in MSP increases, with the additional costs of enrollment at least partly offset by administrative savings.

Moreover, it is harsh and inappropriate to deny an applicant the low-income drug benefit because the applicant will not liquidate a life insurance policy or burial fund. We are especially troubled by an SSA draft of the application for the low-income subsidy that asks whether an applicant has life insurance with a face value of $1,500 or more. Such a policy should not be acceptable; low-income elderly people and people with disabilities should not be disqualified from the low-income drug benefit because they have a modest life insurance policy that is intended to cover their funeral and burial costs when they die. The Food Stamp Program, for example, entirely excludes the value of a life insurance policy from its asset test. At most, the only part of a life insurance policy that should be considered is the cash surrender value to the extent that the value exceeds some much more reasonable amount, such as $20,000.

In addition, retirement accounts such as a 401(k) plan or IRA should either be fully exempt for all beneficiaries, or fully exempt for disabled Medicare beneficiaries up to age 65, with an assumed annuity value, based on the account, considered as income for all beneficiaries aged 65 and over. If calculating an annuity value would be too complicated, a simplified approach could be used, under which a fixed percentage of such an account is treated as income each year, based on Census (or other official) life expectancy tables. In other words, if a person aged 65 is assumed to live 20 years based on the life expectancy tables, five percent of the amount in the individual's 401 (k) or IRA would be counted as income each year. These accounts would *not* be counted as assets.

This is a much fairer and more rational approach. To count such accounts as assets and disqualify people with modest account balances would undercut efforts to encourage low- and moderate-income people to build some savings that can ease their poverty throughout their old age. Counting these accounts as assets for disabled beneficiaries who are below retirement age also may reduce work incentives. If such accounts are counted as assets, such individuals may be forced to liquidate modest retirement accounts. It would be far better to preserve such accounts so that the prospect of enlarging them if an individual with a disability can return to work may operate as a work incentive.

Counting the amounts in such accounts as assets is inappropriate. Such accounts are supposed to help support these people throughout their old age. Counting such accounts as assets implies that the accounts should be emptied out now to help pay for prescriptions, with the individual then left deeper in poverty for the rest of his or her life.

(Finally, we would note that the draft SSA application contains a problematic and confusing treatment of "annuities," which the application says should be treated as an asset rather than as income. The term "annuity" is popularly used for a range of financial instruments, including "life-time annuities." And an individual with a life-time annuity *no longer owns the underlying assets*. Such an individual has essentially sold the assets to the annuity company in return for a stream of income in the form of a guaranteed monthly payment for the rest of the individual's life. In these cases, it is wholly inappropriate to count the value of the underlying assets against the asset test; the individual no longer owns the assets and has no legal access to them. Furthermore, in these cases, the monthly payments that such an individual receives from the annuity company clearly ought to be counted as income. The draft SSA application is likely to lead to confusion and erroneous determinations in this area.)

Treatment of MSP Beneficiaries by SSA

We strongly support the decision reflected in section 423.773(c) to deem Medicare Savings Program ("MSP") beneficiaries automatically eligible for the low-income subsidy. This would greatly ease the administrative burden on states and SSA while also ensuring that many more MSP beneficiaries enroll in the low-income subsidy.

We are concerned, however, that MSP beneficiaries are likely to be treated differently depending on whether they apply for the low-income subsidy through Medicaid or through a SSA office. Inequities and confusion among beneficiaries may result because SSA would apply its standard for assets which may be less generous than the asset eligibility rules for MSPs in place in some states. For example, Alabama, Arizona, Delaware, and Mississippi have eliminated the assets test under the MSP programs. Eligibility requirements for the low-income subsidy should be as generous at the SSA office for subsidy-eligible individuals as at a Medicaid office, regardless of where and how people apply within the same state. Under the proposed rules, in states that have adopted less restrictive asset methodologies, people whose assets are slightly above the limits set in section 423.773 would likely be enrolled in a less generous subsidy, or have their application rejected entirely, if they apply directly through SSA, because SSA will apply the national guidelines proposed in section 423.773. However, the same people would have their application accepted if they applied through their states' Medicaid offices, were screened and then enrolled in an MSP, and were then automatically eligible for the low-income subsidy.

To resolve this problem, we propose that SSA should apply state-specific asset eligibility rules in determining eligibility for the low-income subsidy when they are more generous than under the national standard, an option discussed, though rejected, in the preamble at page 46,727. This means that for applicants from states that have eliminated the asset test or have more generous disregards under section 1902(r)(2) of the Social Security Act for MSP eligibility, SSA should apply the state's more generous rules to determine eligibility if applicable. This option is

permitted under Section 1860D-14(a)(3)(E)(iv) of the statute. (We note that the statute should be amended to allow SSA to also apply state-specific income eligibility rules when they are more generous as well.)

The regulations should also provide that subsidy applicants who appear to have excess assets *or* incomes either be screened by SSA for eligibility in an MSP program or have their applications forwarded to the state Medicaid agency to be screened for MSP eligibility. States would be precluded from requiring beneficiaries to resubmit information, such as income and asset levels, that they have already provided to SSA. Applicants would be enrolled in the appropriate MSP program, be deemed automatically eligible for the low-income subsidy under section 423.773(c) and then be enrolled in the appropriate low-income subsidy. Adopting this policy, which is not precluded by the statute, will ensure that all subsidy applicants are treated equitably and in a manner most favorable to the applicants, as well as increase participation in MSPs.

As part of this policy, the low-income subsidy application should allow an applicant to opt out of screening and enrollment for an MSP, as it is possible that a few applicants may not wish to participate in an MSP. Under Section 1860D-14(a)(3)(v)(II) of the statute, beneficiaries who are determined eligible for MSPs may be enrolled in the low-income subsidy. There is no requirement that beneficiaries actually enroll in an MSP. Therefore, applicants who meet the eligibility requirements for an MSP but who decline to enroll in the program should still be made automatically eligible for the low-income subsidy.

Because enrollment in an MSP can affect the amount of assistance a beneficiary may receive through other public assistance program, such as Section 8 housing vouchers or food stamps, there will be a profound need for beneficiary counseling during the enrollment process. We recommend that CMS plan for this need by making funds available to local agencies, including state health insurance assistance programs (SHIPs) and other community-based organizations.

In addition, we suggest that states not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective but can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP. We include the same suggestion in our comments to section 423.904(c) discussed below.

D. Comments on Subpart S — Special Rules for States — Eligibility Determinations for Subsidies and General Payment Provisions

State Medicaid Screening for Medicare Savings Programs

We believe that section 423.904(c) of the proposed regulations regarding states' obligations to screen subsidy applicants and offer them enrollment in MSPs is inadequate. In particular, proposed section 423.904(c)(2) should specify what "offer enrollment" means. We believe an applicant must be offered the opportunity to enroll during the same visit or contact (in office, by phone, or by mail), without providing further documentation or completing additional

forms. Only if enrollment is easy and convenient would Congress's intent of increasing participation in MSPs be accomplished. Furthermore, because enrollment in an MSP may be the only entry into the subsidy for some low-income beneficiaries, a simple and easy application for MSP programs is essential.

As written, section 423.904(c) would permit states to say they have "offered enrollment" if they tell applicants that they might be eligible for an MSP and can return another time to complete another application form if they wish to apply. Such an outcome would defeat the purpose of the screen-and-enroll provision included in the new Section 1935(a)(3) of the Social Security Act that was established in Section 103(a) of the statute. The low-income subsidy application should include an "opt-out" provision, under which qualified applicants would be enrolled in an MSP unless they affirmatively decline to do so. This provision would make enrollment in an MSP another way to qualify for the low-income subsidy.

Moreover, it is critical that state Medicaid offices provide good quality counseling to applicants, including their potential eligibility for other benefits such as MSPs. In addition, to ensure that enrollment requirements between MSPs and the low-income subsidy are aligned, states should not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective and can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP.

In the interest of further aligning eligibility rules for MSPs and the low-income subsidy and easing administrative burdens, we suggest that CMS should direct states to apply the definitions of resources used in Subpart P, section 423.772, if they are more generous than the MSP standards used in the individual state, in making their resource determinations for MSP applicants.

In addition, should CMS adopt a policy, as has been discussed publicly, under which most subsidy applications to state Medicaid agencies would simply be forwarded to SSA for the actual eligibility determination for the low-income subsidy, the regulations should be clear that screening for MSP eligibility must take place prior to the transmittal of the applications to SSA. Potential beneficiaries should not have to wait to be screened and offered enrollment in MSPs until after SSA processes their low-income subsidy application and provides such information back to the state Medicaid offices (if SSA in fact does so). Furthermore, an individual cannot be told by either SSA or the state that she or he is ineligible for the low-income subsidy until MSP eligibility has been determined (if the individual wishes). It would be highly problematic for an individual to receive a notice from SSA that he or she is ineligible for the low-income subsidy, have her MSP eligibility determined by the state, and then receive a notice from the state that she is eligible for both MSP and the subsidy. Alternatively, the individual may be found ineligible for the low-income subsidy by SSA and subsequently enrolled in a MSP but never redetermined for eligibility for the low-income subsidy. Whatever the mechanics, the individual must be told that MSPs are a route to subsidy eligibility.

Finally, SSA should also screen subsidy applicants for eligibility in MSPs and develop a system with states to enroll eligible beneficiaries. SSA should use the income and resource

disregards used by the state for MSPs, if they are more generous than under the uniform national definition. Applicants should not miss out on the opportunity to enroll in MSPs simply because they apply through SSA rather than state Medicaid offices. The same concerns about beneficiary education and estate recovery discussed above would apply to enrollment through SSA.

State Medicaid Screening and Enrollment for Full Medicaid

We believe that the regulations should also ensure that beneficiaries are screened not only for MSPs but also for eligibility for full Medicaid and offered enrollment if they qualify, consistent with 42 C.F.R. § 435.404. Ideally, all subsidy applicants would be screened for full Medicaid and offered enrollment if they qualify (similar to current screen-and-enroll procedures under the State Children's Health Insurance Program described in 42 C.F.R. § 457.350, and in particular for states that use separate SCHIP applications as described in 42 C.F.R. § 457.350(f)(3)). Because the importance of maintaining a simple application process for the low-income subsidy is paramount, CMS may wish to consider using a simple screening process based on information obtained through the subsidy application. This screening would trigger a follow-up with applicants who appear to be eligible for full Medicaid.

ATTACHMENT
Food Stamp Act [7 U.S.C. § 2020(j)] on SSA's responsibilities

Section 11(j) of the Food Stamp Act:

(1) Any individual who is an applicant for or recipient of supplemental security income or social security benefits (under regulations prescribed by the Secretary in conjunction with the Commissioner of Social Security) shall be informed of the availability of benefits under the food stamp program and informed of the availability of a simple application to participate in such program at the social security office.
(2) The Secretary and the Commissioner of Social Security shall revise the memorandum of understanding in effect on the date of enactment of the Food Security Act of 1985, regarding services to be provided in social security offices under this subsection and subsection (i), in a manner to ensure that—
(A) applicants for and recipients of social security benefits are adequately notified in social security offices that assistance may be available to them under this Act;
(B) applications for assistance under this Act from households in which all members are applicants for or recipients of supplemental security income will be forwarded immediately to the State agency in an efficient and timely manner; and
(C) the Commissioner of Social Security receives from the Secretary reimbursement for costs incurred to provide such services.

CMS-4068-P-1248

Submitter : Mr. Steve Roling **Date & Time:** 10/04/2004 08:10:43

Organization : Missouri Department of Social Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the Medicare Part D proposed rules. The Medicare Drug Program is a very complex program with significant ramifications for a large number of vulnerable Missourians. The Missouri Department of Social Services (DSS) urges the Centers for Medicare and Medicaid Services (CMS) issue the next version of these regulations in a format that will allow one more round of comment, even if it is a shortened comment period. We are concerned that failure to provide for additional public input when the regulation is more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

CMS-4068-P-1248-Attach-1.doc

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October 4, 2004

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Attention: CMS–4068–P

Thank you for the opportunity to comment on the Medicare Part D proposed rules. The Medicare Drug Program is a very complex program with significant ramifications for a large number of vulnerable Missourians. The Missouri Department of Social Services (DSS) urges the Centers for Medicare and Medicaid Services (CMS) issue the next version of these regulations in a format that will allow one more round of comment, even if it is a shortened comment period. We are concerned that failure to provide for additional public input when the regulation is more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

Enrollment Process

General

Missouri is concerned that the under the proposed Medicare Part D rule automatic enrollment of full benefit dual eligibles might not occur until May 15, 2006. This would cause dual eligibles active on January 1, 2006 who do not voluntarily enroll in Medicare Part D to go as long as five and a half months without prescription drug coverage. Many of the individuals who have been long time Medicaid recipients may be confused by the voluntary enrollment process and fail to enroll by January 1, 2006. Medicare's experience with the drug discount card has demonstrated that vulnerable populations often will not enroll on their own initiative in a program such as the Part D benefit, despite the advantages of the benefit being offered. Leaving dual eligibles with no coverage seems in conflict with the purpose of the Medicare Modernization Act (MMA). Automatically enrolling the full benefit dual eligibles prior to January 1, 2006 would not allow much opportunity to select a plan; however, this is preferable to having no coverage. Intermittent eligibility in Medicaid programs may further

complicate the transition to Part D and disrupt access to prescription drugs. Unique Medicaid "spenddown" or "medically needy" programs operate in 39 states. These programs allow people with high medical costs, including nursing home residents, to qualify for Medicaid by spending their income and resources down to a state-defined medical assistance eligibility level. In many cases, an individual may begin a month with a pension check or other source of income that makes them ineligible for Medicaid for the first part of the month, but once that income is put toward the cost of their care (that is, spent down), they become eligible for the remainder of the month. Depending on the spenddown period designed by the state, individuals can cycle on and off of Medicaid eligibility on as often as a monthly basis. This intermittent eligibility will significantly complicate the initial education and enrollment process and must be factored into continuing administrative and policy decisions for states, the federal government, and providers of prescription drug benefits.

Accordingly, Missouri seeks amendment to both §423.34(b) and §423.42(a) in order to clarify that a state may assist an individual with completion of the individual's Private Prescription Drug Plan (PDP) application, including executing the application on the individual's behalf, or may otherwise assist an individual in the Part D enrollment process as long as the individual is provided an opportunity to decline this assistance or "opt out" of any available PDP. Another option CMS should consider is allowing full benefit dual eligibles not enrolled in Part D to continue to receive prescription drug coverage under Medicaid with Federal Financial Participation (FFP) until the automatic enrollment date.

B. Eligibility and Enrollment (Federal Register page 46637)

2. Part D Enrollment Process (§423.34) (Federal Register page 46639)

CMS: *In implementing the automatic enrollment process for full benefit dual eligible individuals, we are considering which entity is best suited to perform the automatic and random enrollment function. We invite comment on the most appropriate method of performing automatic assignment of dual eligibles and the appropriate entity to do so.*

DSS Comments: The Missouri Department of Social Services believes automatic enrollment of full benefit dual eligibles can be handled most efficiently by the states if CMS is able to provide up-to-date information on persons currently enrolled in Medicare Part D. Having the states be responsible for performing the automatic enrollment would allow for the shortest period of time between the Medicaid approval and enrollment in Part D. DSS is concerned that the administrative cost of requiring the states to do the automatic enrollment would be an unfunded mandate. The preamble mentions compensating the states through FFP for administrative expenses or through contractual or other arrangements. Since the cost to develop a

system for automatic enrollment may be extensive, DSS feels states should receive more than the current administrative match for assuming this burden to meet this "new national workload of indeterminate size."

4. Effective Dates of Coverage and Change of Coverage (§423.38)

c. Special Enrollment Period (Federal Register page 46641)

CMS: *The rule states that for special enrollment periods, the effective date of the enrollment will be determined by CMS.*

DSS Comments: CMS should make the effective date of enrollment in Part D retroactive to the date the person's Medicaid was effective and they became a full benefit dual eligible. If the enrollment in Part D is not retroactive to the date Medicaid eligibility began, full benefit dual eligibles will have no prescription drug benefit during the prior quarter coverage. Longstanding Missouri statute requires that medical assistance (Medicaid) is only paid during such times as grants-in-aid (FFP) is provided or made available to the state.

Subpart P: Premiums and Cost-Sharing Subsidies for Low-Income Individuals (Federal Register page 46725)

2. Eligibility Determinations, Redeterminations and Applications (§423.774) (Federal Register pages 46727-46728)

CMS: *We invite comments on state Medicaid agency procedures how to best implement the determination, redetermination, and appeal process.*

DSS Comments: Section 1860D-14(a)(3)(B)(i) of the Act and the proposed 423.774 both say that determinations of eligibility for the subsidies are made by the state Medicaid agency or Social Security Administration (SSA). Our initial interpretation of this was that both agencies were required to make determinations and the Medicare recipient was free to choose which to apply with. However, it has come to our attention that SSA is proposing that the states can comply by taking applications and submitting them to SSA for the eligibility determination. This appears to conflict with Section 1935 of the Act and the proposed 423.904 that require the state Medicaid agency to make determinations of eligibility for the subsidies. If CMS believes that a state Medicaid agency can meet the requirements of both Sections 1860D-14(a)(3)(B)(i) and 1935 by taking applications and submitting them to SSA, that should be clarified in the regulations. The regulation should be clear on what obligation a state choosing this option has for keeping track of what applications were submitted and what happened to them.

The regulations do not specify the time standards within which an eligibility determination must be completed. Would the state Medicaid agency be required to complete determinations within 45 days as is required for most Medicaid eligibility determinations under 42 CFR 435.911? The regulations should specify a time standard that would apply to determinations made either by the state or SSA.

Subpart S: Special Rules for States – Eligibility Determinations for Low-Income Subsidies and General Payment Provisions (Federal Register page 46861)

CMS: *Each of the 50 states and the District of Columbia is required to provide for payment to the Secretary a phased-down contribution to defray a portion of the Medicare drug expenditures for individuals whose projected Medicaid drug coverage is assumed by Medicare Part D.*

DSS Comments: The regulations in Subpart S provide an overview of the clawback (phased-down state contribution) calculation, but it lacks the specifics for the states to estimate the clawback. The comments provided are based somewhat on information provided in conference calls attended by CMS.

The clawback is based on expenditures in calendar year 2003. The base year expenditures are trended based on National Health Expenditure (NHE) trends. The NHE trends are significantly higher than the actual increase experienced by the state. Therefore, the state will be paying a higher clawback and is further impacted since the state will continue to pay this "higher rate" for the life of the Medicare Modernization Act. Based on the last couple of years, it is also highly likely that the NHE trend will be higher than the trend experienced in Missouri Medicaid. This difference will also result in a higher clawback payment from the state.

The rebate adjustment factor is based on the pharmacy expenditures and rebates collected for the same period of time through the CMS-64 reports. When reporting these quarterly, the rebates will lag six months behind the expenditures due to the rebate process. The rebate adjustment factor artificially reduces the actual percent of rebate that is collected, which, in turn, results in a higher clawback that the state will be paying monthly to eternity. A more appropriate rebate adjustment factor would be the expenditures for calendar year 2003 and rebates collected for July 2003 – June 2004.

The clawback calculation apparently does not allow for adjustments. Missouri is a "Pay and Chase" state for pharmacy claims. Since there are no provisions for these collections in the clawback calculation, the gross per capita spent is artificially high, resulting in a higher clawback payment for Missouri. The clawback calculation also does not take into account that Medicaid recipients in calendar year 2003 were the beneficiaries of a drug

formulary that contained more drugs than they may have access to under a PDP. The clawback calculation does not allow adjustment for the more restrictive drug formulary.

Involuntary Disenrollment of Beneficiary by the PDPs (§423.44) Federal Register page 46641

CMS: *The proposed rule provides that PDPs may disenroll individuals whose behavior is disruptive.*

DSS Comments: The Department of Social Services has concerns regarding provisions in the proposed regulations to allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening." These provisions create enormous opportunities for discrimination against individuals with mental illnesses, Alzheimer's, and other cognitive conditions. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and as a result, they could also be subject to a late enrollment penalty, increasing their premiums for the rest of their lives. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage.

Under the MMA, section 1860D-1(b) directs the Secretary to establish a disenrollment process for PDPs using rules similar to a specific list of rules for the MA program. This list does not include reference to section 1851(g)(3)(B) of the Social Security Act which authorizes MA plans to disenroll beneficiaries for disruptive behavior.

Therefore, this provision regarding disenrollment of individuals by the PDP for disruptive behavior should be eliminated entirely or there should be a heightened standard for involuntary disenrollment of dual eligibles with mental health issues. There should also be expansion of the "special enrollment exceptions" for individuals disenrolled by a PDP (such as, for disruptive behavior) so that the individual will have an opportunity to join another PDP and continue with necessary medications. These "special enrollment exceptions" are necessary given the high risk of discrimination presented by the provisions for involuntary disenrollment. CMS should provide a special enrollment period for beneficiaries involuntarily disenrolled. It should include a reasonable time period for plan selection and be exempt from late enrollment penalties. Dual eligible beneficiaries who are involuntary disenrolled will face significant hardship because the Missouri Medicaid program will no longer be able to cover prescription drugs if there is no FFP.

Access to Covered Part D Drugs (§423.120) (Federal Register page 46655)

b. Formulary Requirements (Federal Register page 46659)

CMS: *To the extent that a PDP sponsored or MA organization uses a formulary to provide qualified prescription drug coverage to Part D enrollees, it would be required to meet the requirements of §423.120(b)(1) and section 1860D–4(b)(3)(A) of the Act to use a pharmaceutical and therapeutic (P&T) committee to develop and review that formulary. As a note of clarification, we interpret the requirement at section 1860D–4(b)(3)(A) of the Act that a formulary be ''developed and reviewed'' by a P&T committee as requiring that a P&T committee's decisions regarding the plan's formulary be binding on the plan. However, we request comments on this interpretation. In addition, it is our expectation that P&T committees will be involved in designing formulary tiers and any clinical programs implemented to encourage the use of preferred drugs (e.g., prior authorization, step therapy, generics programs).*

DSS Comments: Continuity of pharmaceutical treatment is of great importance to effective disease management and appropriate healthcare. As the proposed regulations themselves seem to acknowledge, PDP formularies must be developed with appropriate consideration of the point that – especially for older individuals – it is often therapeutically counter-productive, or even dangerous, to abruptly change medications. Accordingly, we believe that coordination of formulary development between State Pharmaceutical Assistance Programs (SPAP) and PDPs is especially important and should be expressly encouraged by the Part D rules.

As we understand the CMS proposal, CMS expects that the model categories and classes developed by United States Pharmacopeia (USP) will be defined so that each includes at least one drug that is approved by the Food and Drug Administration (FDA) for the indication(s) in the category or class. That is, no category or class would be created for which there is no FDA approved drug and which would therefore have to include a drug based on its "off label" indication. While DSS generally approves of the process being utilized by USP we point out an inherent flaw in the decision that, in some cases, only one drug approved in a given therapeutic class will be included in the formulary. In the case of many drugs that require lengthy periods to determine "stable" doses, abruptly changing a beneficiary's medicines in order to ensure reimbursement as a covered Part D drug could have serious consequences to that individual's health and welfare. Such negative outcomes are especially likely in the case of psychotropic compounds.

Moreover, we believe that any established formulary exceptions criteria must be flexible enough to take into account the actual circumstances of a particular beneficiary. The Secretary should provide a guideline to Medicare Advantage Prescription Drug (MA-PD) plans, as well as stand-alone

prescription drug plans, that requires such flexibility. In addition, anything less than a comprehensive formulary should be considered when calculating the state's "phase down/clawback" payment since Missouri had a non-scaled down formulary Missouri does not believe it should pay clawback/phase down for a more restricted drug formulary.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections (Federal Register page 46646)

1. Overview and Definitions (§423.100) (Federal Register page 46646)

c. Long-Term Care Facility (Federal Register page 46648)

CMS: *We request comments regarding our definition of the term long-term care facility in §423.100, which we have interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act, or a nursing facility, as defined in section 1919(a) of the Act. We are particularly interested in whether intermediate care facilities for the mentally retarded (ICF/MRs) or related conditions, described in §440.150, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. It is our understanding that there may be individuals residing in these facilities who are dually eligible for Medicaid and Medicare. Given that payment for covered Part D drugs formerly covered by Medicaid will shift to Part D of Medicare, individuals at these facilities will need to be assured access to covered Part D drugs. Our proposed definition limits our definition to skilled nursing and nursing facilities because it is our understanding that only those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies. However, to the extent that ICF/MRs and other types of facilities exclusively contract with long-term care pharmacies in a manner similar to skilled nursing and nursing facilities, we would consider modifying this definition.*

DSS Comments: As a result of the Olmstead decision, states have been moving seniors and persons with SSI benefits from institutions into less restrictive placements. These placements include ICF/MR facilities for the disabled, community care, and assisted living facilities for the aged. In addition to these less restrictive institutional settings, states have implemented waiver programs for home and community based care as an alternative to placement in a nursing home. Medicare beneficiaries spend down their assets until they are forced into nursing homes. These alternatives provide Medicare eligible beneficiaries with a choice of placement. Exclusive contracts with a long term care pharmacy should not be the deciding factor on whether or not to extend the definition of long term care facility to other forms of housing other than traditional nursing homes; the beneficiaries' qualification for Medicare and their placement should be the deciding factor. States can identify Medicare eligible individuals who were

institutionalized, and can also identify those individuals that, if it were not for the Olmstead decision or an 1115 waiver, would be institutionalized. These individuals are low income Medicare beneficiaries; having a Medicare prescription benefit at no cost will allow their income to be used for daily living expenses and not on prescriptions.

Therefore, we recommend that the final rule include a definition of "long-term care facility" that explicitly includes intermediate care facilities for persons with mental retardation and related conditions and assisted living facilities. We believe that many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

3. Establishment of Prescription Drug Plan Service Areas (§423.112) (Federal Register page 46655)

CMS: *We intend to initially designate both PDP and MA regions by January 1, 2005. In accordance with section 1858(a)(2)(C)(i) of the Act, there will be between 10 and 50 PDP regions within the 50 States and the District of Columbia and at least one PDP region covering the United States territories. The PDP regions, like the MA regions, will become operational in January 2006.*

DSS Comments: The State of Missouri believes that the establishment of PDP regions consistent with MA regions (as described in proposed §422.55) is of far less importance than establishing PDP regions that are defined by individual state boundaries. It is critical to a number of operational aspects of Part D benefits administration that each state should be a separate PDP region. As the proposed rule seems to acknowledge, existing SPAPs will play a critical role in coordinating benefits with the PDPs for the most vulnerable populations to be served under the Part D program, as well as in providing "wrap-around" coverage for beneficiaries within these populations. The administrative complexities and burden of effectuating these goals will be enormously – and unnecessarily – increased to the extent that the boundaries of PDP regions are not consistent with the state boundaries defining the relevant SPAP service areas.

6. Coordination of Benefits with Other Providers of Prescription Drug Coverage (Federal Register page 46700)

a. Coordination with SPAPs (State Pharmaceutical Assistance Programs) (Federal Register page 46701)

CMS: Our goal is to make the coordination of benefits process as functional for the beneficiary, pharmacy, and states as possible.

DSS Comments: SPAPs are prohibited from encouraging enrollees to join a particular PDP, and the law and regulatory language prohibits SPAPs

from discriminating based on the PDP in which the beneficiary is enrolled. The federal law does not prohibit a state from providing consumer advice to its citizens as to which plan might work best with a SPAP, which plan offers the best value, etc. Given the intense need for consumer assistance, we urge that the regulation either be silent on the issue or that the regulation actually encourage the states to help their citizens with the many difficult choices and questions they will be facing.

The proposed regulation portrays a much broader and very different non-discrimination rule than is contained in the statute, and is inconsistent with the express statutory language establishing limitations on that rule Under the statute's express language, a qualifying SPAP would quite plainly be permitted to encourage beneficiaries to enroll in a "preferred" PDP by any otherwise legal means that does not constitute disparate treatment of individuals in respect to determinations of eligibility for, or the amount of, assistance. In other words, while a Part D qualifying SPAP would be required to provide the same amount of "wrap-around" coverage to an individual in an alternative plan as would be provided to the individual if enrolled in a "preferred" PDP designated by the SPAP, this would not prevent the SPAP from implementing a preference for a given PDP through other means. CMS, in its proposed regulations, has rewritten this statutory rule so as apparently to prohibit *any* kind of SPAP activity that might grant preference to a given PDP or steer beneficiaries to a particular PDP; the law does not permit this substitution of agency policy for clearly expressed legislative intent.

The final regulations should include a revision of Section 423.464(e)(1)(ii) so that the rule conforms to the express language and intent of Congress in prohibiting qualifying Part D SPAPs from employing determinations of beneficiaries' eligibility or amount of benefits to favor one PDP over another; but the CMS regulations may not validly expand this statutory rule to preclude any preferential treatment of a PDP by an SPAP.

Subpart J: Coordination Under Part D Plans With Other Prescription Drug Coverage (Federal Register page 46696)

6b. Coordination With Other Prescription Drug Coverage (Federal Register page 46702)

CMS: *Comments requested regarding situations that might involve coordination between states and PDPs.*

DSS Comments: Case management services for our elderly and disabled full benefit dual eligible require the identification of prescription drugs being used by the client. We cannot rely on the patient's information, as they might not be capable of recalling all drugs they are currently using. To be effective in providing the best care to these individuals, their adjudicated drug claims data would be vital. We would expect to see these claims "crossover" to the state from CMS just as fee for service Medicare

claims do presently. The state would not want to set up data exchanges with every PDP versus one with CMS.

6c. Coordination of Benefits (Federal Register pages 46702-46703)

1.a. Covered Part D Drug (Federal Register page 46646-46647)

CMS: *Comments requested concerning gaps that may exist in the combined Medicare Part B and D coverage package.*

DSS Comments: Many of Missouri's full benefit dual eligibles do not have Part B coverage. Missouri is a 209b state and has different eligibility guidelines. These individuals would obtain their Part B covered drugs from Medicaid under the current system. Under the MMA, these drugs would not be covered under the Part D program as they are covered under the Part B. However, since the client does not have Part B but does have Part D (dual eligible), these drugs could not be covered by Medicaid. Interpretation of the law in this manner will limit the access to care these individuals should have available to them.

On page 46703 of the Federal Register it states, "We interpret the definition of covered Part D drug to exclude coverage under Part D for drugs otherwise covered and available under Parts A or B for individuals who choose not to enroll in either program. We interpret the words payment is available to mean that payment would be available to any individual who could sign up for A or B, regardless of whether they are actually enrolled." Thus, for all Part D individuals, Part A drugs and Part B drugs are "available" if they choose to pay the appropriate premiums. Consequently, Part D would not be required to pay for drugs covered under Parts A and B on the basis of a Part D eligible individual's status regardless whether the beneficiary is receiving Part A or B." For Medicaid recipients who are not eligible for Part A but could be enrolled in Part B if they choose to do so through the state buy-in program but do not take advantage of this offer, can their prescription drugs be covered by Medicaid with FFP? If not, dual eligibles will be receiving a lesser pharmacy benefit than they do currently. Our full benefit dual eligible population is accustomed to accessing drugs that are necessary to their health. Medicare's criteria for coverage of Part B drugs is much more restrictive than other insurance entities and/or Medicaid. Who would be responsible for payment if a dual eligible obtains a Part B covered drug as part of a recognized treatment plan by sources other than Medicare, the drug is rejected as non-covered by Medicare Part B using Medicare criteria, and it does not become a Part D drug? Will the beneficiary have to assume liability for their drugs? Would this become a non-covered Medicare drug payable by Medicaid at the normal federal match based on Medicaid coverage criteria? How would such a determination be made and relayed to the state and the provider? Could a process in which "exceptions" are processed for these drugs be implemented? An appeals process could be dangerous to the health of an individual who has relied on these drugs for successful treatments.

Those involved in such scenarios may be very physically or mentally ill and may not have the ability or resources to pursue the appeal process.

6.d. Collection of Data on Third Party Coverage (Federal Register page 46704)

CMS: *Comments on collection of third-party data.*

DSS Comments: The status of third party payer can change many times. Pharmacies will contact health insurance companies and Medicaid agencies now if they have discrepancies with eligibility data at the point of sale. To have them contact the disputed coverage entity should be no greater demand on their resources than they have now. This data would then be fed back to the PDPs through the coordination of benefits process who would send it to CMS for updated records.

The original collection of such data should be incorporated into the application process just as it is with the Medicaid eligibility determination process. This would require mandatory release of information by the beneficiary.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections

b. Dispensing Fees (Federal Register page 46647)

CMS: *We invite comments on three different options for the term dispensing fee.*

DSS Comments: The Department of Social Services believes that option 1 is the best interpretation of dispensing fee. Any supplies and equipment needed for the administration of the medication and any cognitive services should be reimbursed separately.

Subpart M: Grievances, Coverage Determinations, Reconsiderations and Appeals (Federal Register, page 46717)

Coverage Determination (§423.566 through §423.576)

CMS: *The PDP sponsor must make its expedited determination and notify the enrollee and the prescribing physician as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.*

DSS Comments: Currently Medicaid recipients whose prescription requests are not being honored receive a 72-hour supply of medications pending the initial coverage request. They are entitled to notice, face-to-face

hearings, and aid paid pending an appeal if their request is denied and they file their appeal within a specified time frame. All state Medicaid appeals processes are completed more expeditiously than Medicare appeals. The appeals process as described in Subpart M does not accord dual eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity to a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes.

The Missouri Department of Social Services appreciates the opportunity to submit comments on the Proposed Rule for the Medicare Prescription Drug Benefit. We welcome questions you may have or comments you may wish to discuss. Please contact Christine Rackers, Director, Division of Medical Services, at 573/751-6922.

Sincerely,

Steve Roling
Director

SR:kl

CMS-4068-P-1249

Submitter : Mr. David Zentner **Date & Time:** 10/04/2004 09:10:07

Organization : North Dakota Department of Human Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
DEPARTMENT FOR REGULATIONS & DEVELOPMENT

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CMS-4068-P-1250

Submitter : Ms. Denise Feldman **Date & Time:** 10/04/2004 08:10:27

Organization : California Healthcare Consulting, Inc.

Category : Individual

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

please see attached comments

CMS-4068-P-1250-Attach-1.pdf

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CENTERS FOR MEDICARE AND MEDICAID SERIVICES
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CMS-4068-P-1251

Submitter : Barbara Edwards **Date & Time:** 10/04/2004 08:10:41

Organization : Ohio Department of Job and Family Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments from the Ohio Department of Job and Family Services Office of Ohio Health Plans regarding the proposed regulations for the Medicare Part D prescription drug benefit.

CMS-4068-P-1251-Attach-1.doc

Bob Taft
Governor

Tom Hayes
Director

OHIO Job & Family SERVICES

30 East Broad Street • Columbus, Ohio 43215

jfs.ohio.gov

October 4, 2004

Mark McClellan, PhD, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Comments on the Proposed Rule Concerning the Medicare Prescription Drug Benefit

Dear Dr. McClellan,

Thank you for the opportunity to comment on the proposed rules regarding the Medicare Prescription Drug benefit. Within the Ohio Department of Job and Family Services, the Office of Ohio Health Plans administers Ohio Medicaid, the Medicare Premium Assistance Program, and the Ohio Disability Medical Assistance Program. Collectively, these programs cover 1.7 million Ohioans, including more than 200,000 Medicare beneficiaries.

Preserving access to prescription drugs for dual Medicare-Medicaid eligible beneficiaries ("dual eligibles") should be a priority for CMS. In Ohio, as in many states, dual eligibles have access to an open formulary, including many of the "Medicaid-optional" drugs that may not be covered by Medicare Part D (over-the-counter drugs, barbiturates, benzodiazepines, and vitamins). In addition, Ohio Medicaid consumers receive their prescriptions with zero out-of-pocket cost, except when drugs require prior authorization. For our most fragile residents, the benefit proposed in the Medicare Modernization Act (MMA) will replace a comprehensive, zero out-of-pocket plan with a more limited plan which will require out-of-pocket costs that may prohibit indigent Medicare beneficiaries from getting their prescriptions.

Access to prescriptions for Medicare beneficiaries receiving long-term care (LTC) is vitally important. Both patients living in LTC facilities and those receiving services through Medicaid home and community-based waivers should be included in this category. Access to a LTC pharmacy provider through the Prescription Drug Plan (PDP) or Medicare Advantage

Prescription Drug (MA-PD) plan, and appropriate formulary drugs including infusion therapy, are critically important for this population.

MMA requires the states to pay a phased-down state contribution toward the prescription costs of dual eligibles. The calculation of this "clawback" as set out in the proposed rule does not accurately represent the actual costs to either Medicare or to the state in providing this prescription benefit. While CMS staff have indicated that the MMA limits the information used to calculate the payment, Section 1935(c)(3) of the Social Security Act as amended by the MMA states that the Secretary may use "other data" to determine the appropriate amount. Ohio believes that this language allows more information to be used that may more accurately represent the actual costs that states would have incurred for prescription drugs for dual eligibles in the absence of Medicare Part D.

Subpart B: Eligibility and Enrollment

Section II.B.2 of the preamble referring to **Section 423.34(d)** of the proposed regulations discusses the process for auto-enrollment of full-benefit dual eligibles, and solicits comment regarding whether the federal government (CMS or its contractor) or the States (or their contracted entities) should have responsibility for administering the "random" automatic enrollment process for full benefit dual-eligible individuals who do not otherwise enroll in an MA-PD or PDP. Ohio strongly opposes this additional administrative burden, which CMS accurately describes as "a new national workload of indeterminate size," on the States. The governing legislation is clear that this responsibility should fall upon the federal government. Section 1860D-1(b)(1)(C) of the Act directs that, if there is more than one prescription drug plan available to a full-benefit dual eligible individual who has failed to enroll in a PDP or MA-PD plan, "*[t]he Secretary* shall enroll such an individual on a random basis among all such plans in the PDP region" (emphasis added).

Given this express designation of responsibility, neither the Secretary nor CMS has authority to impose responsibility for the auto-enrollment function on the States. The preamble to the proposed rule suggests that administrative costs of auto-enrollment activities by the states might have to be borne, at least in some substantial part, by the States themselves. Moreover, even if administrative costs of carrying out this function were to be 100% federally reimbursed (as would be more appropriate, given that the Part D program falls within the federal Medicare program, not the joint state/federal Medicaid program), it would nevertheless constitute a substantial, additional administrative burden on the States that they are not equipped to perform.

As the preamble to the proposed regulation acknowledges, CMS' assumption of the auto-enrollment responsibility will further the goals of national uniformity in, and facilitate federal oversight over, the process. Auto-enrollment will require accurate and timely information flow between CMS and the States in any event. There is no reason to assume that transmission of accurate Medicaid eligibility data from the States to CMS would be inherently any more problematic than transmission of accurate and timely Part D data from CMS to the States.

Recommendation: CMS should facilitate the auto-enrollment process for dual eligibles, either directly or through a contractor. Ohio believes there is no legitimate rationale for transferring to the States an administrative responsibility that Congress clearly indicated should fall upon the federal government.

Section II.B.2 of the preamble referring to **Section 423.34(d)** of the proposed regulations also discusses the timing of the auto-enrollment for dual eligibles, referring to a process to begin at "the end of the individual's initial enrollment period." We have concerns about the enrollment and the auto-enrollment process as established by this section of the draft regulations in relation to providing adequate communication and assistance in enrolling dual eligibles. First, we are concerned about the timing of the automatic enrollment process for dual eligibles because they will lose Medicaid prescription drug coverage on January 1, 2006. They must enroll, preferably through their own selection, prior to losing their Medicaid prescription drug coverage. The scheduled auto-enrollment process beginning on May 16, 2006, is too late to dovetail with the loss of their Medicaid prescription drug coverage. If this date is to work, CMS must communicate with dual eligibles concerning this change in their prescription drug benefits far in advance of the proposed October 15, 2005, mailing. Second, the proposed rule lists a plethora of concerns around auto-enrolling a full benefit dual eligible in an MA-PD or a PDP, specifying that involuntarily dis-enrolling a dual eligible from one plan in order to auto-enroll them into a plan charging a lower premium is not a viable option under the statute. Though finding a plan and premium that will fit within the low-income subsidy is a concern and further illustrates the need to assist dual eligibles in understanding their options. For this population, the concern is finding a plan which will cover all their medications as previously covered under their Medicaid drug benefit, thereby making the transition to Medicare drug coverage a seamless one.

Recommendation: CMS should change the scheduled auto-enrollment date or change the date that dual eligibles lose their Medicaid coverage, and provide in-person assistance (through federally contracted independent enrollment brokers) in order to adequately educate dual eligibles on their options and minimize the need for the auto-enrollment. In order to provide dual eligibles with the information they need to make an informed choice, PDPs, MA-PDs, CMS and SHIP agencies should not deluge dual eligibles with mailed notices and expect they will understand that they will lose their Medicaid prescription drug coverage, and that they must find a PDP or MA-PD that covers their medications.

Section II.B.10 of the preamble discusses the information that CMS will make available to PDPs and MA-PDs. Divulging beneficiary-specific information to PDPs and MA-PDs could be particularly risky for dual eligible beneficiaries. MA-PD plans have an incentive to enroll dual eligibles because they will receive an additional capitation payment (Medicaid add-on) for these higher risk beneficiaries. The dual eligible population is more vulnerable (due to age, limited English proficiency, limited education, etc.) to the risk of enrolling in a plan that does not meet their needs and having to pay out-of-pocket if their medications are not covered by the plan marketed to them. Some Medicare managed care plans have a reputation for being especially aggressive with regard to enrolling dual eligibles without providing clear information on plan limitations. Dual eligibles will require greater protections and individual assistance to select the plan that most meets their needs.

Recommendation: CMS should establish special protections for the dual eligible population, including prohibitions against direct marketing to dual eligibles by PDPs and MA-PDs.

Subpart C: Voluntary Prescription Drug Benefit and Beneficiary Protections

Section II.C.1.a of the preamble solicits "comments concerning any drugs that may require specific guidance with regard to their coverage under Part D, and any gaps that may exist in the combined 'Part D & B' coverage package." As proposed in MMA, the definition of a Part D drug excludes those drugs which may be excluded under section 1927(d)(2) of the Social Security Act. By excluding these drugs, Medicare beneficiaries may not have access to drugs such as phenobarbital (a barbiturate) or clonazepam (a benzodiazepine) for seizures, or potassium (a mineral) for the heart. For many dual eligible beneficiaries, these drugs are vitally important. The low income subsidies have no provisions for extended coverage to include these drugs. While these drugs are optional for state Medicaid programs, Ohio and most other states do cover these drugs for Medicaid consumers as an important part of the benefit package. Please also see comments below under the heading "Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation" information pertaining to Section II.F of the preamble regarding alternative coverage. Ohio believes that basic alternative coverage including the Medicaid-optional drugs is actuarially equivalent to standard coverage.

Clarification of coverage of prescription drugs under Medicare Part B is essential. The rules regarding Part B coverage are confusing, and if left to the interpretation of PDPs and MA-PDs, drugs not covered under Part B may be excluded from Part D plans. If these drugs are excluded from Part D coverage, our fear is that Medicare beneficiaries would be denied coverage.

Recommendation: CMS should include coverage for "Medicaid-optional" drugs in the Part D benefit for dual eligibles, as part of the standard package or a basic alternative plan, or within an extended package available with the low income subsidies. CMS should also clarify coverage of prescription drugs under Medicare Part B to ensure that all appropriate drugs are covered under either Part B or Part D.

Section II.C.1.c of the preamble asks for "comments regarding our definition of the term long-term care facility in **section 423.100**."

Specifically, comments were solicited concerning whether Intermediate Care Facilities for the Mentally Retarded (ICFs/MR) should be considered LTC facilities. These facilities are residential facilities providing long term care to residents, so as such are LTC facilities. Since virtually all residents of ICFs/MR in Ohio are dual eligibles, and therefore eligible for the low-income subsidies, they should be afforded the same benefits as residents of nursing facilities and skilled nursing facilities, along with all other beneficiaries receiving LTC.

As a result of the U.S. Supreme Court decision *Olmstead v. L.C.*, 527 U.S. 581 (1999), Ohio and other states have been moving seniors and persons with disabilities from institutions into less

restrictive placements. Ohio has implemented waiver programs for home and community based care as an alternative to placement in a nursing home. These alternatives provide consumers with a choice of placement, but allow them to receive the same level of care as those who reside in institutions.

Exclusive contracts with a LTC pharmacy should not be the deciding factor on whether or not to extend the definition of LTC facility to forms of housing other than traditional nursing homes; the beneficiaries' qualification for Medicare and their health care needs should be the deciding factors. Rather than defining "long-term care facility," it may be more useful to define "long-term care." States can identify dual eligible individuals who are institutionalized, and can also identify those individuals that, if it were not for the *Olmstead* decision or an 1115 waiver, would be institutionalized. These individuals are low-income Medicare beneficiaries; having a Medicare prescription benefit at zero out-of-pocket cost will allow their income to be used for daily living expenses and not on prescriptions.

Dual eligible residents of LTC facilities in Ohio are required to use all income toward the cost of care, except for a personal needs allowance of $40 per month. This amount is not enough to pay for the cost of medications obtained from out-of-network pharmacies or non-covered drugs. The personal needs allowance for patients under home and community based services waivers is higher, but is still not high enough to pay the added cost of medications that have previously been covered under the Medicaid pharmacy benefit. Parity between institutionalized and waiver serviced beneficiaries must be maintained. These most needy Medicare beneficiaries must be offered a comprehensive benefit plan with zero out-of-pocket costs.

Recommendation: CMS should include ICFs/MR in its definition of LTC facilities. Furthermore, CMS should define "long-term care" to include both patients in residential facilities as well as those who receive a level of care through a home and community based waiver that would be equivalent to care in a residential LTC facility. All Medicare beneficiaries who are either institutionalized or in Medicaid home and community based waivers should be afforded the same prescription benefits including zero copayments.

Section II.C.4.a of the preamble referring to **Section 423.120** of the proposed regulations discusses access to LTC pharmacies, and whether CMS should require, or merely encourage, PDPs and MA-PDs to include LTC pharmacies in their networks. A requirement that PDPs and MA-PDs include one or more LTC pharmacy providers will ensure access to LTC pharmacy services for all Medicare Part D beneficiaries. By merely encouraging this arrangement, Medicare beneficiaries who enter LTC arrangements while enrolled in a PDP or MA-PD without a contracted LTC pharmacy will be left with only potentially expensive out-of-network options. In addition, a PDP or MA-PD could effectively discriminate against patients in LTC by declining to contract with a LTC pharmacy. The rules governing PDPs and MA-PDs must include beneficiary protections against the few PDPs and MA-PDs which may choose to provide less-than-appropriate care. By requiring each PDP and MA-PD to include at least one LTC pharmacy in its network, beneficiaries will retain a measure of protection. In addition to requiring at least one LTC provider, PDPs and MA-PDs should also be required to contract with any LTC pharmacy that agrees to the PDP's or MA-PD's standard contract.

Recommendation: CMS should require each PDP and MA-PD to include at least one LTC pharmacy in its network, and to contract with any LTC pharmacy that agrees to the PDP's or MA-PD's standard contract.

Section II.C.4.a of the preamble referring to **Section 423.120** of the proposed regulations discusses access to federally qualified health centers (FQHCs), and whether CMS should require, or merely encourage, PDPs or MA-PDs to include FQHC pharmacies in their networks. Similar to the LTC pharmacy question, a requirement that PDPs and MA-PDs include FQHC pharmacy providers will ensure access to pharmacy services for all Medicare Part D beneficiaries. Recognizing that FQHC pharmacies would need different contractual terms, PDPs and MA-PDs should be required to approach these pharmacies and attempt to reach agreement about terms.

Recommendation: CMS should require each PDP and MA-PD to approach all FQHCs in its service area to attempt to negotiate a contract.

Section II.C.4.a of the preamble referring to **Section 423.120** of the proposed regulations discusses access to home infusion pharmacies, and whether CMS should require, or merely encourage, PDPs and MA-PDs to include home infusion pharmacies in their networks. Also similar to the LTC pharmacy question, a requirement that PDPs and MA-PDs include home infusion pharmacy providers will ensure access to pharmacy services for all Medicare Part D beneficiaries. By merely encouraging this arrangement, Medicare beneficiaries who require home infusion services while enrolled in a PDP or MA-PD without a contracted home infusion pharmacy will be left with only potentially expensive out-of network options. By requiring each PDP and MA-PD to include at least one home infusion pharmacy in its network, beneficiaries will retain a measure of protection.

Recommendation: CMS should require each PDP and MA-PD to include at least one home infusion pharmacy in its network.

Section II.C.4.b of the preamble referring to **Section 423.120** of the proposed regulations "invite[s] comments regarding standards and criteria that [CMS] could use to determine that a PDP sponsor or MA organization's formulary classification system that is not based on the model classification system does not in fact discriminate against certain classes of Part D eligible beneficiaries." To be sure that an appropriate formulary system is in place, CMS should consider the United States Pharmacopeia (USP) model guidelines to be the minimum acceptable to meet the criteria. This means that the PDP's or MA-PD's proposed classification system must contain at least as many **equivalent** categories and classes of drugs as USP's model. In addition, CMS must verify that a variety of dosage forms are available. Appropriate drug therapy may involve the use of alternate dosage forms such as injectable and easier-to-swallow oral forms (e.g. liquids or rapidly dissolving tablets) for patients unable to swallow tablets or capsules. Drugs for topical, ophthalmic, nasal, otic, vaginal, and rectal administration should also be included in PDP and MA-PD formularies.

Part of the goal of CMS' approval of PDP and MA-PD formulary classifications must be protection from unintended consequences of cost containment. Particularly in an elderly

population such as the one served by Medicare, inappropriate drug therapy may lead to hospitalization, worsening morbidity, and mortality. The added costs of these consequences would be borne by Medicare Parts A and B, rather than by the Part D PDP. This misaligned financial incentive must be mitigated by requirements to provide drugs in appropriate categories.

With the continued trend toward prescription drugs being granted over-the-counter (OTC) status, it is important that PDPs and MA-PDs not be able to exclude a required category or class of drugs because OTC options are available. These required categories and classes should be included in every plan's list of covered drugs.

Recommendation: CMS should use USP's model guidelines as the baseline for what is acceptable. PDP and MA-PD formularies must include a variety of dosage forms in at least as many equivalent categories and classes of drugs as USP's guidelines. The formulary classification must protect both the beneficiary and Medicare Parts A and B from unintended consequences of cost containment.

Subpart F: Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation

Section II.F.4 of the preamble referring to **Section 423.265** of the proposed regulations discusses actuarial equivalence of plans. This section considers differences in plan cost sharing that may be considered actuarially equivalent, but gives little information about plans that may choose to provide coverage of optional drugs under basic alternative plans. Section 1860D-2(a)(2)(A)(ii) of the Social Security Act as amended by MMA provides for "[c]overage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A)" regarding Medicaid-optional drugs. By including these drugs, to be used as alternatives to other Part D drugs, PDPs and MA-PDs will provide a more comprehensive benefit without incurring higher costs than the basic plan. This option should be considered in the regulations and Part D plans should be encouraged to provide this coverage. As mentioned above, coverage of drugs such as phenobarbital (a barbiturate) and clonazepam (a benzodiazepine) are necessary for appropriate care of seizure disorders. OTC drugs such as laxatives, aspirin, and antacids provide cost-effective care for common ailments. The availability of drugs for cough and cold symptoms will reduce inappropriate and unnecessary prescribing of antibiotics which may cause antibiotic resistance and increase hospitalizations and other health care costs. While state Medicaid programs have the option to not cover classes of drugs including those listed here, most provide at least limited coverage. Ohio provides a comprehensive benefit including a selection of agents used for the symptomatic relief of cough and colds, prescription vitamins and mineral products, nonprescription drugs, barbiturates, and benzodiazepines.

Recommendation: CMS should issue regulations encouraging basic alternative coverage including optional drugs. A benefit plan providing this alternative coverage is actuarially equivalent to the standard plan, and offers Medicare beneficiaries a more comprehensive benefit package. PDPs and MA-PDs should be encouraged to provide this basic alternative coverage.

Subpart J: Coordination under Part D Plans with Other Prescription Drug Coverage

Section II.J.6.b of the preamble referring to **Section 423.464** of the proposed regulations invites comments regarding coordination of benefits between state Medicaid programs and PDPs and MA-PDs. While this section is specific to coordination after the implementation of Part D, it is also important to consider the transition into Part D. Dual eligible beneficiaries in Ohio and most other states have a comprehensive drug benefit including open formulary and zero out-of-pocket cost for most prescriptions. This benefit will be replaced by a Part D plan which will probably provide a much more limited formulary and will require copayments for each prescription. Medicare must ensure that the transition from Medicaid prescription coverage to Part D is seamless, and no beneficiary will be unable to obtain medications. The transition process needs to ensure that no dual eligible experiences a lapse in coverage for any reason.

This seamless transition will only be accomplished with an organized, easy-to-understand auto-enrollment process. Because Medicaid coverage will end on December 31, 2005, it is imperative that all dual eligibles be enrolled in a PDP or MA-PD before Part D coverage begins. Once enrolled, the PDP or MA-PD should cover the beneficiary's existing medications during a transition period during which the PDP or MA-PD, beneficiary, and beneficiary's physicians work together to change the drug regimen to conform to the plan's formulary or to receive prior authorizations for necessary medications. Appeals and redeterminations need to be done on an accelerated timeline during the transition period, and beneficiaries must be informed of their right to appeal.

During this transition period, dual eligibles should not be subject to higher out-of-pocket costs for out-of-network pharmacies. While beneficiaries may decline the PDP or MA-PD chosen for them in an auto-enrollment process, it will take some time for the beneficiary to choose a more appropriate PDP or MA-PD that includes his or her preferred pharmacy. For dual eligibles in LTC facilities, extra protections during this transition period are even more important because they are generally locked in to a single pharmacy provider which has contracted with the facility.

Recommendation: CMS should ensure a seamless transition period for dual eligible beneficiaries. This transition period should include expedited appeals, an open formulary, and no penalties for out-of-network pharmacy use. This transition period should last for at least six months, to give the beneficiary, physicians, and the PDP or MA-PD enough time to change any drugs that are nonformulary or to appeal the formulary decision.

Section II.J.6.b of the preamble referring to **Section 423.464** of the proposed regulations invites comments regarding coordination between state Medicaid programs and PDPs and MA-PDs. This coordination of benefits must allow states flexibility to either wrap around or not wrap around the Part D benefit. State assistance may take the form of a State Pharmaceutical Assistance Plan (SPAP) as defined in the regulations, a Medicaid state plan, or another state-financed arrangement. **Regardless of the form of assistance, states should have the ability to choose not to wrap around the benefit while being satisfied CMS has assured that the state's Medicare beneficiaries are receiving appropriate drug coverage.** States should also

have the flexibility, if they do choose to wrap around the benefit, to either pay the difference between the low-income premium subsidy and the premium for a basic or extended plan, or to pay on a per-claim basis. Related to states' decision not to wrap around the Part D benefit, CMS should provide a State Plan Amendment option to exclude dual eligibles, or any consumer eligible for Medicare, from any outpatient drug coverage under Medicaid.

Recommendation: CMS should write regulations protecting the states' ability to either wrap around or not wrap around the Part D benefit, and to choose the structure of any wrap around benefit. For states that choose not to wrap around, CMS should provide protection through the state plan to exclude any Medicare-eligible consumer from Medicaid pharmacy services.

Subpart S: Special Rules for States – Eligibility Determinations for Low-Income Subsidies and General Payment Provisions

Section II.S.1 of the preamble referring to **Section 423.904** of the proposed regulations discusses states' obligations for processing applications for the low-income subsidies. States should be able to meet this obligation by simply accepting applications and forwarding them to the Social Security Administration (SSA) for eligibility determinations to be made. Similarly, all redeterminations and appeals should be done by SSA. This approach will encourage consistency to a national standard and provide accountability to all Medicare beneficiaries. Any provision in the law that a state must perform any eligibility determination for a federal program is an unfunded mandate, and as such should be eligible for 100% federal reimbursement for any state resources expended. Staff time for Ohio to implement this program will include creating rules within the Ohio Administrative Code, training of front-line workers, training of supervisory staff, and time for hearings, appeals, and oversight. In order to accomplish this unfunded mandate, information system changes would need to be made in a short amount of time. If states are to be required to begin accepting applications by July 1, 2005, these system changes are not possible. Ohio also needs time to obtain state statutory authority to perform any functions related to the Medicare benefit but unrelated to state programs. In Ohio, we have the authority to administer the Medicaid program, including the Medicare premium assistance program, but not to administer Medicare. The requirement for states to perform any function regarding eligibility for Medicare is unnecessarily burdensome.

Recommendation: CMS should issue regulations which are clear that a state's only obligation in processing applications for low-income subsidies is to accept applications to be forwarded to SSA for processing. Any resources contributed by a state to the Medicare program should be eligible for 100% federal reimbursement.

Section II.S.4 of the preamble referring to **Section 423.908** of the proposed regulations discusses the calculation of the Phased-Down State Contribution. The calculation, as proposed in rule, closely follows the instructions from MMA. However, the authorizing legislation does contain a provision, in its amendment to Section 1935(c)(3) of the Social Security Act, to use "information reported by the State in the medicaid financial management reports (form CMS-64) for the 4 quarters of calendar year 2003 *and such other data as the Secretary may require*" (emphasis

added). Ohio believes that this language allows the Secretary to consider information that does not appear on the forms CMS-64 for calendar year 2003. The intent of the legislation is to approximate the amount that would have been spent by states for Part D drugs for dual eligibles in the absence of Medicare Part D, based on the experience of 2003. Congress clearly recognized that the forms CMS-64 would not contain the full picture of states' experience in 2003. For example, drug rebates are billed approximately two months after the end of the quarter during which they were earned. Thus, rebates for much of 2003 were not billed or received until well into 2004. Federal rebate liabilities have been steadily increasing. By considering only the rebates that were received in 2003, the calculation more closely reflects 2002 experience.

A second issue is that many states, including Ohio, implemented or planned cost-saving measures in 2003 which will reduce pharmacy costs into the future. For example, Ohio implemented a Preferred Drug List (PDL) program in April 2003 which has shown savings of about 5% in overall pharmacy program costs. As with the federal rebates, the supplemental rebates associated with the PDL were not billed until several months later, so most of the revenue was received in 2004 and reported on forms CMS-64 for quarters in 2004. The Ohio PDL has been introduced in phases, with the first phase in April 2003, second phase in October 2003, and the third phase to be implemented in October 2004. Savings projections for calendar year 2005 are close to 8% of overall program costs. These additional savings should be considered by the Secretary under the "other data" provision of MMA, because they would more closely reflect the costs to Ohio for the pharmacy benefit for dual eligibles in the absence of Medicare Part D. Along with the PDL, a copayment of $3 was instituted for drugs requiring prior authorization. This copayment has improved our cost savings by encouraging Medicaid consumers to use less expensive drugs that do not require a copayment. These savings should also be considered.

A third consideration for the calculation of the phased-down payment is the inflation factor used. The legislation directs the Secretary to use the "most recent National Health Expenditure projections" to determine the inflation factor. State Medicaid programs in general, and Ohio Health Plans in particular, have consistently contained growth to a factor lower than the National Health Expenditure projections. Ohio's recommendation is that CMS consider each state's performance relative to the National Health Expenditure data, and to use a factor appropriate to each state, not to exceed the national projection.

Each state should be required to submit data that explains adjustments to be made to the "clawback" calculation. Because there is no provision for the baseline amount to be recalculated in the future, it is imperative that the liability be accurately calculated. To consider only information that was submitted in standard reports will not reflect the full experience of the states in 2003. Because of the significance of the 2003 baseline number, CMS should develop an appeals process for the phased-down state contribution calculation. This process will enable states to have a process through which to resolve any disagreement with CMS' calculations.

Recommendation: CMS should use the statutorily authorized consideration of "other data" provided by the states to determine an accurate, fair representation of the state's cost for

pharmacy benefits for dual eligibles in the absence of Medicare Part D. Each state's calculation should be different based on experience. This one-time calculation to be used in perpetuity must accurately reflect state experience. As such, a process should be developed for states to appeal CMS' determination of the payment amount.

Conclusions

Ohio Health Plans look forward to working with CMS on the implementation of Medicare Part D. Preserving access to prescription drugs for dual eligibles, the most disadvantaged seniors in our state, is a priority. It is imperative that these and all Medicare beneficiaries have access to a comprehensive drug benefit that is affordable. The cost of providing this benefit should not be unfairly shifted to states through an inappropriate Phased-Down State Contribution payment. Please consider these recommendations before issuing final regulations. If you have any questions, please do not hesitate to contact me at (614) 466-4443.

Respectfully Submitted,

Barbara Coulter Edwards
Deputy Director for Ohio Health Plans
Ohio Department of Job and Family Services

Submitter : Dr. James Nawarskas **Date & Time:** 10/04/2004 08:10:36

Organization : New Mexico Society of Health-System Pharmacists

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment for important comments

CMS-4068-P-1252-Attach-1.doc

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014
www.cms.hhs.gov/regulations/ecomments

To Whom It May Concern:

The purpose of this letter is to comment on the Medication Prescription Drug Improvement and Modernization Act of 2003 (MMA), specifically the Medication Therapy Management Program (MTMP).

The New Mexico Society of Health-System Pharmacists represents pharmacists that practice in a variety of health care settings (hospitals, federal clinics and health systems, academia, managed-care organizations, etc.). The mission of our organization is to advance the provision of pharmaceutical care and achieve optimal patient outcomes.

Currently, under New Mexico law, pharmacists can have full prescriptive authority under the supervision of a physician to provide medication therapy management limited to the scope of the physician's practice. Additionally, all registered pharmacists in New Mexico can have prescriptive authority for the following: pediatric and adult immunizations, emergency contraception, and tobacco cessation products.

Representing the New Mexico Society of Health-System Pharmacists, we make the following recommendations for successful implementation of the MTMP which will in turn lead to improved patient care.

It is our position that CMS should include in the rules:

1. **That all pharmacists are included as qualified providers of MTMP**. Pharmacists in health systems currently provide MTM services in anticoagulation clinics, cardiovascular risk reduction clinics, congestive heart failure clinics, asthma clinics, etc. These services have been repeatedly associated with improvements in the quality of patient care and reductions in healthcare costs.
2. **Targeted beneficiaries should include all patients with at least one chronic disease**. Current plans to identify beneficiaries qualified to receive MTMP focus on patients having multiple chronic conditions, receiving multiple medications and who are expected to incur high prescription drug costs. Under-use of medications often is as serious a drug-related problem as is over-use and therefore MTM eligibility should ***not*** be based solely on number of medications currently prescribed.
3. **Reimbursement rates must be determined nationally by CMS using any willing provider guidelines and ensuring appropriate coverage areas**. Ensuring standardized rates of reimbursement would inhibit PDPs from contracting with groups purely based on cost at the sacrifice of MTMP quality.

Reimbursement rates should be based upon the complexity of the service provided and commensurate with reimbursement for other healthcare providers.

4. **The patient must have freedom of choice of providers**. This would encourage competition between providers based on quality, ultimately leading to improved patient outcomes.
5. **CMS must ensure that contractors have full coverage for patient and provider access in rural and underserved areas**.

Thank you for allowing us the opportunity to provide comments on the proposed rules.

Sincerely,

James J. Nawarskas, Pharm.D., Ph.C., BCPS
President
New Mexico Society of Health-Systems Pharmacists
Phone: 505-272-0584
Email: jnawarskas@salud.unm.edu

Joe R. Anderson, Pharm.D., Ph.C., BCPS
Legislative Chair
New Mexico Society of Health-Systems Pharmacists

Elizabeth A. Flynn, R.Ph., Ph.D.
Immediate Past President
New Mexico Society of Health-System Pharmacists
Phone: 505-746-8924
flynnel@auburn.edu

CMS-4068-P-1253

Submitter : Mr. Paul Latchford **Date & Time:** 10/04/2004 08:10:09

Organization : Monumental Life Insurance Company

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4068-P-1253-Attach-1.doc

Monumental Life Insurance Company

Direct Response Division
520 Park Avenue
Baltimore, Maryland 21201-4500

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: to CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

RE: Comments on Medicare Modernization Act of Proposed Rule Part 403

To Whom It May Concern:

We are writing to comment on the proposed rules of August 3, 2004, which would amend 42 CFR 403.205. CMS proposes to amend the federal regulatory definition of a "Medicare Supplemental Policy" to include a stand-alone limited health benefit policy or plan. Additionally, CMS proposes a disclosure form to be sent by Medigap carriers regarding Medicare Part D.

Proposed Changes to Medicare Supplemental Definition

CMS should make no changes to the current definition of Medicare Supplemental Policy except to conform to the MMA changes regarding what is not a Medicare Supplement Policy.

The MMA requires that the definition of Medicare Supplemental Policy only change to add a prescription drug plan under Part D as a type of coverage not included in the definition of the Medicare Supplemental Policy and to replace the term Medicare+Choice with Medicare Advantage. Any other changes to the definition of Medicare Supplemental Policy proposed by CMS are not authorized by the MMA. The agency does not have statutory authority to advance any changes above and beyond the two provided pursuant to the MMA.

CMS proposes to amend the definition of Medicare Supplemental Policy by including a rider attached to an individual or group policy, a stand alone limited health benefit plan or policy that supplements Medicare benefits and is sold primarily to Medicare beneficiaries or that otherwise meets the definition of the Medicare supplement policy as defined in the section, and any rider attached to a supplemental policy to become an integral part of the basic policy. This is already addressed as a matter of state law.

Additionally, CMS proposes to delete section 403.205(d)(1 through 5). In the current law these subparts are specifically listed as exclusions from the definition of Medicare Supplemental Policy. CMS has no statutory authority to delete these provisions and therefore may not removed pursuant to the proposed rule.

Notice to Medigap Prescription Policyholders.

We recommend that CMS retain the version of the "notice" required by section 104 of the MMA for Medigap carriers that was adopted by the NAIC and submitted to CMS. The NAIC approved version of the notice meets all of the statutory requirements of the MMA. We should not as Medigap carriers be required to make any assessments regarding the "value" of coverage nor to promote Medicare Advantage. The notice should go no further than to meet such requirements.

We appreciate the opportunity to offer comments on these proposals and thank you for your consideration of these comments.

Sincerely
Paul Latchford
Vice President and Counsel

CMS-4068-P-1254

Submitter : **Kevin Cranston** **Date & Time:** **10/04/2004 08:10:37**

Organization : **Massachusetts Department of Public Health**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Massachusetts Department of Public Health, HIV/AIDS Bureau

CMS-4068-P-1254-Attach-1.doc

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

MITT ROMNEY
GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

RONALD PRESTON
SECRETARY

CHRISTINE C. FERGUSON
COMMISSIONER

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014

File Code: CMS-4068-P

To Whom It May Concern:

On behalf of the state of Massachusetts, I appreciate the opportunity to comment on the proposed regulations entitled, "42 CFR Parts 403, 411, 417 and 423 Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule," 69 FR 46632. I am extremely concerned that many of the proposed regulations could negatively impact drug coverage for people living with HIV in our state, as well increasing the financial burden on the already strapped Massachusetts AIDS Drug Assistance Program (ADAP).

1.) Explicitly excluding ADAPs from being able to provide wrap-around coverage in a manner that would allow beneficiaries to reach the catastrophic limit seriously undermines the federal government's priority of providing comprehensive health care to people living with HIV/AIDS. ADAPs are an integral component of the safety net for people living with HIV/AIDS in this country and have a long history of filling gaps left by other federal programs, including Medicaid and Medicare. We strongly recommend that the final rule count cost-sharing subsidies from ADAPs as incurred costs for beneficiaries.

Massuchusetts is very concerned that the regulation also disallows state-appropriated dollars spent by ADAPs to be counted as incurred costs. It is discriminatory and unacceptable to single out state dollars used to provide medications to people living with HIV/AIDS while at the same time allowing state dollars to be used for State Pharmaceutical Assistance Programs' (SPAPs) expenditures on behalf of a beneficiary. Under the proposed regulations, SPAPs are allowed to wrap-around in a way that all costs spent on the behalf of a beneficiary count as incurred costs. States should have the flexibility to provide prescription drugs to a variety of populations, including people living with HIV/AIDS, with the state dollars appropriated. It is inexcusable to

exempt people living with HIV/AIDS from receiving this type of assistance from their state, while allowing people with other medical conditions to benefit from the use of state dollars. Ironically, persons with AIDS who live in states with SPAPs and who are eligible for assistance will have SPAP costs count toward incurred costs, while those who rely on ADAP will not.

2.) While we understand that CMS is hopeful that all prescription drug plans (PDPs) will include all necessary HIV-related drugs on their formularies, it is not required. Therefore, even individuals who benefit from the low-income protections included in the benefit may find themselves turning to ADAPs to receive the remaining necessary medications.

Massachusetts strongly supports the CMS recommendation to implement "open formularies" for special populations and strongly recommends that people with HIV/AIDS be defined as a special population. We feel this is critical to ensuring that Medicare beneficiaries with HIV/AIDS have continued and unhindered access to all of the drugs that are medically necessary for treating the disease. Furthermore, an "open formulary" will prove cost effective because it will prevent the use of more intensive and costly health care resources such as inpatient hospitalization that will occur if Medicare beneficiaries with HIV/AIDS are denied access to medically necessary prescription drugs. While the private drug plans are not at risk for this potential cost shifting, the federal government will incur these costs either through higher Medicaid expenditures or higher Medicare Part A and B expenditures.

3.) Strengthening the language regarding coverage of drugs for off-label use. It is imperative that prescription drug plans be required to cover medically accepted uses of drugs for off-label use that are standard practice in the medical community. For HIV disease, as with many complex conditions, clinical practice frequently progresses ahead of label indications as physicians learn what drug combinations best target their patient's symptoms and side effects. As an example, tenofovir (Viread) has proven effective for treating hepatitis B for people with HIV, although treatment for hepatitis B is not yet an indicated use of the drug.

4.) Imposition of co-payments. People with HIV/AIDS depend on a daily regimen of multiple medications (most of which are non-generic). Even minimal co-payments will create a financial burden for individuals who will be left to choose between paying for medications and meeting other needs, like food and housing. Dual eligibles must maintain the protection that they currently have under Medicaid and not be denied a drug for failure to pay cost sharing.

Again, thank you for the opportunity to submit comment on the proposed rule to implement the Medicare Part D prescription drug benefit. Please contact me at kevin.cranston@state.ma.us if you need further information.

Sincerely,

Kevin Cranston, MDiv
Acting Director

CMS-4068-P-1255

Submitter : Mr. Kenneth Whittemore, Jr. **Date & Time:** 10/04/2004 08:10:56

Organization : SureScripts

Category : Health Care Industry

Issue Areas/Comments

Issues 1-10

BACKGROUND

RE: CMS?4068?P; Medicare Program; Medicare Prescription Drug Benefit; 42 CFR, Part 423, Section 159, Electronic Prescription Program

This letter is in response to the proposed rule that the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register, Volume 69, Number 148, beginning on page 46632 on August 3, 2004. SureScripts appreciates the opportunity to comment on the proposed rule with respect to those provisions that will support the implementation of an electronic prescription program designed to improve the overall prescribing process for millions of Medicare beneficiaries. In fact, SureScripts has already testified before, and offered additional advice and assistance to, the National Committee on Vital and Health Statistics Subcommittee on Standards and Security as it gathered input this past summer on electronic prescribing standards that might be used for the electronic prescribing program for Medicare. We look forward to continuing to work with CMS to implement said standards and these proposed rules in a manner that improves the safety, efficiency, and quality of the overall prescribing process for all essential stakeholders.

CMS-4068-P-1255-Attach-1.doc

CMS-4068-P-1256

Submitter : Mr. Scott Shields **Date & Time:** 10/04/2004 08:10:49

Organization : Aventor

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

On behalf of Dey, L.P., we are pleased to provide CMS with comments to CMS-4068-P. We have attached our full comments and an executive summary of the comments.

CMS-4068-P-1256-Attach-2.doc

CMS-4068-P-1256-Attach-1.doc

Executive Summary
Comments on "Medicare Program; Medicare Prescription Dug Benefit; Proposed Rule"
(CMS-4068-P)

Dey, L.P. appreciates the opportunity to comment on the following issues addressed in the above-referenced proposed rule and its preamble:[1]

- Subpart C – Benefits and Beneficiary Protections
  - Section 423.100 (Definition of "Covered Part D Drug")
  - Section 423.120 (Access to Covered Part D Drugs)

- Subpart D – Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans
  - Section 423.153 (Cost and Utilization Management, Quality Assurance, Medication Therapy Management Programs, and Programs to Control Fraud, Abuse, and Waste)

Key Overall Point: CMS acknowledges the statutorily-mandated distinction between Part B and Part D drugs. Our principal concern is that the agency inappropriately suggests that certain Part B drugs with characteristics such as those described in the proposed rule's preamble – i.e., drugs covered as incident to a physician's service or furnished through an item of DME – could be covered under Part D.

"Covered Part D Drug": Dey supports the principle enunciated in the rulemaking that Part D "wraps around" Part B, providing beneficiaries with drug coverage that is seamless. However, portions of the preamble extend this "wrap around" principle beyond reasonable bounds. Specifically, the preamble cites examples that could be interpreted to confer Part D coverage on infusion and injectable drugs in situations that are currently within the Part B claims administration authority of the DMERCs. Similarly, in addressing dispensing fees for Part D drugs, CMS identifies options that, if implemented with respect to infusion drugs, could be applied more broadly – and inappropriately – to other Part B services.

> *Recommendation*: CMS should make clear that DME drugs used in situations now covered under Part B are excluded from coverage under Part D.

Access to Covered Part D Drugs: The rulemaking appropriately addresses means for ensuring that beneficiaries have access to Prescription Drug Plans (PDPs) that include in their networks' long-term care pharmacies and home infusion pharmacy providers. However, because these pharmacies/providers offer drug-related services that are typically covered under Part B, CMS should take special care to ensure that Part D coverage does not substitute for coverage available under Part B. In fact, we read the preamble's language on these points almost to invite such substitution. For example, CMS seeks comments on whether PDPs should receive performance incentives for producing Medicare savings under Parts *A and B* – virtually an open invitation to replace Part B drug coverage with Part D coverage if the PDP believes it will save money.

[1] 69 Fed Reg 46632 (Aug. 3, 2004).

The Medicare Modernization Act (MMA) clearly did not contemplate this type of Part D-Part B substitution. Indeed, the MMA, in establishing a Chronic Care Improvement Program, provided a separate means for CMS (on a demonstration basis) to test methods for identifying clinical and economic synergies among Parts A, B, and D.

> *Recommendation*: CMS should make clear that PDPs may not substitute Part D drug coverage in situations in which Part B drug coverage is available.

Medication Therapy Management: CMS solicits comments on whether the terms "multiple covered Part D drugs" and "multiple chronic diseases" should be defined by the agency itself or by PDPs. Both terms implicate use of disease management tools – tools that Dey supports. However, we are concerned that inappropriately inserting these tools into Medicare Part D, but not into Part B, could exert a counterproductive, asymmetrical effect. That is, by rewarding PDPs for exacting savings on a drug used in a situation that makes it Part D-covered (when, in other situations, it is Part B-covered) could discourage PDPs from considering the clinical factors DMERCs have long taken into account in administering Part B drug claims.

> *Recommendation*: CMS, not PDPs, should define the key terms. In so doing, the agency should maintain a level playing field among Medicare contractors, preventing PDPs from inappropriately reducing utilization for a subset of the situations in which a drug is used.

Drug Utilization Management: The preamble, in addressing industry standards for drug utilization management, suggests incentives to reduce costs "when medically appropriate" – a phrase not defined.

> *Recommendation*: The phrase "medically appropriate" should be defined to include criteria for ensuring that compounding of drugs is performed in a fashion consistent with patient safety and FDA's requirements.

DATE: October 4, 2004

Centers for Medicare and Medicaid Services

Department of Health and Human Services

Attention CMS-1429-P

P.O. Box 8012

Baltimore, Maryland 21244-8012

Re: [CMS--4068-P] Medicare Program; Medicare Program; Medicare Prescription Drug Benefit

Dear Sir or Madam:

Dey, L.P. is pleased to submit the following comments regarding the above-referenced proposed rule (Proposed Rule).[1] Dey, L.P. welcomes the opportunity to work with the Centers for Medicare and Medicaid Services (CMS) as it develops policy for drugs currently covered as a Part B benefit with the potential for coverage as a Part D benefit in 2006.

Dey, L.P. develops, manufactures, and markets prescription pharmaceuticals for the treatment of respiratory illnesses, including chronic obstructive pulmonary disease (COPD), a condition that represents a significant financial burden for the Medicare program and a serious threat to patient longevity and quality of life.

We propose that CMS clarify in the final rule to specifically exclude from Part D those drugs covered under Part B because they are incident to durable medical equipment (DME).

We are providing comments on three sections of the Proposed Rule that hold implications for the availability of drugs provided as a Part B benefit that may, under some circumstances, be provided as a Part D benefit:

1. Section 423.100, regarding the definition of a covered Part D drug;
2. Section 423.120, regarding access to covered Part D drugs; and
3. Section 423.153 in Subpart D Cost Control and Quality Improvement Requirements for Prescription Drug Plans

Various examples in the proposed rule could establish a precedent for changing coverage from an existing benefit (Part B) to a new one (Part D), thereby violating the "wrap around" principle that CMS has enunciated for Part D.

We suggest that CMS specify clearly in the final rule that drugs currently covered under Part B, either incident to a physician service, or incident to the DME benefit, be excluded from Part D coverage until such time as the Secretary issues the report on this subject (required under the Medicare Modernization Act) and the Congress acts to give CMS the authority to implement any recommended changes stemming from the report.[2]

[1] Proposed Rule, 69 Fed Reg 46631 (Aug. 3, 2004).
[2] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, sec. 101(d).

1. **Subpart C. Voluntary Prescription Drug Benefit and Beneficiary Protections**

   a. ***Proposed Section 423.100 Definition***[3]

The proposed rule includes a definition of two terms that would benefit from more specificity:

- "Covered Part D Drug,"[4] and
- "Dispensing fee."[5]

Covered Part D Drug

CMS addresses the complex issue of drugs that can be covered under Part A, B or D, depending on the form of administration and site of service. While the Part D benefit is expected to be a "wrap-around" to the other benefits, the rulemaking contains descriptions of infusion or injectable drugs that have characteristics similar to a nebulized drug, and others that are administered through DME, where the drug product could be picked up at a pharmacy and be self-administered at home.

Our concern is that the examples include situations that are currently within the purview of the DMERCs and are intended to be addressed in subsequent regulations regarding the competitive acquisition programs for Part B drugs, supplies, medical equipment and related services. We recognize that some drug delivery mechanisms are not covered under Part B, and that beneficiaries could benefit from the "wrap-around" nature of the Part D benefit.

[3] 69 Fed Reg 46646.
[4] 69 Fed Reg 46646.

However, a drug administered through DME should remain a Part B covered service when it is used in a setting which is currently covered by the DMERCs; furthermore, we propose that it should be specifically excluded from Part D. Coverage for these products has evolved over many years, and the coverage criteria and decisions reflect the complex issues that need to be considered in order to structure a program that does not disrupt existing services. This consideration is beyond the scope of reform contemplated by Congress, prior to an analysis by the Secretary.

Part D Dispensing Fee

We commend CMS for clearly stating that the definition of a dispensing fee would apply specifically to Part D, and we agree with the agency's preference for the first of the three options described in the proposed rule; i.e., a single fee associated solely with dispensing of the prescription. We recognize the need for CMS to consider Options 2 and 3 (involving the necessary equipment and supplies and the necessary professional services of a nurse or pharmacist) for home infusion drugs.

However, if Options 2 and 3 are part of the final rule, PDPs should be excluded from applying such fees to reimburse for the costs of services currently subject to Part B coverage. Our concern is that permissible instances in which Options 2 and 3 may be needed (e.g., to reimburse for the costs of supplies and services associated with home infusion drugs that may not be covered currently under Part B) could be applied more broadly and inappropriately to other Part B covered services. Our concern is specifically

[5] 69 Fed Reg 46647.

grounded in the reimbursement circumstances surrounding Dey's product, DuoNeb® Inhalation Solution ("DuoNeb"), used in the treatment of COPD. We presented these concerns in our September 17, 2004 letter in response to **[**CMS-1429-P] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005. A summary of the rationale is provided in Exhibit A.

b. Proposed Section 423.120 Access to Covered Part D Drug[6]

Our concerns relate to two provisions regarding the ways in which Medicare beneficiary access to pharmacies can be assured. Specifically, we have concerns regarding CMS preamble language pertaining to availability of PDP access to 1) long term care pharmacy, and 2) home infusion pharmacy providers.

1) Long Term Care Pharmacy

While it is appropriate for CMS to consider whether the new Medicare Prescription Drug Plans (PDPs) should be required to include long-term care pharmacies in their plans and to take into account how the PDP might reimburse these pharmacies for services such as infusion therapy and 24 hour medication delivery, our concern is that such services should be excluded from Part D coverage if Part B coverage is available.

2) Home Infusion Pharmacy

The issue is the same for home infusion pharmacies, although we note with some concern that CMS is seeking comments on ways to encourage PDPs, who do not have a medical benefit and therefore cannot realize efficiencies from reduced hospital costs, to establish

contracts with home infusion pharmacies. The potential to offer performance incentives for Part D contractors for savings under Part A or Part B goes beyond the scope of what MMA contemplated. These types of savings could more appropriately be captured under the Chronic Care Improvement Program, which MMA established as a demonstration.

2. Subpart D. Cost Controls and Quality Improvement Requirements for Prescription Drug Benefit Plans

a) Proposed Section 423.153 Cost and Utilization Management, Quality Assurance, Medication Therapy Management Programs and Programs to Control Fraud, Abuse and Waste

Two provisions of this proposed section could be detrimental to Medicare beneficiaries' continued access to Part B covered drugs and related services:

- Cost Effective Drug Utilization Management[7] (relating to the use of compounded drugs); and
- Medication Therapy Management[8] (relating to providing appropriate nebulizer utilization).

Cost Effective Drug Utilization Management

CMS solicits comments on industry standards for cost effective drug utilization management, which includes the use of incentives to reduce costs, "when medically

[6] 69 Fed Reg 46655.
[7] 69 Fed Reg 46666.
[8] 69 Fed Reg 46668.

appropriate," which is not defined. We suggest that the term "medically appropriate" should specify criteria as to when using compounded drugs would be considered a medically appropriate incentive to reduce costs.

Specifically, we believe CMS should ensure that compounding is done on a patient-name prescription basis, and that pharmacies use all compounding and admixing precautions to ensure product sterility and freedom from microbe ingress contamination. Patient safety is crucial, and the quality of the compounded product should be comparable to a commercial drug product.

Another area of concern regarding compounding is that the FDA prohibits pharmacy compounding of two or more separate FDA-approved products when a combination product approved by the FDA is commercially available.[9]

Specifically, in the past six months alone, the FDA has cited and sent warning letters to several pharmacies for the following compounding violations: preparing drug products that are commercially available, and compounding drugs "without the necessary controls to ensure drug product sterility and potency."[10,11,12]

[9] Food and Drug Administration. Compliance Policy Guidance for FDA Staff and Industry. Sec. 460.200 (Pharmacy Compounding). June 7, 2002. Accessed August 10, 2004 at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html.
[10] FDA warning letter to Axium Healthcare Pharmacy, June 7, 2004, at http://www.fda.gov/cder/warn/2004/AXIUM%20%20wl.pdf.
[11] FDA warning letter to Gentere, Inc., July 13, 2004, at http://www.fda.gov/foi/warning_letters/g4863d.htm.
12 FDA warning letter to delta Pharma, Inc., September 17, 2004, at http://www.fda.gov/foi/warning_letters/g4965d.htm.

Violations of the FDA policy against compounding commercially-available drugs affect DuoNeb, since it is a currently marketed, sterile, non-allergenic, premixed combination drug; these manufacturing processes are designed to lower the risk of drug cross-contamination and to minimize waste. The premixed, unit-dose combination of the two agents within DuoNeb enhances patient safety by minimizing the chance for medication errors, and it eliminates the need for the Medicare patient to nebulize two different solutions, resulting in faster treatment times and improved compliance.

As for the second category of violation – compounding drugs "without the necessary controls to ensure drug product sterility and potency" – quite obviously patient safety is at risk, and a threat to public health is created. We also note that, in 2002, the FDA sampled 29 drugs from compounding pharmacies and found that 10 were subpotent.[12] In all, the compounded drugs sampled by the FDA registered a 34 percent failure rate – far in excess of the comparable two percent rate for commercially-available drugs.[13]

These examples highlight the complexity unique to prescription drugs covered under Part B and the need for greater clarity and precision in the Part D proposed rule.

Medication Therapy Management Program

CMS solicits comments on whether it should define the terms "multiple covered Part D drugs" and "multiple chronic diseases", or allow the PDPs to define the terms as part of their bids to CMS. While we support the use of appropriate disease management tools

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[12] Report: Limited FDA Survey of Compounded Drug Products. Food and Drug Administration. Accessed August 24, 2004 at http://www.fda.gov/cder/pharmcomp/survey.htm.
[13] *Id.*

such as the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, our concern is that CMS maintain a level playing field among its contractors and not create an advantage for PDPs who potentially could be rewarded for reducing nebulizer use among a sub-set of COPD patients, without adequately considering clinical factors such as those included in the DMERC coverage policies.

Conclusion

Dey, L.P. appreciates the opportunity to comment on these three proposed sections that – absent additional clarification – could affect Medicare beneficiaries' access to life-saving and quality-of-life enhancing medications. We base our observation on examples contained in the proposed rule that, while casually presented, belie the underlying complexity that results when coverage could be provided under different benefits, depending on the route of administration and site of service. Coupled with the concerns we raised in our response to the proposed rule on Part B payment, we are compelled to reiterate our recommendation that CMS develop a cohesive strategy for inhalation drug therapy based on clinical guidelines and correct assumptions as to the medical necessity of nebulizer-based therapy by some patients. In addition, including pharmacy compounding as an activity whose costs may be included in the dispensing fee could be troublesome, given that on certain occasions pharmacy compounding is not appropriate and should not be reimbursed by PDPs.

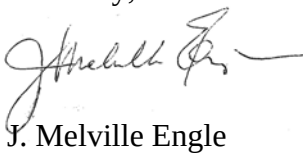
We urge CMS to revisit the proposed changes regarding a revised (or incremental) dispensing fee by conducting a study of the appropriate activities and their costs, and by considering the considerable operating and patient-support expenses borne by pharmacies.

The concept of a "service fee" may be a more appropriate description of the various pharmacy activities and expenses.

Dey, L.P. believes that CMS needs to be more specific in the final regulation about the Part D benefit for those prescription drugs that can be covered under the Part B benefit. The MMA includes several provisions related to the latter that will be implemented over the next few years and also calls for the Secretary to study these issues and report to Congress. We know the complexity of the issues related to inhalation products and support an approach that considers them in the overall context of respiratory disease costs to the Medicare program. It is important to get the right prescriptions to patients using the most appropriate delivery mechanism, be it nebulizers, MDIs, or dry powder inhalers (DPIs), all of which are found in clinical practice guidelines and will be included in Medicare's benefits as of 2006. CMS and its contractors need to strive for consistency with existing Medicare policies and FDA polices to ensure that payment policy changes do not create incentives for activities that are not consistent with the coverage of products under existing benefits and the assurances provided to the public by the FDA.

Thank you for the opportunity to present our views with respect to these selected provisions detailing how the Part D benefit will be implemented.

Sincerely,



J. Melville Engle

President and CEO

Nebulizers versus MDIs

We feel compelled to correct the record regarding the stance CMS has taken regarding the relative and comparative value of nebulizers versus MDIs. In the portion of the Proposed Rule preamble pertaining to MMA Section 305, CMS states that Medicare beneficiaries have a "strong" financial incentive to use nebulizers since the alternative inhalation drug delivery mechanism, metered dose inhalers (MDIs), currently are not covered under Part B, and beneficiaries will have to wait until January 2006 to be covered under the new Part D drug benefit. CMS also states that, based on a literature review, nebulizers are no more effective than MDIs in delivering bronchodilators, and CMS predicts a substantial shift from nebulizers to MDIs once the latter become covered under Part D beginning in 2006.[14] We fear CMS may underestimate the clinical value, patient preference and improved outcomes for nebulized respiratory medication which is based on a reduction of symptoms and improved quality of life, not financial incentives.

While it is true that some studies have shown that nebulizers and inhalers are equally effective, the performance of inhalers was augmented by spacers.[15,16,17] Spacers are designed to deliver MDI-delivered medication more easily and effectively. In common

[14] Proposed Rule, 69 Fed Reg 47546, 47548.
[15] Turner MO, Patel A, Ginsburg S, Fitzgerald JM. Bronchodilator delivery in acute airflow obstruction. A meta-analysis. *Arch Intern Med*. 1997 Aug 11-25;157(15):1736-44.
[16] Duarte AG, Momii K, Bidani A. Bronchodilator therapy with metered-dose inhaler and spacer versus nebulizer in mechanically ventilated patients: comparison of magnitude and duration of response. *Respir Care*. 2000 Jul;45(7):817-23.
[17] Schuh S, Johnson DW, Stephens D, Callahan S, Winders P, Canny GJ. Comparison of albuterol delivered by a metered dose inhaler with spacer versus a nebulizer in children with mild acute asthma. *J Pediatr*. 1999 Jul;135(1):22-7.

practice, studies have shown that patients only use spacers to be used with inhalers approximately 50 percent of the time.[18,19] **Without** accessories such as spacers, much of the medication is left in the mouth and throat, thus reducing absorption and efficacy.[20]

In addition, the literature is replete with studies showing that many patients, up to 89%, do not employ proper inhaler technique.[21,22,23] Therapeutic benefit depends on sufficient deposition of drugs in the medium and small airways; this is largely determined by a competent inhaler technique.[24,25] The most recent report of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) states that "COPD patients may have more problems in effective coordination and find it harder to use a simple Metered Dose Inhaler (MDI) than do healthy volunteers or younger asthmatics."[26]

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[18] Dow L, Phelps L, Fowler L, Waters K, Coggon D, Holgate ST. Respiratory symptoms in older people and use of domestic gas appliances. *Thorax* 1999; 54: 1104-1106. Fifty-four percent of the study population using MDIs used spacers; 45 percent of the study population using MDIs did not us a spacer.
[19] Bynum A, Hopkins D, Thomas A, Irwin C, Copeland N. The Effect of Telepharmacy Counseling on Metered-Dose Inhaler Technique Among Adolescents with Asthma in Rural Arkansas. Presentation. The University of Arkansas for Medical Sciences. 2000 American Telemedicine Association Annual Meeting. Accessed September 15, 2004 at http://www.atmeda.org/news/2000_presentations/Rural/Bynum.pps. Fifty-one percent of the study population did not use spacers with MDIs.
[20] Selroos O, Halme M. Effect of a volumatic spacer and mouth rinsing on systemic absorption of inhaled corticosteroids from a metered dose inhaler and dry powder inhaler. *Thorax*. 1991 Dec;46(12):891-4.
[21] Erickson SR, Horton A, Kirking DM. Assessing metered-dose inhaler technique: comparison of observation vs. patient self-report. *J Asthma.* 1998;35(7):575-83.
[22] ICSI Health Care Guidelines: Chronic Obstructive Pulmonary Disease, Third Edition/Dec 2003. Accessed September 2, 2004 at http://www.icsi.org/knowledge/detail.asp?catID=29&itemID=157.
[23] Johnson DH, Robart P. Inhaler technique of outpatients in the home. *Respir Care*. 2000 Oct;45(10):1182-7.
[24] Newman SP, Pavia D, Clarke SW. How should a pressurized beta-adrenergic bronchodilator be inhaled? *Eur J Respir Dis* 1981;62:3–20.
[25] Newman SP, Moren F, Pavia D, et al. Deposition of pressurized aerosols in the human respiratory tract. *Thorax* 1981;36:52–5.
[26] Global Initiative for Chronic Obstructive Lung Disease, Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2004 Update), at 68, available at http://www.goldcopd.com.

Market research has confirmed the practical superiority of nebulizers to MDIs, as judged from the patients' perspective. One study compared the value of nebulizer systems with MDIs from the patient's perspective, based on an analysis of 1,369 questionnaires.[27] According to the study, nebulizer systems were preferred and considered by patients to be more effective at symptom control than MDIs. Key findings were as follows:

- Fifty-seven percent (57%) of patients surveyed said their symptoms were better controlled with a nebulizer system than with an MDI.
- Eighty-two percent (82%) said the nebulizer system controlled their symptoms for a longer period of time than the MDI.
- Over 80% of patients said the nebulizer system had given them a better quality of life than an MDI alone. Nearly 70% of patients surveyed said the nebulizer system had helped them avoid a trip to the emergency room.
- Fifty-six percent (56%) of these patients said use of a nebulizer system helped to avoid hospitalization.
- Fifty-eight percent (58%) of these patients had avoided unscheduled office visits by using their nebulizer systems.

In short, nebulizers are the preferred method of delivery of bronchodilators for a large proportion of COPD patients, including Medicare beneficiaries. In the preamble, CMS expresses concern that the access of beneficiaries to nebulized bronchodilators in 2005 might be restricted, due to the reduction in Part B payment rates for frequently used

[27] Safian Communications, Inc. Patient Assessment of Efficacy of Nebulizer Systems on Their Respiratory Health. April 1995 (report available on request).

bronchodilators.[28] We agree this is a serious concern, but we submit that it is not a short-term problem that will disappear in 2006. Beneficiaries' continued need for nebulized bronchodilators, even after MDIs become covered under Part D, will make it all the more essential that CMS adequately reimburse providers for these drugs under Part B on an ongoing basis.

[28] Proposed Rule, 69 Fed Reg 47549.

EXHIBIT B

Circumstances Where Compounded Combination Albuterol and Ipratropium Should Not Be Covered Under Medicare

FDA Prohibition of Certain Types of Pharmacy Compounding

Certain types of pharmacy compounding are discouraged by FDA policy, as articulated in Compliance Policy Guide (CPG), Section 460.200, issued on June 7, 2002.[29] The CPG contains factors that the agency considers in deciding whether to exercise its enforcement discretion. One factor is whether a firm **compounds drug products that are commercially available, or which are essentially copies of commercially available FDA-approved products**.[30]

If one or more of the factors identified in CPG section 460.200 are present, such compounding pharmacies may be manufacturing drugs which are subject to the new drug application (NDA) requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA), but for which the FDA has not approved an NDA, or which are misbranded or adulterated. If the FDA has not approved the manufacturing and processing procedures used by these facilities, the FDA has no assurance that the drugs produced are safe and efficacious. Safety and efficacy issues pertain to such factors as chemical stability, purity, strength,

[29] Compliance Policy Guidance for FDA Staff and Industry. Sec. 460.200 (Pharmacy Compounding). Food and Drug Administration. June 7, 2002. Accessed August 10, 2004 at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html.

[30] Emphasis supplied. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.

bioequivalency, and bioavailability. Dey, L.P. is concerned that patients may be receiving unsafe, unsterile drugs of unknown potency and composition, a needless risk when, in the case of pharmacy-compounded albuterol and ipratropium, an FDA-approved inhalation solution is available in DuoNeb® Inhalation Solution.

Based on 1) the NDA requirements of the FFDCA, and 2) CPG §460.200, pharmacy-compounded combinations of albuterol and ipratropium that contain equivalent amounts of the active ingredients in DuoNeb® Inhalation Solution are prohibited by the FDA.

Medicare Denial of Payment for Certain Types of Pharmacy Compounding

If the FDA prohibits pharmacy-compounded combinations of albuterol and ipratropium, then chapter 15, section 50.4.7 of the Medicare Benefit Policy Manual, entitled "Denial of Medicare Payment for Compounded Drugs Produced in Violation of Federal Food, Drug, and Cosmetic Act," should apply. The applicable portion of §50.4.7 reads as follows:

> Section 1862(a)(1)(A) of the Act requires that drugs must be reasonable and necessary in order to be covered under Medicare. This means, in the case of drugs, the FDA must approve them for marketing. Section 50.4.1 instructs carriers and intermediaries to deny coverage for drugs that have not received final marketing approval by the FDA, unless instructed otherwise by CMS. The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §180, instructs carriers to deny coverage of services related to the use of noncovered drugs as well. Hence, if DME or a prosthetic device is used to administer a noncovered drug, coverage is denied for both the nonapproved drug and the DME or prosthetic device.[31]

[31] Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual. Chapter 15 (Covered Medical and Other Health Services); §50.4.7 (Denial of Medicare Payment for Compounded Drugs

In order to provide consistency across all benefit categories, all Medicare contractors, including PDPs should adhere to provisions such as those in the Medicare Benefit Policy Manual. This would ensure that any claim for a drug that requires FDA approval but is not FDA-approved would be denied, regardless of the benefit category under which the claim was made. For example, payment for combination products such as albuterol and ipratropium, and the delivery system used to administer the drugs, should be limited to FDA-approved formulations.

Produced in Violation of Federal Food, Drug, and Cosmetic Act). Rev. 13. May 28, 2004. Accessed August 11, 2004 at http://www.cms.hhs.gov/manuals/102_policy/bp102c15.pdf.

CMS-4068-P-1257

Submitter : Diane Paulson **Date & Time:** 10/04/2004 08:10:00

Organization : Medicare Advocacy Project, GBLS

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-4068-P-1257-Attach-1.doc

CMS-4068-P-1257-Attach-2.doc

Medicare Advocacy Project
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September 30, 2004

http://www.cms.hhs.gov/regulations/ecomments

Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-4068

Dear Madam or Sir:

On behalf of the clients represented by the undersigned, we wish to submit the following comments on your proposed rule for the Medicare Prescription Drug Benefit. The Medicare Advocacy Project has over 15 years of experience advocating on behalf of Medicare beneficiaries, particularly those with low incomes; the Massachusetts Law Reform Institute is a statewide advocacy organization representing low income individuals, including elders and persons with disabilities; and the Disability Law Center (DLC) is a private, nonprofit protection and advocacy agency that provides free legal assistance to individuals with disabilities throughout Massachusetts. A key mandate of DLC is ensuring that people with disabilities are able to access needed supports to live and work in the community. Because of the limited time allowed and the magnitude of the proposed rule, we are not commenting on CMS-4069, dealing with Establishment of the Medicare Advantage Program. Neither are we commenting on all the sections of the proposed prescription drug rule. Rather, we are focusing on the impact of the rule on low income beneficiaries and persons with disabilities, particularly in the Eligibility and Enrollment and Grievances, Coverage Determination, and Appeals sections. In addition, we support and agree with the more detailed and comprehensive comments submitted on one or both of the proposed rules by the Medicare Consumers Working Group and the Center for Medicare Advocacy, Inc.

We also request that time be provided for another comment period due to the many unaddressed or only vaguely addressed issues. The final regulations could include a number of errors and provisions that result in unintended consequences because so much of the final regulations will not have been seen by the public. We urge CMS to issue the next version of these regulations in a format that will allow one more round of comment, even if a shortened comment period. This is a very complex program with significant ramifications for a large number of citizens. We are concerned that failure to provide for additional public input when the regulations are more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

PART 423-VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

General comments.

1. Many pro-consumer statements in the preamble do not appear in the proposed rule. These protections bear no weight unless captured in the regulations. More should be done to reflect the Preamble's good intentions in the body of the regulations. For example:

> The Preamble discusses providing affected enrollees, prescribers, pharmacists, and pharmacies with written notice when a drug will be removed from the formulary or moved to a different tier for cost-sharing. The regulatory language does not specify that the notice should be in writing. Requirement for written notice is critical and should be specified.
>
> The Preamble gives examples of situations when a plan will be required to allow an enrollee to use a non-network pharmacy. These include situations such as when an enrollee's plan does not contract with the long-term care pharmacy which an enrollee in a nursing home must use. The regulations should include the examples CMS discusses in the preamble.

2. There are a number of areas where the law is unclear or contradictory and these areas are creating serious problems for the regulation drafters. CMS should take advantage of the law's provision calling for the submission of technical and corrective amendments. While this was supposed to have been done by June 8, 2004, it should still be done, and Congress should address these issues as soon as possible.

3. Simplicity, as well as additional support for information and counseling, is necessary to ensure that beneficiaries are reached in a comprehensible way. The sheer size and complexity of these regulations is a testament to the fact that this new law is incredibly confusing. If beneficiaries are confused, enrollment and use of the new program will be very difficult, particularly for lower income, sicker, and limited English proficiency beneficiaries. Thus whenever it is possible, CMS should seek to simplify the new program.

Addressing some of our specific concerns:

Subpart B-Eligibility and Enrollment

1. The draft regulations addressing enrollment of beneficiaries into private drug plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDPs) do not adequately address the need for hands-on outreach, particularly to low-income beneficiaries, or to beneficiaries with special needs, such as mental illness. More attention must be given to developing materials and education and enrollment campaigns focused on informing beneficiaries with disabilities, including mental illness and cognitive impairments, and those with other special needs about the new drug benefit and helping them to enroll in the best plan available.

2. Of particular concern, is enrollment of the dual eligibles. Beneficiaries covered by both Medicare and Medicaid are by definition poor and cannot afford to pay privately fo fill any gaps in medication. Congress and the Administration promised that dual eligible beneficiaries would be better off with this new Part D drug benefit than they were receiving drug coverage through Medicaid. To honor this promise, coverage of medications for dual eligibles and other special populations must be grandfathered into the new Part D benefit. In addition, CMS must require plans to establish an alternative flexible formulary for dual eligibles as suggested in the preamble to the proposed regulations. This flexible formulary would incorporate utilization management techniques that focus on improving inefficient and ineffective provider prescribing practices but

do not restrict access to medications through prior authorization, fail first, step therapy, or therapeutic substitution requirements.

3. The regulations do not adequately address how drug coverage for the dual eligibles will be transferred to Medicare on January 1, 2006. There are issues both of timing and implementing the enrollment process in a way that will ensure that these beneficiaries do not confront a loss of benefits or a gap in drug coverage, either of which could have disastrous health consequences. Specific comments on enrollment of dual eligibles and our recommendations appear in our comments on §§423.34, 423.36, 423.48 and on Subpart P.

A. We are concerned with ensuring continuity of care for dual eligibles and access to needed prescriptions. These issues and concerns apply equally to all dual eligibles, and particularly to those with special health care needs, as well as to other populations with specific needs (See our comments in Subpart C, §423.120.)

B. The proposed regulations would force dual eligibles to enroll (or be automatically enrolled) in the "benchmark" or average cost plans in their areas because the low-income subsidy they will receive will only cover the premium for these plans. The formularies for these plans will not be as comprehensive as the drug coverage these individuals currently have through Medicaid. Even though Massachusetts has restricted access to drugs in its Medicaid program with preferred drug lists and prior authorization requirements, Massachusetts has taken many steps to ensure that special populations can readily access medically necessary drugs. For example, individuals who have been stabilized on one antidepressant are not required to try another one.

C. Without access to the coverage they need, dual eligibles will be forced to switch medications, which for certain populations, such as beneficiaries with HIV/AIDS or mental illness can have serious adverse consequences. Also, failing to ensure continuity of care for dual eligibles may benefit the plans, but will undoubtedly lead to Medicare and/or state increased costs for more physician and emergency room visits, and hospitalizations. The regulations do provide a special enrollment period for dual eligibles to use "at any time" (§423.36). However, being able to enroll in a different Part D plan is inadequate to meet the special needs of dual eligibles.

D. In the preamble to the proposed regulations, CMS points to an exceptions process as a means of securing coverage of off-formulary medications (See our comments to **Subpart M-Grievances, Coverage Determination and Appeals**) But the process proposed is extremely complex and cumbersome to navigate for someone having a psychiatric crisis, facing cognitive impairments, or in the midst of aggressive chemotherapy-to list just a few examples. Moreover, the timelines established are inordinately drawn out; for example, an expedited determination could take as long as two weeks. Drug plans are not required to provide an

emergency supply of medications until at least two weeks following a request. Exception, grievance and appeal processes should not be used to substituted for open formulary access to medications.

§423.34 Enrollment Process.

§423.34 (b) Enrollment.
The final rule should provide that an authorized representative may complete the enrollment form on behalf of a Part D eligible individual.

§423.34(c), Notice Requirement.
The notice must be in writing and inform an individual who is denied enrollment of his or her appeal rights, including the right to appeal the imposition of a penalty for late enrollment.

§423.34(d) Enrollment requirement for full benefit dual eligibles.
In the Preamble, CMS requested comments on whether CMS or the states should perform automatic enrollment of dual eligibles. State officials have more readily available data identifying the dual eligibles in their state and they also will be involved in the enrollment process because they are already required to perform low-income subsidy enrollment. In addition, there is an incentive for them to enroll these individuals in Medicare drug plans because without drug coverage they will increase utilization of other Medicaid services. Thus, states should be afforded the ability to conduct auto-enrollment and receive full federal financing for this function. In addition, CMS should develop its own systems for automatic enrollment of dual eligibles in states that do not elect to do so. Also, because the proposed rule leaves unanswered key questions about who will conduct automatic enrollment of dual eligibles and how it will occur, CMS must give the public the opportunity to provide input on any proposal it develops on this issue before publishing a final regulation.

§423.34(d)(1) General Rule.
The draft regulations provide that dual eligibles will be automatically enrolled in a Part D plan if they do not enroll themselves, by the end of the initial enrollment period, which, under §423.36, is May 15, 2006. However, their Medicaid prescriptions drug coverage will end on January 1, 2006. This proposed timeline for automatic enrollment must be changed because it could expose millions of dual eligibles to a four and half month coverage gap that could have serious health consequences for this vulnerable population. Given the difficulty of reaching this population coupled with inadequate provisions for outreach and education, it is almost certain that a substantial number of dual eligibles will face a several month gap in coverage between the end of Medicaid's drug benefit and automatic enrollment. This is untenable, and directly in conflict with Congress' and the Administration's promise that dual eligibles will be better off under Medicare Part D. The transfer of drug coverage from Medicaid to Medicare Part D should be delayed. Absent a delayed transition date for dual eligible drug coverage, however, dual eligibles should be randomly assigned and enrolled in a plan that best suits their needs as early as November 15, 2005 but no later than December 1, 2005. While we would prefer to provide individuals an extended period to make informed choices, it is critical to complete auto-enrollment as early as possible to leave as much time as possible to distribute plan information

and cards to beneficiaries, allow them to switch plans, and educate them about their new drug coverage before January 1, 2006. To make this process work more smoothly, states can begin profiling individual drug histories to prepare for random auto-assignment among plans that are appropriate for the individual even before plan information is released on October 15, 2005. Additionally, CMS should fund a campaign of individualized counseling and assistance both before and after auto-enrollment to explain to individuals their choices and how to enroll in a plan; explain, if applicable, how to get benefits under the plan to which they have been auto-assigned; and explain, if applicable, that they can choose a different plan from the one to which they have been auto-assigned and assist in choosing and enrolling in such a plan.

§423.34(d)(1)(ii)
CMS must develop a solution to the issue of automatic enrollment of dual eligibles who are enrolled in MA plans that have a prescription drug benefit with a premium that is above the low-income benchmark. The solution should be the one least disruptive to medical care and should not force a dual eligible to choose among continued MA enrollment, paying added premiums, or foregoing drug coverage. For institutionalized dual eligibles, the difference between the premium and the premium subsidy should be considered an incurred medical expense and deducted from their monthly "patient paid amount" to the facility. For non-institutionalized dual eligibles, in states with pharmacy assistance programs (SPAPs) which will wrap around Part D coverage and will cover dual eligibles, the SPAPs should be authorized to pay the difference. For medically needy individuals, the cost differential would be an incurred medical expense contributing toward their spenddown, if appropriate. Otherwise, individuals should be counseled about the premium discrepancy and about their right to withdraw from the MA plan and return to original Medicare. Ideally, dual eligibles who want to remain in the MA plan should be allowed to do so and not have to pay any amount by which the MA-PD basic premium exceeds the low-income benchmark amount.

§423.34(d)(2), When there is more than one PDP in a PDP region.
Because not every PDP plan may be appropriate for each dual eligible (for example, due to formulary restrictions), CMS should limit "on a random basis" to "among such plans in the region that meet the beneficiary's particular drug needs." Also, this subsection undermines the §423.859 right of assured access to a choice of at least two qualifying plans, by acknowledging that there may be regions where there is only one PDP in a PDP region with a monthly beneficiary premium at or below the premium subsidy amount.

§423.36 Enrollment Periods.

§423.36(a)(3)(ii) Exception.
It is not clear who these beneficiaries would be.

§423.36(c) Special Enrollment Periods.
This section should be expanded to provide "special enrollment exceptions" for individuals disenrolled by a PDP (such as for disruptive behavior) so that the individual will have an opportunity to join another PDP and continue with necessary medications. These "special enrollment exceptions" are necessary given the high risk of discrimination presented by the

provisions for involuntary disenrollment. CMS should provide a special enrollment period for these beneficiaries. It should include a reasonable time period for plan selection and be exempt from late enrollment penalties. It should also be expanded to make clear that involuntary loss of creditable prescription drug coverage includes loss because the beneficiary, or beneficiary's spouse, stops working; because COBRA coverage ends or because the premiums became unaffordable.

§423.36(c)(4) Special Enrollment Periods and Dual Eligibles.
We support granting dual eligibles special enrollment periods. However, this provision does not adequately address their needs. It is unlikely that there will be much choice of low-cost drug plans in each region, particularly in rural areas which have not historically attracted many Medicare+Choice plans. For example parts of Cape Cod and Western Massachusetts have no Medicare+Choice plans. In addition, these individuals will not have the resources to pay for more comprehensive coverage. Moreover, the special enrollment provisions do not specify that dual eligibles would not be subject to a late enrollment fee if this complex process of disenrollment and reenrollment resulted in a gap in coverage of over 63 days.

In addition, full benefit dual eligibles should receive notice explaining their right to a special enrollment period when they enroll in a plan, and every time their PDP changes its plan in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

§423.36(c)(8)
The regulations should include a special enrollment period similar to the one for dual eligibles for all beneficiaries eligible for a full or partial-low income subsidy. This is necessary because if coverage for a drug is denied, these low-income beneficiaries will be unable to afford to pay for drugs during a period of appeal, or if their appeal is denied and they are locked into a plan that does not cover a drug they need.

Special enrollment periods should also be provided for all institutionalized individuals, not just institutionalized dual eligibles, since their access to needed drugs may be compromised by the design of the plans and by pharmacy access requirements, such as if their long-term care pharmacy is not required to be included in the network of all PDPs. Individuals with life-threatening situations and individuals whose situations are pharmacologically complex should have the same rights as well.

§423.38 Effective Dates.

§423.38(c) Special Enrollment Periods.
Effective date should be first day of first calendar month following special enrollment in which individual is eligible for Part D.

§423.42 Coordination of enrollment and disenrollment through PDPs

§423.42(c)(2)
Notice of disenrollment should be in writing.

§423.44 Disenrollment by the PDP.

§423.44(b)(2)(I)
CMS requested comments about the requirement to involuntarily disenroll individuals from a PDP if they no longer reside in the service area. This raises the issue of "snowbirds"-the large number of Medicare beneficiaries who move for large parts of the year. This is a problem in Massachusetts where many elders winter in warmer climates. The churning-the enrolling and disenrolling-that plans serving this population will face as they apply this section will be enormous. Because of different formularies between plans and problems of coordination, the regulations should seek to minimize plan changes and maintain continuity of care. This section, as written, could result in a significant number of plan changes, disrupting continuity of care.

Some suggested ways to address this issue better would be to require that plans as a condition of participation have a system of visitor or traveler benefits, consider exempting regional PDPs and PDPs with out-of-network services from the disenrollment requirement, require plans to provide prospective enrollees specific information on traveler benefits and "out-of-plan service policies" and clearly define the time period that a plan could consider an enrollee as "no longer resid(ing) in the PDP's service area." such that it accommodates seasonal travelers who maintain a residence in the service area.. In many cases, 90 day mail order service and arrangements with other plans will make enrolling and disenrolling unnecessary. However, beneficiaries must have a clear understanding of how a plan will serve them while temporarily out of the service area; how when they are traveling and need emergency pharmaceutical services their plan will (or will not) reimburse for those services.

§423.44(d)(2)
Provisions in the proposed regulations to allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" create enormous opportunities for discrimination against individuals with mental illnesses, Alzheimer's, and other cognitive conditions. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and accordingly be subject to a late enrollment penalty permanently increasing their premiums. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage. Moreover, CMS lacks statutory authority to authorize PDPs to involuntarily disenroll beneficiaries. Under the MMA, section 1860D-1(b) directs the Secretary to establish a disenrollment process for PDPs using rules similar to a specific list of rules for the Medicare Advantage program. This list does not include reference to section 1851(g)(3)(B) of the Social Security Act which authorizes MA plans to disenroll beneficiaries for disruptive behavior. Thus, these proposed regulations must not be included in the final rule.

Concerns with specific provisions in this section and recommendations for beneficiary protections, which, at a minimum should be provided, are as follows:

§423.44(d)(2)(vi) Reenrollment in the PDP.
In the preamble, CMS appears to be asking for comments on whether a PDP should be allowed to refuse reenrollment of an individual who has been involuntarily disenrolled if there is no other drug plan in the area. As discussed above, it is our position that there is no statutory basis for involuntarily disenrollment. If the regulations allow this for disruptive behavior, then the plans must be required to allow reenrollment. Those individuals most likely to be subject to involuntary disenrollment will not have the resources to pay for their medications out-of-pocket. These individuals are entitled to this benefit. Disruptive behavior does not disqualify you from access to prescription drug coverage and may in fact be an indication that one is in need of medical assistance. Individuals who are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period and may therefore be subject to a late penalty and increased premium as a result. This result is unfair in light of the fact that the disruptive behavior may have resulted from denial of access to needed medications. CMS should therefore provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior, must waive the late enrollment penalty for these individuals, and the regulations must include detailed articulated protections to lessen the risks inherent in authorizing sanctions for "disruptive behavior."

§423.44(d)(2)(vii) Expedited Process.
This provision should be deleted from the final rule. The proposal to establish an expedited disenrollment process in cases where an individual's disruptive or threatening behavior has caused harm to others or prevented the plan from providing services is undefined, and provides no standards, requirements or safeguards. It allows plans to employ this mechanism on the basis of behaviors described in the broadest of terms - terms which could easily be mis-applied or applied capriciously or punitively. Thus, it would undermine all the minimal protections that would otherwise apply.

§423.46 Late enrollment penalty.
CMS should delay implementation of this section for two years. The drug benefit is a new and complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. The Medicare-endorsed prescription drug discount card program has shown that, even with significant outreach, the majority of individuals eligible for the $600 low-income subsidy have not yet enrolled. We disagree that healthy beneficiaries will not apply. We believe that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness and cognitive disabilities. Implementation of the late enrollment penalty should be delayed for individuals eligible for the low-income subsidy who may not understand that they have to apply separately for the subsidy and a drug plan, thinking that application for the subsidy is sufficient.

This section should provide that when the late enrollment penalties are implemented, there will be an opportunity for enrollees to appeal late enrollment penalties; that late enrollment penalties will be coordinated with "special enrollment periods" to ensure that individuals who take advantage of the special enrollment periods do not face late penalties; that individuals who are involuntarily disenrolled are exempt from this penalty; and that if an employer or other entity

providing drug coverage to Medicare beneficiaries fails to provide adequate or correct notice of the creditable status of that coverage or a change in status of that coverage, and that coverage is not creditable, there are no late enrollment penalties.

§423.48 Information about Part D.
Medicare beneficiaries can only exercise an informed choice about their drug plan if they have adequate information about drug plan options available to them. The information should be provided annually, in writing, and include details about the plan benefit structure, cost-sharing and tiers, formulary, pharmacy network, and appeals and exception process. In order to assure that beneficiaries have the required information, the standards should be included in regulations that are binding and enforceable, and not in guidance. Minimally, the regulations should require plans to provide premium information, including whether individuals who receive the low-income subsidy will have to pay a part of the premium and, if so, the amount they will have to pay; the benefits structure and comparative value of the plans available to them; the coinsurance or copayment amounts they will need to pay for each covered Part D drug on the formulary; the specific negotiated drug prices upon which coinsurance calculations will be based and that will be available to beneficiaries if they confront the gap in coverage; formulary structure, the actual drugs on the formulary, and how the formulary can change during the plan year; participating pharmacies, mail order options, out-of-service options; and exception, appeals and grievance processes. Plans should be required to provide this information to potential enrollees in a clear manner using a standard format that will allow beneficiaries to easily compare plans. Plans should be required to provide information on negotiated prices in an easily accessible format.

The regulations should also include specific requirements for plans and states, as well as outline activities CMS will undertake, to ensure that every effort will be made to reach dual eligibles. By summer 2005 CMS and the states should launch a concerted outreach and assistance campaign for dual eligibles to alert them about the need to enroll in a Part D plan and to help them make appropriate choices. The outreach campaign would be intended to prevent default enrollment. In addition, as early as possible, and no later than October15, 2005 (assuming information is available), CMS or the states should mail standardized, easy-to-understand notices to dual eligibles that, among other things: inform them of their eligibility to receive the low income drug benefit if they enroll in a PDP or MA-PD; list choices of health plans (clearly denoting those that meet the benefit premium assistance limit) and contact information for each plan; explain that individuals will be randomly enrolled in a prescription drug plan beginning November 15 (or, if different, the appropriate date) if they fail to opt out or enroll in a plan themselves; explain how they may change their drug plans if they wish at any time; and inform them of where in their community they can go to get help with enrollment. These notices should be tested for readability by focus groups and experts. If the states are required to provide this information, CMS should reimburse 100 percent of the states' costs.

§423.50 Approval of marketing material and enrollment forms.
The marketing rules for the PDPs and MA-PDPs should be developed in the historical context of other Medicare programs. From selective marketing to outright fraud, Medicare programs historically have been afflicted with marketing abuses and scams. We urge that CMS be vigilant to identify and prohibit these problematic areas and practices as it develops final regulations.

§423.50 (e) Standards for PDP marketing.
Telemarketing should expressly be prohibited. Door-to-door solicitation is prohibited under this section and telemarketing presents many of the same dangers. The regulations should specifically prohibit prescription drug plans from initiating telephone or e-mail contact with potential enrollees, unless the potential enrollee requests contact through such means in response to a direct mail or other advertisement.

In the Preamble, CMS asked for comments on whether it would be advisable to permit prescription drug plan sponsors to market and provide additional products (such as financial services, long term care insurance, credit cards) in conjunction with Medicare prescription drug plan services. CMS should not allow plans to market other services, nor should it seek to encourage other entities, such as financial institutions, to participate as PDPs. The potential for abuse—both cherry picking of healthier beneficiaries into plans and avoidance of financial services to less healthy individuals—is enormous. CMS also asked for comments on the applicability of MA marketing requirements for PDP marketing. PDP marketing requirements should be at least as restrictive as MA marketing because of the high potential both for confusion and for individuals to be directed to—and locked-into—plans that do not best meet their needs. Beneficiaries look to providers for balanced, unbiased information, and they should be able to rely on the information that these sources provide. However, if providers or pharmacies are allowed to market plans, there is the potential for aggressive marketing of certain PDPs, regardless of whether or not that PDP is the best for the beneficiary. The adverse consequences of making a bad selection based on promotion from a trusted source are high.

§423.56 Procedures to determine and document creditable status of prescription drug coverage.

§423.56 (e) Notification.
It is essential that beneficiaries understand whether they have creditable coverage. Failure to understand the issue of creditable coverage can lead to a lifetime of higher Part D premiums. CMS must set forth specific requirements that plans provide information to Medicare beneficiaries enrolled in those plans clearly stating whether or not the coverage they have is creditable. Minimally, in 2005, information on whether coverage is creditable or not should be provided in more than one mailing, and included in such documents as quarterly retiree income statements, medical billing correspondence, etc. After 2005, CMS should develop standard notices, through its Beneficiary Notice Initiative, to be used. In years after 2006, when creditable status changes, special notification is needed to insure that beneficiaries know as soon as the decision is made to reduce coverage, so they can begin shopping for a PDP and avoid a lifetime of premium penalties. Because this is such important notification, it should be sent by registered mail, or e-mail with proof of receipt. Additionally where beneficiaries are not adequately informed by an employer or other entity that their coverage is not creditable, CMS should take action on behalf of all the individuals of that employer or other entity to provide a special enrollment period (SEP). Each individual adversely impacted by the failure of the employer or other entity to inform adequately should not have to apply or appeal for a SEP.

Subpart C-Benefits and Beneficiary Protections

§423.100 Definitions.
"Dispensing fee" should be broadly framed, in order to permit the payment of costs associated with home infusion therapy. Of the options provided in the preamble to the proposed rule, we support option 3. We do not believe that a narrowly crafted definition of dispensing fee is appropriate because the conference report at § 1860D-2(d)(1)(B) references negotiated prices in a manner that indicates that Congress intends to define negotiated prices in a way that arrives at the most accurate prices when considering a variety of both concessions and fees. Since the antibiotics, chemotherapy, pain management, parenteral nutrition and immune globulin and other drugs that are administered through home infusion are indisputably covered Part D drugs, and equipment, supplies and services are integral to the administration of home infusion therapies, costs associated with such administration should be included in the definition of dispensing fee, in order to arrive at the most accurate determination of the negotiated price. Option 1 makes an arbitrary and inappropriate distinction between costs associated with dispensing a covered Part D drug and associated costs for the delivery and administration of a covered Part D drug, and option 2 does not capture all the true costs associated with dispensing a covered Part D drug.

"Long-term care facility" should explicitly include ICF/MRs and assisted living facilities.
We recommend that the final rule include a definition of "long-term care facility" that explicitly includes intermediate care facilities for persons with mental retardation and related conditions (ICF/MRs) and assisted living facilities. This is important because many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

§423.104 Requirements related to qualified prescription drug coverage.
The final rule defines "person" so that family members can pay for covered Part D cost-sharing. The law precludes contributions from employer sponsored health plans from being counted as incurred costs and counting toward the deductible or out of pocket limit. Contributions from one employer-sponsored benefit should not receive differential treatment over contributions from another type of employer-sponsored benefit. Contributions from employer-sponsored group health coverage should be counted as an incurred cost, similar to contributions from HSAs, HRAs, and FSAs. The final rule should also count cost-sharing subsidies from AIDS Drug Assistance Programs (ADAPs) as incurred costs. The regulations also specifically state that state-appropriated dollars spent by ADAPs cannot be counted as incurred costs. It is discriminatory and unacceptable to single out state dollars used to provide medications to people living with HIV/AIDS and not allow them to count as incurred costs, while at the same time allowing state dollars paid by State Pharmaceutical Assistance Programs' (SPAPs)to count as incurred costs.

§423.104(e)(2)(ii) Establishing limits on tiered copayments.
The final rule should not allow Part D plans to apply tiered co-payments without limits. Rather, it must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs.

§423.104(h) Negotiated prices.(1) Access to negotiated prices.
No plan should be allowed to impose 100% cost-sharing for any drug. Such cost-sharing should be considered as per se discrimination against the group or groups of individuals who require that prescription.

§423.120 Access to covered Part D drugs.

§423.120(a) Assuring Pharmacy Access.
Pharmacy access standards must be met in each local service area, rather than by permitting plans to apply them across a multi-region or national service area. Permitting plans to meet the access standards across more than one local service area could cause individuals in some local service areas to not have convenient access to a local pharmacy. Also, only retail pharmacies should be counted for the purpose of meeting pharmacy access standards. It would undermine the principle that Medicare beneficiaries will have convenient access to a local pharmacy if the access standards could be met by counting pharmacies that serve only specific populations and which are not available to all parts of the general public. The final rule should require prescription drug plans to offer to contract with Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (I/T/U) pharmacies and make available a standard contract. Should the final rule not contain this requirement and in situations where an I/T/U pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy. The final rule should also require prescription drug plans to offer to contract with all LTC pharmacies and make available a standard contract. Over 80% of nursing home beds are in facilities that require the resident to use a long-term care pharmacy. Should the final rule not contain this requirement and in situations where a LTC pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy. Furthermore, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through higher cost-sharing for out-of-network access.

§1860D-11(e)(2)(D) authority to review plan designs to ensure that they do not substantially discourage enrollment by certain Part D eligible individuals.
CMS should use the authority provided under section 1860D-11(e)(2)(D) to review plan designs, as part of the bid negotiation process, to ensure that they are not likely to substantially discourage enrollment by certain Part D eligible individuals. Previous experience with Medicare+Choice plans shows that private insurers use a variety of techniques to discourage both initial and continued enrollment in a plan by enrollees with more costly health care needs. For example, Medicare+Choice plans have offset reduced cost-sharing for doctors visits with increased cost sharing for services such as skilled nursing facility care, home health care, hospital coinsurance, and cost sharing for covered chemotherapy drugs that are utilized by people with chronic and acute care needs. CMS should thus analyze formularies, cost-sharing tiers and cost-sharing levels, and how cost-sharing (including both tiers and levels) is applied to assure that people with the most costly prescriptions are not required to pay a greater percentage of the cost of those drugs. CMS also needs to assure that a variety of drugs are included in a

formulary at the preferred cost-sharing tier to treat chronic conditions and conditions that require more costly treatments. As stated above, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through higher cost-sharing for out-of-network access.

§423.120(a)(6) Level playing field between mail-order and network pharmacies.
The final rule should ensure that beneficiary out-of-pocket costs used for the purchase of covered Part D drugs count as incurred costs. A key principle of the MMA is that Medicare beneficiaries have convenient access to a local pharmacy. This principle is undermined by permitting plans to charge beneficiaries the cost differential for receiving an extended supply of a covered Part D drug through a network retail pharmacy versus a network mail-order pharmacy. However, notwithstanding this objection, the final rule should permit the cost differential charged to beneficiaries to count as an incurred cost.

§423.120(b) Formulary requirements.
We do not believe it is appropriate for the final rule to constrain prescribers' capacity to prescribe drugs for off-label uses. By not permitting a class to exist in the USP model guidelines solely because all commonly used medications are being used for off-label indications could lead plans to deny coverage for off-label uses. Off-label prescribing has become a common-and accepted-practice across the field of medicine. For example no drugs that are currently used in the treatment of lupus (a serious, life-threatening auto-immune disorder) have the treatment of lupus as an on-label indication. For the treatment of mania, certain anti-convulsants and calcium channel blockers have proven effective and certain anti-convulsants have proven effective for treatment of bipolar disorder, although these uses are not FDA-approved on-label indications. We thus oppose any provisions in the final rule that place new limits on the ability of prescribers to prescribe drugs for off-label uses-or that legitimize the denial of coverage for covered Part D drugs simply because they are used for an off-label indication.
We support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must be protected from tiered cost-sharing that could to these defined populations must be made available at the preferred level of cost-sharing for each drug. We recommend that this treatment apply to at least the following overlapping special populations: dual eligibles, institutionalized populations, persons with life-threatening conditions, and persons with pharmacologically complex conditions.

We recommend that if the final rule limits the notice requirements to persons directly affected by the change, then plans must be required to provide notice in writing, mailed directly to beneficiary, 90 days prior to the change, and the notice must inform the beneficiary of their right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary. We also recommend that the final rule place strict limits on mid-year formulary changes, requiring plans to justify a decision to remove drugs from a formulary such as the availability of new clinical evidence indicating that a particular covered Part D drug is unsafe or contraindicated for a specific use or when all manufacturers discontinue supplying a particular

covered Part D drug in the United States. Should the final rule fail to effect such a restriction, plans should be required to continue dispensing all discontinued drugs until the end of the plan year for all persons currently taking a discontinued drug as part of an ongoing treatment regimen.

§423.124 Special rules for access to covered Part D drugs at out of network pharmacies.
The final rule must establish requirements on plans to dispense a temporary supply of a drug (wherever a prescription is presented, irrespective of whether or not it is at a network pharmacy) in cases of emergency. If the emergency situation involves a coverage dispute, the plan must dispense refills until such time as the prescription expires or the coverage dispute is resolved, through either a plan decision to provide coverage for the drug or through completion of the appeal process. This requirement must also specify that a temporary supply must be dispensed even in cases where beneficiaries are unable to pay applicable cost-sharing.

The final rule should also limit out-of-network cost-sharing to no more than the difference between the maximum price charged to any in-network Part D plan in which the pharmacy participates and the in-network price. While we recommend that this limitation apply in all circumstances, at a minimum, it must be applied through the final rule, to the scenarios described in the preamble to the proposed rule.

§423.128 Dissemination of plan information.

§423.128 (d) Provision of specific information.
It is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center. The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program.

§423.128(e) Claims Information.
In addition to the required explanation of benefits elements in the proposed regulation, the explanation of benefits should also include information about relevant requirements for accessing the exceptions, grievance and appeals processes.

Subpart J-Coordination Under Part D With Other Prescription Drug Coverage

§423.464(e) Coordination with State Pharmaceutical Assistance Programs (SPAPs).

SPAPs and new SPAPs must be able to help beneficiaries 'fill in the donut,' and we appreciate CMS's efforts to coordinate this assistance. To assure that beneficiaries are receiving seamless coverage and not facing undue out of pocket expenses, an exchange of data between the PDP and the SPAP is necessary. This should include (but not be limited to) an exchange of eligibility files, exchange of claims payment and information about the drugs on the PDPs formulary and any changes to it. Also, AIDS Drug Assistance Programs (ADAPs) should be recognized as

State Pharmacy Assistance Programs and allowed to wrap around the Medicare Part D drug benefit.

Subpart M-Grievances, Coverage Determination, and Appeals

The proposed regulations fail to meet the requirements of the Due Process Clause of the Fifth Amendment to the United States Constitution. As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid recipients whose prescription requests are not being honored currently receive a 72-hour supply of medications pending the initial coverage request. They are entitled to notice, face-to-face hearings, and aid paid pending an appeal if their request is denied and they file their appeal within a specified time frame. All state Medicaid appeals processes are completed more expeditiously than Medicare appeals. The appeals process as described in Subpart M does not accord dual eligibles and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity for a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes. While we recognize that the most efficient means of protecting enrollees, amending MMA to provide for an appeals process similar to Medicaid, is beyond the authority of CMS, CMS can take steps in the final regulations to improve notice and the opportunity for speedy review.

Sections 1860D-4(f), (g), and (h) require that Part D plan sponsors establish grievance, coverage determination and reconsideration, and appeals processes in accordance with Sections 1852(f), (g) of the Social Security Act. As will be discussed in more detail below, CMS has failed to comply with the language of those provisions. Overall, the incredibly onerous exceptions process does not comply with the statutory requirements or meet the basic elements of due process. In addition, CMS, in implementing Section 1852(c) and in settlement of *Grijalva v. Shalala*, 153 F.3d 1115 (9th Cir, 1998), *vacated and remanded*, 526 U.S. 1096 (1999), adopted 42 C.F.R. §422.626, which establishes the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review for Part D. CMS needs to incorporate a similar process for Part D in order to establish a process in accordance with Section 1852(c). A similar fast-track process would also be more in keeping with due process requirements.

As a general comment, this entire subpart needs to be made much simpler. To have two tracks, depending on (1) whether one personally pays for a drug and files an appeal or (2) does not obtain the drug and files an appeal, is far too complicated. The time frames, paperwork, and processes should be simplified into one course of action that beneficiaries may hope to understand.

§423.560 Definitions.

This section defines "appeal" to exclude grievance and exceptions processes, and defines “authorized representative” as an individual authorized by an enrollee to deal with appeals. The definition of “authorized representative” needs to clarify that a doctor or representative, including a State Prescription Drug Plan (since the SPAP may be at risk in the event of PDP

actions) can be an authorized representative, and that authorized representatives can deal with exceptions and grievances as well as appeals.

§423.562 General provisions.

§423.562(b)(5)(iii)

Reconsideration by an Independent Review Entity (IRE) should be automatic, as in the Medicare+Choice plans

§423.562(c)(1)

This subsection precludes an enrollee who has no further liability to pay for prescription drugs from appealing. However, it is important to be able to appeal formulary changes. A comprehensive change in this limitation is essential to protect the health of beneficiaries. At a minimum, SPAPs should be able to appeal on behalf of an enrollee and the section should clarify that a low-income institutionalized individual can appeal a determination, even if she has no co-payment responsibilities.

§423.566 Coverage determinations.

§423.566(b) Actions that are coverage determinations.

This subsection needs to clarify further what constitutes a coverage determination. The proposed definition does not include in the list of coverage determinations from which an appeal can be taken a determination by the PDP that a drug is not a covered drug under Part D. An enrollee should be entitled to appeal to determine whether, in fact, a drug the plan claims is not covered under Part D is so covered. The definition should also clarify that denials of enrollment in a Part D plan, involuntary disenrollment from a Part D plan, and the imposition of a late enrollment penalty are coverage determinations subject to the appeals process. Finally, the regulation should state that the presentation of a prescription to the pharmacy constitutes a coverage determination. If the pharmacy does not dispense the prescription, then the request for coverage should be deemed denied, and the enrollee should be entitled to notice and to request a re-determination. Without such clarification, enrollees will not be informed of their rights, and the appeals process will become meaningless.

§423.568, Standard timeframes and notice requirements for coverage determinations.

§423.568(a) Timeframe for requests for drug benefits.

The plan should be required to provide oral notice as soon as it determines that it will extend the deadline for considering whether it will cover a drug, including notice of the right to request an expedited grievance. The oral notice should be followed-up in writing.

§423.568(b) Timeframe for requests for payment.

This section should be eliminated. There should be no distinction in time frames when an enrollee requests payment.

§423.568(c), Written notice for PDP sponsor denials.

Who gives notice? The proposed regulations place the responsibility for providing notice of a coverage determination on the plan sponsor. This presumes a situation in which the person presents a prescription, the pharmacy contacts the plan, and then the plan takes 14 days to decide whether or not to cover a drug. In reality, the pharmacy, in most instances, tells the enrollee that the plan will not cover the drug. Without notice provided by the pharmacy, most enrollees will not know to tell the pharmacy to submit the prescription anyway so they can get a notice from which to appeal. They also may not know or understand their right to seek expedited consideration of the initial coverage determination, or an exception if the drug is not on the formulary or on too high a tier. If the enrollee pays out of pocket and then seeks reimbursement from the plan, she will not be eligible for expedited consideration.

The regulations should require the plan sponsor to develop a notice explaining the right to seek a redetermination, and to ask for expedited review. The pharmacy should be required to give the notice to the enrollee. Any potential burden of such a requirement is reduced by the need to maintain electronic communications between the pharmacies and the plans in order to keep up-to-date with formularies, coinsurance, and calculations of an enrollee's out-of-pocket expenses.

The proposed regulations talk about using "approved notice language in a readable and understandable form." The regulations need to be more specific, including information about what is required to use the exceptions process. We suggest that notice should

Include information about exceptions and appeal rights immediately upon denial (including upon determination that a drug is not covered on formulary and including denials issued by the pharmacist), explain why coverage was denied and provide options in addition to the appeal procedures for obtaining necessary medications;

Include clinical or scientific basis for denial; and

Be available in multiple languages and note the availability of language services.

In addition, all notices need to be available in alternate formats to accommodate people with disabilities, and in languages other than English where a portion of the population is not English speaking. The requirements of plans and the rights of beneficiaries in this area must be spelled out in much more detail. There is also an overarching need to consider literacy problems and encourage simplicity.

§423.568(e) Effect of failure to provide timely notice.
It is nowhere spelled out how the beneficiary is apprised of this right.

§423.570 Expediting certain coverage determinations.

§423.570(a) Request for expedited determination.
CMS requests comments on who should be able to request determinations and re-determinations. An authorized representative should be able to request expedited consideration just as the authorized representative may request a coverage determination. In emergency situations, enrollees with mental health concerns and other vulnerable individuals may need someone else to act on their behalf.

§423.570(c) How the PDP sponsor must process requests.
All coverage determinations and appeals concerning drugs, including those in which the enrollee has paid for the drug, should be treated as requests for expedited review. An enrollee would suffer adverse consequences if required to wait for the longer time periods; many people will simply go without prescribed medications pending the outcome of the review. Doubling the timeframes and disallowing expedited review in cases when enrollees pay for their drugs out-of-pocket could adversely affect the health of those who forego other necessities like food and heat in order to pay for their medicine.

At a minimum, all requests for exceptions should be automatically given expedited consideration. Where someone seeks expedited review of a request to continue a drug that is no longer on the formulary, the plan should be required to process the request in 24 hours under the provision that requires an expedited review to be completed as fast as the beneficiary's condition requires. The enrollee should be given a 72-hour supply of the medicine, which is renewable if the plan decides to take longer than 72 hours. The medicine should be treated as an on-formulary drug.

If requests for an exception are not automatically treated as a request for expedited review, the rules should state that the doctor's certificate requesting expedited review and requesting an exception should be one and the same.

§423.570(d)(2)
A beneficiary should not have to wait for a written notice to learn of the right to file an expedited grievance and the right to resubmit a request with prescribing physician support.

§423.572 Timeframes and notice requirements for expedited coverage determinations.

§423.572 (b) Extensions of timeframe.
The timeframe (of 72 hours) can be extended by the plan up to 14 days on showing that an extension is in the interests of the enrollee. The regulations should be modified to read best interest of the enrollee and define interests of the enrollee to include those situations in which the drug plan seeks additional information to substantiate the enrollee's request, or when the enrollee requests additional time to gather supporting information. The regulations should also require the plan to inform the enrollee of the extension immediately, both orally and in writing, rather than "by the expiration of extension." Also, the written notice should include more than just the reasons for the delay.

There should be no extended time period for requests for payment of drugs already received. This imposes extreme hardship on low-income beneficiaries and those with multiple prescriptions who may choose to unnecessarily spend money on their medications because of the uncertainty and length of the appeals process rather than spend the money on other urgent necessities of life.
It is not clear from the proposed regulations what notice a beneficiary will receive when sometime during the year a plan changes its formulary and the drug(s) it covers. The statute says plans must make the change in information available on the internet, the Preamble discusses a

mailed notice, and the draft regulation simply says 'notice.' A change in formulary, or a change in the tiering of a drug on the formulary should be clearly explained to a beneficiary taking that drug which has been changed. That notice should be written notice and the receipt of that notice should serve as a trigger for the beneficiary's legal rights.

§423.572(d) Content of the notice of expedited determination.
See §423.568(c) comments above.

§423.572(e) Effect of failure to provide a timely notice.
How does a beneficiary know s/he can appeal the lack of timely notice?

§423.578 Exceptions process.
The proposed regulations do not explain how an enrollee will get notice about the exceptions process and/or that a drug is not included on the formulary. The only notice requirement is found in §423.120(b), which requires the plan sponsor to provide at least 30 days notice to CMS, affected enrollees, pharmacies, pharmacist and authorized prescribers before removing a drug or changing a drug's preferred or tiered status. Although the preamble talks about written, mailed notice, and the statute requires posting on the Internet, the regulatory language merely says that notice must be given.

To meet basic due process requirements concerning termination of benefits, the notice of the change must be in writing and must include an explanation of how to use the exceptions process, including the requirements for a doctor's certificate, the right to a hearing, and the reasons why a drug is not included on or removed from the formulary, or why the tier is changing, and the evidence required to establish an exception.

Proposed section §423.120(b) provides insufficient time for the notice, given the substantial burden placed on the enrollee to either get a new prescription or to gather the medical evidence. Many beneficiaries will not be able to get a doctor's appointment within 30 days, and many will not be able to change drugs without a medical evaluation. The final regulations should state that notice must be provided 90 days in advance of the change.

In addition, the exception process section should include a subsection on notice that (1) refers to §§423.120(b) and (2) requires plan sponsors to develop a notice that explains the exceptions process, the situations in which someone may seek an exception, and the information that is required to support an exception request, which the pharmacy will give to an enrollee who requests coverage for a non-formulary drug or requests to be assessed a lower cost-sharing amount.

§423.578 (a)(2).
This subsection fails to meet the statutory requirement that the Secretary establish guidelines for an exception process. The plan statutory language is not permissive; it does not say that plans may establish additional criteria if they wish. It says that the Secretary is to establish criteria and the plans are to abide by them. Plans should have no discretion whatsoever. The fact that they may establish differing tiered structures is not relevant to the statutory right to request an

exception to whatever structure they devise. In fact, the flexibility accorded to plans is why beneficiaries need strong guidelines to protect their interests.

Where the proposed regulations include guidance for criteria, the criteria listed exceed the scope of the statute. The proposed regulations list a "limited number of elements that must be included in any sponsor's exception criteria," but this list includes criteria that do not apply based on the statutory provision that states an exception applies if a physician determines that a preferred drug would not be as effective or would have adverse effects or both.

The proposed rules also fail to provide adequate guidance to physicians concerning whether the standard requiring the doctor to certify that a preferred drug would not be as effective or would cause adverse effects has been met.

The final regulation should require that the lowest co-pay that applies should apply to drugs for which an enrollee has won an exception to the tiered cost-sharing structure. That's the whole point of this process - to infuse some equity upon a showing that none of the other medications covered are as effective or may cause harm.

The final rule should also include the following omitted criteria: regulations permitting continued access to a drug at given price when there is a mid-year formulary change, and regulations requiring sponsors to give enrollees an opportunity to request exceptions to a plan's tiered cost-sharing structure other than on a case-by-case basis.

§423.578(b) Request for exceptions involving a nonformulary drug.
This subsection fails to meet the statutory requirement that the Secretary establish guidelines for an exception process. In the preamble, CMS states that "[r]equiring sponsors to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied" and will help ensure these formularies "are based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs ." However, the proposed regulations give drug plans complete discretion in determining the criteria they will use to determine exceptions requests. In addition, independent review entities "would not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." By failing to adequately define the criteria plans may use to consider exceptions requests or provide any meaningful oversight over these criteria, these proposed regulations would not ensure that formularies are based on scientific evidence and would not establish a transparent process. The regulations as written subvert CMS's stated goals.

The proposed rules set an impossibly high bar for receiving an exception by requiring prescribing physicians to produce clinical evidence and medical and scientific evidence to demonstrate that the on-formulary drug is likely to be ineffective or have adverse effects on the beneficiary. Clinical trials generally do not include older people, people with disabilities and people with co-morbidities. While some such evidence does exist, it has not been developed for all drugs and conditions. However, a physician may have extensive experience treating these kinds of patients with the condition or illness at issue and this experience should be given at least

equal weight in making such determinations. In fact, the statutory standard requires deference to the doctor's determination that all on-formulary medications would not be effective or cause adverse consequences. This required deference is not reflected in the proposed rules. It is also important that the final rules recognize the existence of individual differences in reactions to the same drug and that exceptions be available to someone who can not tolerate or who does not benefit from a drug even though that drug is beneficial to most people.

The NPRM proposes to authorize plans to require a long list of information in the written certification from the prescribing physician that an off-formulary drug is needed. This list is overly long and repetitive and may encourage drug plans to establish burdensome paperwork requirements as a hurdle to prevent physicians and consumers from following through on an exceptions request. Moreover, this proposed rule also leaves the required contents entirely up to the plan's discretion by including the catch-all phrase - "any other information reasonably necessary". The requirements for this written certification should be standardized to facilitate use of the exceptions process by providers and consumers. These standards would also help achieve CMS's stated goal of establishing a transparent process.

An important provision was left out of the requirements for receiving a dosing exception. The proposed rule states that in order to receive an exception, the physician must demonstrate that the number of doses available is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. This rule must also allow exceptions if the prescribing physician demonstrates that the number of doses available would cause an adverse reaction or harm to the enrollee - as provided in the proposed rules for other kinds of exceptions requests.

The final regulation should clarify that formulary use includes not just dose restriction, but the format of the dosage (liquid vs capsule, etc.) and packaging, such as bubble wraps for long-term care facility residents.

§423.578(c)(2) When a sponsor does not make a timely decision.
The regulation provides for a one month's supply of a drug, but only if the plan does not act timely on an exceptions determination. If the request for an exception is not given expedited treatment, the sponsor can take two weeks to issue a decision, meaning the enrollee would wait two weeks before getting the supply of medicine. Even if the exception is treated as a request for expedited review, the enrollee would still have to wait 72 hours (unless s/he could show the decision needed to be made more quickly because of her/his condition.) Most people wait to the last minute to refill a prescription, often because of drug plan and pharmacy restrictions.

It is also unclear how an enrollee knows about these rights when a sponsor does not make a timely decision.

The enrollee should be entitled to a one month's supply upon presenting the request for a refill and upon presenting a new prescription for a non-formulary drug. Plans should be required to make exception determinations and notify the enrollee in 24 hours as required under Medicaid for prior authorization determinations. 42 U.S.C. §1386r-8(d)(5)(A).

We cannot overemphasize the importance of drug coverage and ensuring no gaps in the intake of medication. In mental health and HIV/AIDS, for example, it is essential that medications be available quickly and without interruption. In the HIV/AIDS sector, for example, consistent research proves that the risk of drug resistance and resulting treatment failure significantly increases with each missed dose of therapy.

423.578(c)(3), When an exception request is approved.
The lowest coinsurance amount should apply anytime an enrollee wins an exception through this process because the drug at issues has been determined medically necessary with no on-formulary drug as a suitable alternative. The exception for the non-formulary drug thus meets the criteria for an exception to the tiered cost-sharing structure as well.

The regulation needs to clearly set forth the requirement that notice be provided when a decision is made on an exception request. The notice should explain that the decision is a coverage determination and explain the appeal rights that are available.

We commend CMS for specifying that, once an exception request is granted, a plan sponsor may not require the enrollee to keep requesting exceptions in order to continue receiving the drug. However, we are concerned that the "exception" to this protection which allows the plan to discontinue a drug if safety considerations arise, is too broad. The final regulation should be revised to permit reversal of a previously granted exception only if the FDA determines that the drug is no longer safe for treating the enrollee's disease or medical condition.

We are concerned that the timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed provisions raise similar concerns. It is extremely unfair to require longer time frames if a beneficiary has paid out of pocket for a needed medication when their alternative would be to wait two weeks to a month for a determination or an emergency one-month supply of the needed drug. Beneficiaries' health and safety may well be at risk if they are forced to forego other necessities because of the added, and most likely very significant, expense of paying out of pocket for their medicines. Although the proposed regulations include some provisions for an emergency supply of medications while a plan is considering an exceptions request, it is unreasonable and bad health policy to make beneficiaries wait two to four weeks before the drug plan must provide an emergency supply. In addition, plans should be required to demonstrate that an extension of the standard time frame for exceptions determinations is in the best interest of the enrollee and the final rule must charge independent review entities with exercising oversight over these extensions. Plans should be required to make determinations regarding exceptions requests and notify the enrollee of these determinations in 24 hours as required under Medicaid for determinations regarding prior authorization requests (42 U.S.C. 1396r-8(d)(5)(A)).

§423.580 Right to a redetermination
The proposed regulations only authorize an enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) to request a redetermination or an expedited redetermination. The enrollee's authorized representative must also be allowed to request a redetermination and an expedited redetermination. Since the proposed regulations would allow an enrollee's authorized

representative to file a request for Determinations and Exceptions, it does not make sense to not allow an enrollee's representative to pursue a claim further through the redetermination, reconsideration, and higher levels of appeal. In fact, the proposed regulations define an authorized representative as an individual authorized to act on behalf of an enrollee "in dealing with any of the levels of the appeals process".

§423.584 Expediting certain re-determinations.
The regulations need to describe in detail the notice responsibilities for both standard and expedited re-determinations, including what must be provided in the notice. This is crucial, given that the next level of review to the IRE is not automatic, as it is with Medicare Advantage plans. The notice should explain the reason for the denial, including the medical and scientific evidence relied upon, the right to request review, or expedited review, to the IRE, including timeframes and the right to submit evidence in person and orally.

§423.584(a) Who may request an expedited redetermination.
See §423.580 regarding allowing an individual's authorized representative to request an expedited re-determination.

§423.584(d)(2).
The information in the letter should also be provided orally. The enrollee should not have to wait three days for this information.

§423.586 Opportunity to submit evidence.
The regulations should establish clear criteria for informing the enrollee and the physician that they can submit evidence in person, as well as clear procedures for in-person review.

§423.590 Timeframes and responsibility for making redeterminations.
The regulation should be amended so that a plan can only extend the timeframe for a re-determination if requested to do so by the enrollee, or if the plan can demonstrate that the extension is in the best interest of the enrollee (for example, the plan needs to obtain additional information to support the enrollee's request). As previously stated, all re-determination requests, and particularly those involving exceptions, should be treated as expedited, and plans should not be given more time to resolve re-determination requests involving payment requests.

§§423.590(c) Effect of failure to meet timeframe for standard redetermination and (e) Failure to meet timeframe for expedited redetermination.
Again, how does enrollee know this and know what to do?

§423.600 Reconsideration by an independent review entity (IRE).
CMS needs to clarify in the final regulations that the role of the IRE is to provide independent, de novo review, especially in regard to the exceptions process. The preamble states that "…The IRE's review would focus on whether the PDP had properly applied its formulary exceptions criteria for the individual in question…..the IRE will not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." If the IRE does not review all the

evidence and issue a reconsideration decision based on its own analysis, then enrollees will be denied independent review, and the requirements of due process will not have been met.

Further, because, as noted above, CMS is required by the statute to set standards for the exceptions process, the IRE must have authority to determine whether the PDP's exceptions criteria comply with the statute. Otherwise, enrollees will have no mechanism for review of arbitrary and improper standards.

Since the Part D process is supposed to follow the MA process, the regulations should follow the MA regulations and require that denials automatically be sent to the IRE for reconsideration. The regulations as written create a barrier to the first level of independent review for enrollees who have difficulty following the complicated process. We dispute CMS's statement in the preamble that many of the drug appeals will involve small monetary amounts. Rather, most will involve medications for chronic conditions that enrollees take on an on-going basis; the yearly sum of the cost-sharing will be quite substantial, especially considering the income level of most people with Medicare. In addition, by requiring the enrollee to file a request for ALJ review, the first truly independent review available, CMS can satisfy the statutory requirement that the enrollee files the appeal.

If the final regulations continue to place the burden of requesting a reconsideration on the enrollee, they need to clarify that an authorized representative can act on the enrollee's behalf. Again, without such clarification, enrollees who lack the capacity to file a reconsideration request will be denied their due process rights. In addition, the prescribing doctor should also be permitted to request a reconsideration, especially since the enrollee needs the doctor's statement in order to request IRE review of an unfavorable exception request.

Finally, the enrollee should be allowed to request a reconsideration orally, especially where the request is for an expedited review.

§423.600(b).
We are pleased that CMS is requiring the IRE to solicit the view of the treating physician. We believe the IRE should also be required to solicit the view of the enrollee. However, because in our experience the MA independent contractor is often reluctant and unwilling to accept the views of and evidence from the beneficiary, the final regulation needs to be more specific. The regulation needs to specify how this will occur, including contact by telephone, email, or face-to-face meeting.

§§423.600(d).
The regulations need to establish a set timeframe by which the IRE must issue its decision in order for this process to be transparent. Enrollees will have no knowledge of the contract between CMS and the IRE and thus will not know how long they will have to wait for a reconsideration decision. Also, if contractual, the time frame can change with each new contract, putting enrollees at greater risk of adverse health consequences from being denied needed medicines. The regulation should also state that an enrollee may appeal to an ALJ if the IRE fails to act within the regulatory time frame and how the enrollee will be apprised of this right.

§423.602 Notice of reconsideration determination by the independent review entity.
The language concerning what the notice must entail is ambiguous. The notice must "inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under 423.610." Does this mean that the notice tells you that you can go to an ALJ, but only if your claim is large enough? Or does this mean the IRE only has to tell you about your right to an ALJ hearing if your claim meets the threshold amount? The latter interpretation is problematic for several reasons, including the fact that you can aggregate claims. The final regulation should state that the notice must inform the enrollee of his or her right to an ALJ hearing, and the procedure for requesting such a hearing, including the dollar amount required to request a hearing.

§423.610 Right to an ALJ Hearing.
Congress recognized the special needs of the low income, and how even small copayment amounts can cause many lower income individuals to forgo filling prescriptions. We urge CMS to provide exceptions to the ALJ threshold requirements for those receiving the Medicare subsidy. For example, the amount at controversy for a lower-income individual could be deemed to be the amount that would be at controversy if the individual were a non-subsidy eligible individual receiving the standard benefit.

It is unclear what §423.610(c) intends when it says, "Two or more appeals may be aggregated by the enrollee… if (I) the appeals have previously been reconsidered by an IRE…" Does this mean that an enrollee will have to file a new appeal each month for a prescription to treat an on-going chronic condition? Such a requirement would be unduly burdensome for enrollees, drug plans, the IRE, and the ALJs. The final regulation needs to clarify that when the plan denies coverage, in order to satisfy the jurisdictional amount an enrollee should be able to add up the cost of the medicine for a year, if the medicine treats an on-going chronic condition, or for the number of refills authorized if the underlying condition is not chronic.

Subsection (ii) says the request for the hearing must list all of the appeals to be aggregated and must be filed within 60 days after all of the IRE reconsideration determinations being appealed have been received. If you are consolidating appeals, and the first denial is in April and the last one you need to get to the jurisdictional amount is in August, will you still be timely? Or does it have to be 60 days from the first denial in April?

§423.612 Request for an ALJ Hearing.
The regulation should specify that, if an appeal is filed with the PDP, the PDP must submit the file to the IRE within 24 hours of receipt of the request, and the IRE must transmit the file to the ALJ within 24 hours. Our experience is that, without set time frames, some current reviewing entities take long periods of time, adding to the delay in the processing and resolution of ALJ appeals.

The regulations also need to require the IRE to include all of the information in the file, such as doctor's statements, statements by the enrollee, and any other evidence submitted by the enrollee, including information not relied upon in making its decision. It has been our experience that

contracting entities, including MA plans, often omit evidence submitted by the enrollee when transferring a file to the ALJ or other level of review.

§§423.634, Reopening and revising determinations and decisions and 423.638 How a PDP sponsor must effectuate expedited redeterminations or reconsidered redeterminations.
Subsection (c) in both of these draft regulations allows the PDP to take up to 60 days to implement a reversal by the IRE, an ALJ, or higher. That's totally unacceptable, since further delays may cause increased health consequences to people who have foregone medication pending appeal. Favorable decisions should be implemented in the same 72 hour time period as reversals at earlier levels of review.

Subpart P - Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§432.772 Definitions.
"Family size." We support defining family members as relatives in the household receiving at least half of their support from the applicant or applicant's spouse. In order to minimize burdens on beneficiaries, the regulations should specify that applicants will be able to self-attest to the status of dependents, without providing further documentation.

"Full subsidy eligible individuals." The definition should refer to the language of §§423.773(b) and(c), in order to avoid ambiguity.

"Income." The definition should make clear that income not actually owned by the applicant, even if his or her name is on the check, should not be counted.

"Institutionalized individual." The definition should include those individuals eligible for home and community based services under a Medicaid waiver (see, e.g., definition of "institutionalized spouse" at 42 U.S.C. § 1396r-5(h)(1)(A)), since those individuals must meet the acuity standards for Medicaid coverage in a nursing facility, and should include individuals in ICF-MRs and individuals in any institution in which they are entitled to a personal needs allowance.

The definition should not include the language "for whom payment is made by Medicaid throughout the month" since an individual could conceivably be a full benefit dual eligible recently returned from a hospital stay whose nursing facility stay would be paid for by Medicare Part A for the entire month. Even though in that month all their drugs are likely to be paid for by Medicare Part A, as a practical matter, for continuity and minimum disruption, they should not lose their status as an "institutionalized individual." The same reasoning should apply to a full benefit dual eligible individual who might be hospitalized during an entire month, during which their entire stay would also be paid for by Medicare Part A.

"Personal representative." The portion of the definition that permits an individual "acting responsibly" on behalf of an applicant needs further clarification as to who would determine that the individual is acting responsibly and what circumstances would constitute a per se conflict of interest.

"Resources." We support the limitation of countable resources to liquid assets. However the definitions of liquid assets and what it means to be able to be converted into cash in 20 days need to be clarified. The final rule should include a specific list of countable resources to promote clarity for state and beneficiaries. Resources should not include burial plots, burial funds or life insurance of any value, nor should it include any officially designated retirement account, such as an IRA, 401(k), 403(b) etc. Alternatively, the respective exclusions for the value of life insurance and burial funds should be increased to a reasonable amount, such as $10,000 per asset. Most potential low-income beneficiaries have assets below this level.

Excluding these resources will ease the application process for consumers and eligibility workers, as well as reduce administrative costs by reducing the time and effort required to verify assets. This is consistent with both Congress's and CMS's intent. Resource assessments should not include any consideration of transferred assets, as would otherwise be required under SSI rules.

We note that a current draft of the SSA application for the low-income subsidy inquires whether an applicant has life insurance with a face value of $1,500 or more. CMS must ensure that any proposed SSA application is harmonized with these rules on assets and income. As noted above, life insurance should not count towards assets, and this question should be eliminated.

§423.773 Requirements for eligibility.
We support the proposal to make dual eligibles (both full dual eligibles and those in Medicare Savings Programs (MSPs)) automatically eligible for the low-income subsidy. As we explain below, however, we believe a great deal more specificity is needed in this section. We are particularly concerned that the proposed rule leaves room for ambiguity regarding these beneficiaries' status. We believe that the proposed eligibility rules for partial dual eligibles will result in inequities and confusion. In addition, the draft regulations do not adequately explain how low-income beneficiaries are to be notified about their eligibility, nor do they explain how prescription drug plans are to determine which beneficiaries are enrolled in the low-income subsidy. The proposed rules also do not adequately protect low-income beneficiaries whose enrollment is delayed or is processed erroneously.

§423.773(a) Subsidy eligible individual.
Although the statute defines a subsidy eligible individual as one enrolled in a Part D plan, the requirement in Subpart S that states take applications for the low-income subsidy beginning July 1, 2005, before Part D plans are available to be enrolled in makes it clear that CMS believes people should be able to apply for the low-income subsidy without being enrolled in a Part D plan. This is actually imperative, as otherwise, an individual would be forced to pay a plan premium that the subsidy, in fact, pays for them. The subsidy eligibility determination would be done "conditionally" - conditioned upon the individual enrolling in a Part D plan. The regulations should reflect this reality and clearly direct both SSA and state Medicaid programs determining eligibility that the individual can both apply and be determined subsidy eligible before she or he has enrolled in a plan

§423.773(b) Full subsidy eligible individual.

The indexing of resources should indicate that rounding is always up to the next multiple of $10.

§423.773(c) Individuals treated as full subsidy eligible.
This section should conform to Subpart S § 423.904(c)(3) which requires states to notify all deemed subsidy eligible individuals of their subsidy eligibility. It should specify that the notice must be given by July 1, 2005 for those individuals eligible at that time. For those who subsequently become eligible, notice should be given at the same time the individual is notified of their eligibility for the benefit that qualifies them to be treated as a full subsidy individual. The notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. For those who will lose Medicaid coverage January 1, 2006, the notice should explain their appeal rights as well. Individuals should also be told of their right to appeal the level of subsidy to which they are entitled.

Section 209(b) states and non-1634 states must coordinate with the Social Security Administration to determine how to provide notice to SSI recipients who are not receiving Medicaid and who therefore do not appear on the state's Medicaid rolls.

§423.773 states that both full benefit dual eligibles and MSP beneficiaries are eligible for the low income subsidy, but it does not explicitly state that these beneficiaries are automatically enrolled in the subsidy program. The regulations should be absolutely clear that an individual treated as full subsidy does not have to take any further action with respect to the subsidy (i.e., make application or in any other way verify their status), but only to enroll in a Part D plan. This will help smooth the transition from Medicaid drug coverage for dual eligibles, and should improve participation for others.

§423.773(c)(3).
We support the decision reflected in this proposed subsection to deem MSP beneficiaries automatically eligible for the low-income subsidy. We are concerned, however, that inequities and confusion among beneficiaries may result because SSA will not apply the more generous income and asset MSP eligibility rules in place in some states (for example, Alabama, Arizona, Delaware, and Mississippi, which have eliminated consideration of assets for MSPs). Eligibility requirements should be the same for all subsidy-eligible individuals in a state, regardless of where and how they apply. Under the proposed regulations, in states that have adopted less restrictive income and asset methodology, people whose assets or income are slightly above the limits set in § 423.773 would be enrolled in a less generous subsidy, or have their application rejected entirely, if they apply directly through SSA, because SSA will apply the national guidelines proposed in §423.773. However, the same people would have their application accepted if they applied through their states' Medicaid offices, were screened and then enrolled in an MSP, and were then automatically eligible for the low-income subsidy.

To resolve this problem, we propose that SSA apply state-specific income and asset eligibility rules in determining eligibility for the low-income subsidy, an option discussed, though rejected, in the preamble. This means that for applicants from states that have eliminated the asset test or

increased disregards under §1902®)(2) for MSP eligibility, SSA should apply the state's rules to determine eligibility. This option is permitted under §1860D-14(a)(3)(E)(iv) of the statute.

Alternatively, the regulations should provide that subsidy applicants who appear to have excess assets or incomes would either be screened by SSA for eligibility in an MSP program, or have their applications forwarded to the state Medicaid agency to be screened for MSP eligibility. States would be precluded from requiring beneficiaries to resubmit information, such as income and asset levels, that they have already provided to SSA. Applicants would be enrolled in the appropriate MSP program, and then be enrolled in the appropriate low-income subsidy under proposed § 423.773(c). Adopting this policy, which is not precluded by statute, will ensure that all subsidy applicants are treated equitably, as well as increase participation in MSPs.

As part of this alternative policy, the low-income subsidy application should allow an applicant to opt out of screening and enrollment for an MSP, as some applicants may not wish to participate in an MSP. Under §1860D-14(a)(3)(v)(II) of the statute, beneficiaries who are determined eligible for MSPs may be enrolled in the low-income subsidy. There is no requirement that beneficiaries actually enroll in an MSP. Therefore, applicants who meet eligibility requirements for an MSP, but who decline to enroll in the program, should still be automatically eligible for the low-income subsidy.

Because enrollment in an MSP can affect the amount of assistance a beneficiary may receive through other public assistance program, such as Section 8 housing vouchers or food stamps, there will be a profound need for beneficiary counseling during the enrollment process. We recommend that CMS plan for this need by making funds available to local agencies, including state health insurance assistance programs (SHIPs), and other community-based organizations.

This draft regulation states that a state Medicaid agency must notify full benefit dual eligibles that they are eligible for the low-income subsidy and should enroll in a Part D plan. The regulations do not state, however, when this notice should be issued, or what the notice should say. Consistent with our comments above and those accompanying 423.904(c)(3), the notification should be sent to beneficiaries on or near July 1, 2005, when states will have made the automatic eligibility determinations.

We also suggest that CMS develop model notices based on input from beneficiaries, which would explain the purpose of new subsidy simply and clearly. The notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. It should also explain as simply as possible what level of subsidy the beneficiary will receive, and the beneficiary's appeal rights if she believes the subsidy level is in error.

The draft regulation fails to address eligibility issues for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) state. These beneficiaries should be informed of their likely eligibility for a low-income Medicare subsidy and given an opportunity to enroll. When they have met their spenddown, they should be informed of their entitlement to a lower co-payment, if applicable, as a deemed subsidy eligible.

Our recommendations for redeterminations of these beneficiaries are discussed below, in §423.774.

§423.773(d) Other subsidy eligible individuals.
The indexing of resources should indicate that rounding is always up to the next multiple of $10.

§423.774 Eligibility determinations, redeterminations, and applications.

§423.774(a) Determinations of whether an individual is a subsidy eligible individual.
This subsection provides that determinations of eligibility for the subsidy are to be made by state Medicaid agencies or by SSA, depending on where an individual applies. We believe that in order to ensure prompt enrollment in both the subsidy and ultimately in a plan, the regulations should specify that a determination notice must be sent to the applicant no later than 30 days after the application is filed. Because determinations for the low-income subsidy should be a simple process, very little time should be required to render a decision. Both SSA and states should be required to notify CMS with 24 hours of a individual being determined eligible for the subsidy.

§423.774(b) Effective date of initial eligibility determination.
In order to avoid delays in the ability of beneficiaries to use their subsidy benefits while their application is pending, the final rule should offer beneficiaries the option of applying through a presumptive eligibility system. Such a system would be especially helpful to beneficiaries who have enrolled in a Part D plan but are not yet receiving the low-income subsidy. Applicants can complete a short form at a provider's office or other location in which they declare their family size, income and assets. If their income and assets are below the relevant eligibility levels, they are found presumptively eligible. Applicants may still be required to complete a full application within a prescribed period of time (typically 30 to 60 days) if additional information is required. In the meantime, however, beneficiaries are given temporary cards that they can present to health care providers and receive services immediately. Experience has shown that the error rate for these enrollment systems is very low. In the rare cases where beneficiaries are later found ineligible, they and their providers are held harmless for the benefits they receive during the presumptive eligibility period.

Applicants for the low-income subsidy could be found presumptively eligible at state Medicaid offices, SSA offices, pharmacies, or other providers. If the low-income subsidy application form is simple enough, applicants could complete the form itself and self-attest to their income and assets. If they appear to be eligible, they would be enrolled in the appropriate subsidy while their application is processed. They would receive some form of temporary certification stating that they have been presumptively enrolled, which their pharmacy would accept while their application is processed. Such a system would encourage beneficiaries to apply, as they would be able to see the benefits of the system immediately.

§423.774(c) Redetermination and appeals of low-income subsidy eligibility.
There should be a provision for prompt reconsideration of a subsidy eligibility determination, for beneficiaries who believe they have either been erroneously denied eligibility or approved for the

wrong subsidy category. The provisions applying the appeal rules of state Medicaid plans or SSA do not provide for a prompt reconsideration process. Because obtaining prescription drugs is so vital, and especially because low-income beneficiaries are unable to pay the costs of their prescription drugs out of their own pockets, a quick reconsideration process is essential.

The draft regulation refers to redeterminations and appeals under the state Medicaid plan. This is inadequate, as frequent redeterminations in place in some states will cause some beneficiaries to drop out of the program. To maximize enrollment, the rule should establish that all determinations are for one year, per the Secretary's authority under the statute. We also urge CMS to adopt an annual, passive, and simple redetermination for all beneficiaries, whether they have enrolled through SSA or states. Should it be necessary, the Secretary should direct the Commissioner of SSA to create such a system. Under a passive redetermination system, beneficiaries would be sent a statement of the relevant information on file and asked to respond only if any of that information had changed over the year. If they do not respond, their coverage would continue unchanged for another year.

If states are not required to adopt passive redeterminations, we urge that redeterminations be made as they are under the state's MSP programs, or under the most passive, simplified redetermination process used for any category of coverage under the state plan.

§423.774(d), Application requirements.
This section should make clear to both states and SSA that no documents should be required of the individual as long as the applicant authorizes the agency to verify information from financial and other institutions. Documentation production should be only the absolute last resort.

Also, as we mentioned in our comments to §423.773 above, the proposed rule does not address eligibility determinations and recertification periods for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) state. Once beneficiaries become deemed subsidy eligible individuals by completing their spenddown, they should retain that status for a full year, until their next redetermination for the low-income subsidy, regardless of whether they go off Medicaid. Otherwise, individuals who go in and out of medically needy status, depending on the length of their state's budget period, will have extremely confusing changes regarding their Medicare low-income drug subsidy.

§423.800 Administration of Subsidy.

§423.800(a), Notification of eligibility for low-income subsidy.
We are concerned that there is no provision in §423.800(a) specifying a time period by which CMS must notify a plan that an enrollee is eligible for a subsidy. This is an essential step in the process, because without the subsidy, prohibitive costs will prevent low-income beneficiaries from using their Part D benefits. We propose that CMS be required to inform Part D plans of beneficiaries' enrollment in the subsidy no later than 24 hours after the application for the subsidy is approved. As this will likely be an electronic notification, it should not be burdensome. It is vital that plans know which beneficiaries are enrolled in the subsidy, so that these low-income beneficiaries do not have to pay the full cost of their prescriptions while their subsidy application is process.

§23.800(e), Reimbursement for cost sharing paid before notification of eligibility for low-income subsidy.
The draft reimbursement provisions are inadequate to protect low-income beneficiaries. The proposed regulation would require plans to reimburse low-income beneficiaries for excess copayment and premium amounts made after the effective date of the subsidy application. This is not a realistic solution to the problem facing beneficiaries who have prescription drug needs before their Part D plans are notified that the beneficiaries are subsidy-eligible and need to have their records adjusted accordingly. Low-income beneficiaries will not be able to afford to pay these costs out of their own pockets with the expectation of being reimbursed later. Instead, these beneficiaries will forego prescription drug coverage until their plan processes their subsidy, making the first month or more of their subsidy period meaningless.

Adoption of a presumptive eligibility system recommended above would alleviate this problem. As an additional alternative, the regulations should provide that beneficiaries may present their notice of approval for the subsidy to their pharmacy when they seek prescription drugs. Pharmacies should accept this notice as adequate to relieve the beneficiary from making a co-payment, and instead seek reimbursement for the beneficiary's plan.

Subpart S - Special Rules for States - Eligibility Determinations for Subsidies and General Payment Provisions

§423.904 Eligibility determinations for low-income subsidies.

§423.904(a) General Rule.
This subsection should cross reference the entire Subpart P, or, at a minimum the definitions included in §423.772.

§423.904(b) Notification to CMS.
The rule should direct states to notify CMS of eligibility determinations within 24 hours of making them, as we previously recommended with respect to SSA determinations.

§423.904(c) Screening for eligibility for Medicare cost-sharing and enrollment under the State plan.
The proposed regulation regarding states' obligations to screen subsidy applicants and offer them enrollment in Medicare Savings Programs ("MSPs") are inadequate. In particular, the regulation should specify what "offer enrollment" means. We believe an applicant must be offered the opportunity to enroll during the same visit or contact (in office, by phone, or by mail), without providing any further documentation or completing any additional forms. Only if enrollment is easy and convenient will Congress's intent of increasing participation in MSPs be accomplished. Furthermore, because under the current rules, enrollment in an MSP may be the only entry into the subsidy for some beneficiaries, a quick and easy application for MSP programs is essential. As written, the regulation would permit states to say they have "offered enrollment" simply if they tell applicants that they might be eligible for an MSP and may return another time to complete another application form if they wish to apply. Such an outcome would defeat the

purpose of the screen and enroll provision included in the new §1935(a)(3) established in §103(a) of the statute. Instead, as proposed in our comments to Subpart P, the low-income subsidy application should include an "opt-out" provision, under which qualified applicants would be enrolled in an MSP unless they affirmatively decline to do so. This provision would explain that enrollment in an MSP may be another way to qualify for the low-income subsidy.

As we explained in our comments to Subpart P, because enrollment in an MSP may affect receipt of other public benefits, there is a tremendous need for good quality counseling of beneficiaries. In addition, in order to ensure that enrollment requirements between MSPs and the low-income subsidy are aligned, states should not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective and can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP.

In the interest of further aligning eligibility rules for MSPs and the low-income subsidy and easing administrative burdens, we suggest that CMS direct states to apply the definitions of resources used in Subpart P, §423.772, in making their resource determinations for MSP applicants.

In addition, should CMS adopt a policy, as has been discussed publicly, under which most subsidy applications to state Medicaid agencies would be forwarded to SSA for the actual eligibility determination, the regulations should be clear that the screening for MSP eligibility must take place prior to the processing of the applications to SSA. Potential beneficiaries should not have to wait to be screened and offered enrollment in MSPs. Furthermore, an individual cannot be told, by either SSA or the state that she or he is ineligible for the low-income subsidy until MSP eligibility has been determined (if the individual wishes). It would be incredibly confusing for an individual to receive a notice from SSA that she is ineligible for a subsidy, have her MSP eligibility determined by the state, then receive a notice from the state that she is eligible for both MSP and the subsidy. Whatever the mechanics, the individual must be told that MSPs are a route to subsidy eligibility.

Finally, as we discussed in our comments to §423.773, SSA should also screen subsidy applicants for eligibility in MSPs as well, and develop a system with states to enroll eligible beneficiaries. Applicants should not miss out on the opportunity to enroll in MSPs because they apply through SSA rather than state Medicaid offices. The same concerns about beneficiary education and estate recovery discussed above apply to enrollment through SSA.

The regulations should also ensure that beneficiaries are screened for eligibility for full Medicaid and offered enrollment if they qualify, consistent with 42 C.F.R. §435.404. Ideally, all subsidy applicants would be screened for Medicaid, and offered enrollment if they qualify. Because the importance of maintaining a simple application process for the subsidy is paramount, CMS may wish to consider using a simple screening process based on information obtained through the subsidy application. This screening would trigger a follow-up with applicants who appear to be eligible for full Medicaid.

Many Medicare beneficiaries who are eligible for a low-income subsidy under the Part D Program will also be eligible for other important benefits. Some of these benefits, such as food stamps, are also administered by states and have eligibility rules that very closely correspond with the new eligibility rules for the Part D subsidies. Historically participation by seniors and people with disabilities in these programs has been low, despite the fact that the benefits that low-income Medicare beneficiaries would be able to receive could help them struggle less to make ends meet every month. The Part D enrollment process offers an historic opportunity to connect Medicare beneficiaries to these other programs.

Beyond saying that applications may be filed either with a State's Medicaid program or with SSA, the proposed rule has very little detail about how the application process is likely to work. We urge CMS to specify that the new eligibility process should dovetail with other programs so that low-income Medicare beneficiaries can be enrolled as seamlessly as possible in all the state- or SSA-administered benefits for which they qualify

423.904(d)(3)(ii), Cost-effectiveness of information verification.
This section should be modified to permit states to use the verification process established by the Social Security Administration to verify the income and assets of people who apply for a Part D subsidy through a state Medicaid agency.

PART 403-SPECIAL PROGRAMS AND PROJECTS

Subpart B-Medicare Supplemental Policies

Disclosure notices advising consumers of their statutory rights must be short, simple, easy to understand, and address as few issues as possible. The proposed disclosure notice concerning Medigap policies H, I, and J included in the Preamble is too long, provides unnecessary information, and includes information that may not be accurate for all beneficiaries. We suggest that the letter be modified as follows:

Delete the information about Medicare Part D at the beginning of the disclosure notice;
Delete statements about the value of Part D benefits, which are irrelevant to the issue of changes to Medigap;
Delete the second statement about the need to notify the Medigap issuer if a person later enrolls in Medicare Part D. This information is repetitive; and

Delete the information concerning enrollment issues about Medicare Part D which is unrelated to whether a Medigap policy provides creditable coverage.

In addition, we encourage CMS to develop a different notice for people who will have creditable coverage as their options will be different from those of people whose Medigap policies are not deemed to provided creditable coverage. The specific information this group of beneficiaries will need about their creditable coverage, and any required action, will vary depending on whether their coverage is employer sponsored retiree coverage, a Medigap Plan J, a pre-standard Medigap plan, or a Medigap with a rider or an innovative benefit.

The discussion in the Preamble to the Regulation beginning with Subpart T 4(c)(iii) references the difficulty of determining creditable coverage and the inability to even make that determination in advance of a final rule to implement Part D. We expect there will be confusion on this issue and that mistakes may be made by issuers in applying an actuarial test to groups of policies issued all over the country. We expect additional confusion due to the proposal to modify the definition of Medicare Supplement (Medigap) policies in §403.205 to include riders and freestanding benefits for prescription drugs. We are requesting two remedies for Medicare beneficiaries who are initially notified of creditable coverage when the coverage is no longer or never was creditable: a Special Enrollment Period in Part D and a guaranteed issue right to a Medigap policy without prescription drug benefits. We are also requesting the extension of the right to a guaranteed issue policy to Dual Eligibles who lose their eligibility to Medicaid benefits.

Thank you for the opportunity to submit comments on the proposed rule. We hope that this will not be the final opportunity to do so.

Very truly yours,

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September 30, 2004

http://www.cms.hhs.gov/regulations/ecomments

Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-4068

Dear Madam or Sir:

On behalf of the clients represented by the undersigned, we wish to submit the following comments on your proposed rule for the Medicare Prescription Drug Benefit. The Medicare Advocacy Project has over 15 years of experience advocating on behalf of Medicare beneficiaries, particularly those with low incomes; the Massachusetts Law Reform Institute is a statewide advocacy organization representing low income individuals, including elders and persons with disabilities; and the Disability Law Center (DLC) is a private, nonprofit protection and advocacy agency that provides free legal assistance to individuals with disabilities throughout Massachusetts. A key mandate of DLC is ensuring that people with disabilities are able to access needed supports to live and work in the community. Because of the limited time allowed and the magnitude of the proposed rule, we are not commenting on CMS-4069, dealing with Establishment of the Medicare Advantage Program. Neither are we commenting on all the sections of the proposed prescription drug rule. Rather, we are focusing on the impact of the rule on low income beneficiaries and persons with disabilities, particularly in the Eligibility and Enrollment and Grievances, Coverage Determination, and Appeals sections. In addition, we support and agree with the more detailed and comprehensive comments submitted on one or both of the proposed rules by the Medicare Consumers Working Group and the Center for Medicare Advocacy, Inc.

We also request that time be provided for another comment period due to the many unaddressed or only vaguely addressed issues. The final regulations could include a number of errors and provisions that result in unintended consequences because so much of the final regulations will not have been seen by the public. We urge CMS to issue the next version of these regulations in a format that will allow one more round of comment, even if a shortened comment period. This is a very complex program with significant ramifications for a large number of citizens. We are concerned that failure to provide for additional public input when the regulations are more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

PART 423-VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

General comments.

1. Many pro-consumer statements in the preamble do not appear in the proposed rule. These protections bear no weight unless captured in the regulations. More should be done to reflect the Preamble's good intentions in the body of the regulations. For example:

> The Preamble discusses providing affected enrollees, prescribers, pharmacists, and pharmacies with written notice when a drug will be removed from the formulary or moved to a different tier for cost-sharing. The regulatory language does not specify that the notice should be in writing. Requirement for written notice is critical and should be specified.
>
> The Preamble gives examples of situations when a plan will be required to allow an enrollee to use a non-network pharmacy. These include situations such as when an enrollee's plan does not contract with the long-term care pharmacy which an enrollee in a nursing home must use. The regulations should include the examples CMS discusses in the preamble.

2. There are a number of areas where the law is unclear or contradictory and these areas are creating serious problems for the regulation drafters. CMS should take advantage of the law's provision calling for the submission of technical and corrective amendments. While this was supposed to have been done by June 8, 2004, it should still be done, and Congress should address these issues as soon as possible.

3. Simplicity, as well as additional support for information and counseling, is necessary to ensure that beneficiaries are reached in a comprehensible way. The sheer size and complexity of these regulations is a testament to the fact that this new law is incredibly confusing. If beneficiaries are confused, enrollment and use of the new program will be very difficult, particularly for lower income, sicker, and limited English proficiency beneficiaries. Thus whenever it is possible, CMS should seek to simplify the new program.

Addressing some of our specific concerns:

Subpart B-Eligibility and Enrollment

1. The draft regulations addressing enrollment of beneficiaries into private drug plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDPs) do not adequately address the need for hands-on outreach, particularly to low-income beneficiaries, or to beneficiaries with special needs, such as mental illness. More attention must be given to developing materials and education and enrollment campaigns focused on informing beneficiaries with disabilities, including mental illness and cognitive impairments, and those with other special needs about the new drug benefit and helping them to enroll in the best plan available.

2. Of particular concern, is enrollment of the dual eligibles. Beneficiaries covered by both Medicare and Medicaid are by definition poor and cannot afford to pay privately fo fill any gaps in medication. Congress and the Administration promised that dual eligible beneficiaries would be better off with this new Part D drug benefit than they were receiving drug coverage through Medicaid. To honor this promise, coverage of medications for dual eligibles and other special populations must be grandfathered into the new Part D benefit. In addition, CMS must require plans to establish an alternative flexible formulary for dual eligibles as suggested in the preamble to the proposed regulations. This flexible formulary would incorporate utilization management techniques that focus on improving inefficient and ineffective provider prescribing practices but

do not restrict access to medications through prior authorization, fail first, step therapy, or therapeutic substitution requirements.

3. The regulations do not adequately address how drug coverage for the dual eligibles will be transferred to Medicare on January 1, 2006. There are issues both of timing and implementing the enrollment process in a way that will ensure that these beneficiaries do not confront a loss of benefits or a gap in drug coverage, either of which could have disastrous health consequences. Specific comments on enrollment of dual eligibles and our recommendations appear in our comments on §§423.34, 423.36, 423.48 and on Subpart P.

A. We are concerned with ensuring continuity of care for dual eligibles and access to needed prescriptions. These issues and concerns apply equally to all dual eligibles, and particularly to those with special health care needs, as well as to other populations with specific needs (See our comments in Subpart C, §423.120.)

B. The proposed regulations would force dual eligibles to enroll (or be automatically enrolled) in the "benchmark" or average cost plans in their areas because the low-income subsidy they will receive will only cover the premium for these plans. The formularies for these plans will not be as comprehensive as the drug coverage these individuals currently have through Medicaid. Even though Massachusetts has restricted access to drugs in its Medicaid program with preferred drug lists and prior authorization requirements, Massachusetts has taken many steps to ensure that special populations can readily access medically necessary drugs. For example, individuals who have been stabilized on one antidepressant are not required to try another one.

C. Without access to the coverage they need, dual eligibles will be forced to switch medications, which for certain populations, such as beneficiaries with HIV/AIDS or mental illness can have serious adverse consequences. Also, failing to ensure continuity of care for dual eligibles may benefit the plans, but will undoubtedly lead to Medicare and/or state increased costs for more physician and emergency room visits, and hospitalizations. The regulations do provide a special enrollment period for dual eligibles to use "at any time" (§423.36). However, being able to enroll in a different Part D plan is inadequate to meet the special needs of dual eligibles.

D. In the preamble to the proposed regulations, CMS points to an exceptions process as a means of securing coverage of off-formulary medications (See our comments to **Subpart M-Grievances, Coverage Determination and Appeals**) But the process proposed is extremely complex and cumbersome to navigate for someone having a psychiatric crisis, facing cognitive impairments, or in the midst of aggressive chemotherapy-to list just a few examples. Moreover, the timelines established are inordinately drawn out; for example, an expedited determination could take as long as two weeks. Drug plans are not required to provide an

emergency supply of medications until at least two weeks following a request. Exception, grievance and appeal processes should not be used to substituted for open formulary access to medications.

§423.34 Enrollment Process.

§423.34 (b) Enrollment.
The final rule should provide that an authorized representative may complete the enrollment form on behalf of a Part D eligible individual.

§423.34(c), Notice Requirement.
The notice must be in writing and inform an individual who is denied enrollment of his or her appeal rights, including the right to appeal the imposition of a penalty for late enrollment.

§423.34(d) Enrollment requirement for full benefit dual eligibles.
In the Preamble, CMS requested comments on whether CMS or the states should perform automatic enrollment of dual eligibles. State officials have more readily available data identifying the dual eligibles in their state and they also will be involved in the enrollment process because they are already required to perform low-income subsidy enrollment. In addition, there is an incentive for them to enroll these individuals in Medicare drug plans because without drug coverage they will increase utilization of other Medicaid services. Thus, states should be afforded the ability to conduct auto-enrollment and receive full federal financing for this function. In addition, CMS should develop its own systems for automatic enrollment of dual eligibles in states that do not elect to do so. Also, because the proposed rule leaves unanswered key questions about who will conduct automatic enrollment of dual eligibles and how it will occur, CMS must give the public the opportunity to provide input on any proposal it develops on this issue before publishing a final regulation.

§423.34(d)(1) General Rule.
The draft regulations provide that dual eligibles will be automatically enrolled in a Part D plan if they do not enroll themselves, by the end of the initial enrollment period, which, under §423.36, is May 15, 2006. However, their Medicaid prescriptions drug coverage will end on January 1, 2006. This proposed timeline for automatic enrollment must be changed because it could expose millions of dual eligibles to a four and half month coverage gap that could have serious health consequences for this vulnerable population. Given the difficulty of reaching this population coupled with inadequate provisions for outreach and education, it is almost certain that a substantial number of dual eligibles will face a several month gap in coverage between the end of Medicaid's drug benefit and automatic enrollment. This is untenable, and directly in conflict with Congress' and the Administration's promise that dual eligibles will be better off under Medicare Part D. The transfer of drug coverage from Medicaid to Medicare Part D should be delayed. Absent a delayed transition date for dual eligible drug coverage, however, dual eligibles should be randomly assigned and enrolled in a plan that best suits their needs as early as November 15, 2005 but no later than December 1, 2005. While we would prefer to provide individuals an extended period to make informed choices, it is critical to complete auto-enrollment as early as possible to leave as much time as possible to distribute plan information

and cards to beneficiaries, allow them to switch plans, and educate them about their new drug coverage before January 1, 2006. To make this process work more smoothly, states can begin profiling individual drug histories to prepare for random auto-assignment among plans that are appropriate for the individual even before plan information is released on October 15, 2005. Additionally, CMS should fund a campaign of individualized counseling and assistance both before and after auto-enrollment to explain to individuals their choices and how to enroll in a plan; explain, if applicable, how to get benefits under the plan to which they have been auto-assigned; and explain, if applicable, that they can choose a different plan from the one to which they have been auto-assigned and assist in choosing and enrolling in such a plan.

§423.34(d)(1)(ii)
CMS must develop a solution to the issue of automatic enrollment of dual eligibles who are enrolled in MA plans that have a prescription drug benefit with a premium that is above the low-income benchmark. The solution should be the one least disruptive to medical care and should not force a dual eligible to choose among continued MA enrollment, paying added premiums, or foregoing drug coverage. For institutionalized dual eligibles, the difference between the premium and the premium subsidy should be considered an incurred medical expense and deducted from their monthly "patient paid amount" to the facility. For non-institutionalized dual eligibles, in states with pharmacy assistance programs (SPAPs) which will wrap around Part D coverage and will cover dual eligibles, the SPAPs should be authorized to pay the difference. For medically needy individuals, the cost differential would be an incurred medical expense contributing toward their spenddown, if appropriate. Otherwise, individuals should be counseled about the premium discrepancy and about their right to withdraw from the MA plan and return to original Medicare. Ideally, dual eligibles who want to remain in the MA plan should be allowed to do so and not have to pay any amount by which the MA-PD basic premium exceeds the low-income benchmark amount.

§423.34(d)(2), When there is more than one PDP in a PDP region.
Because not every PDP plan may be appropriate for each dual eligible (for example, due to formulary restrictions), CMS should limit "on a random basis" to "among such plans in the region that meet the beneficiary's particular drug needs." Also, this subsection undermines the §423.859 right of assured access to a choice of at least two qualifying plans, by acknowledging that there may be regions where there is only one PDP in a PDP region with a monthly beneficiary premium at or below the premium subsidy amount.

§423.36 Enrollment Periods.

§423.36(a)(3)(ii) Exception.
It is not clear who these beneficiaries would be.

§423.36(c) Special Enrollment Periods.
This section should be expanded to provide "special enrollment exceptions" for individuals disenrolled by a PDP (such as for disruptive behavior) so that the individual will have an opportunity to join another PDP and continue with necessary medications. These "special enrollment exceptions" are necessary given the high risk of discrimination presented by the

provisions for involuntary disenrollment. CMS should provide a special enrollment period for these beneficiaries. It should include a reasonable time period for plan selection and be exempt from late enrollment penalties. It should also be expanded to make clear that involuntary loss of creditable prescription drug coverage includes loss because the beneficiary, or beneficiary's spouse, stops working; because COBRA coverage ends or because the premiums became unaffordable.

§423.36(c)(4) Special Enrollment Periods and Dual Eligibles.
We support granting dual eligibles special enrollment periods. However, this provision does not adequately address their needs. It is unlikely that there will be much choice of low-cost drug plans in each region, particularly in rural areas which have not historically attracted many Medicare+Choice plans. For example parts of Cape Cod and Western Massachusetts have no Medicare+Choice plans. In addition, these individuals will not have the resources to pay for more comprehensive coverage. Moreover, the special enrollment provisions do not specify that dual eligibles would not be subject to a late enrollment fee if this complex process of disenrollment and reenrollment resulted in a gap in coverage of over 63 days.

In addition, full benefit dual eligibles should receive notice explaining their right to a special enrollment period when they enroll in a plan, and every time their PDP changes its plan in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

§423.36(c)(8)
The regulations should include a special enrollment period similar to the one for dual eligibles for all beneficiaries eligible for a full or partial-low income subsidy. This is necessary because if coverage for a drug is denied, these low-income beneficiaries will be unable to afford to pay for drugs during a period of appeal, or if their appeal is denied and they are locked into a plan that does not cover a drug they need.

Special enrollment periods should also be provided for all institutionalized individuals, not just institutionalized dual eligibles, since their access to needed drugs may be compromised by the design of the plans and by pharmacy access requirements, such as if their long-term care pharmacy is not required to be included in the network of all PDPs. Individuals with life-threatening situations and individuals whose situations are pharmacologically complex should have the same rights as well.

§423.38 Effective Dates.

§423.38(c) Special Enrollment Periods.
Effective date should be first day of first calendar month following special enrollment in which individual is eligible for Part D.

§423.42 Coordination of enrollment and disenrollment through PDPs

§423.42(c)(2)
Notice of disenrollment should be in writing.

§423.44 Disenrollment by the PDP.

§423.44(b)(2)(I)
CMS requested comments about the requirement to involuntarily disenroll individuals from a PDP if they no longer reside in the service area. This raises the issue of "snowbirds"-the large number of Medicare beneficiaries who move for large parts of the year. This is a problem in Massachusetts where many elders winter in warmer climates. The churning-the enrolling and disenrolling-that plans serving this population will face as they apply this section will be enormous. Because of different formularies between plans and problems of coordination, the regulations should seek to minimize plan changes and maintain continuity of care. This section, as written, could result in a significant number of plan changes, disrupting continuity of care.

Some suggested ways to address this issue better would be to require that plans as a condition of participation have a system of visitor or traveler benefits, consider exempting regional PDPs and PDPs with out-of-network services from the disenrollment requirement, require plans to provide prospective enrollees specific information on traveler benefits and "out-of-plan service policies" and clearly define the time period that a plan could consider an enrollee as "no longer resid(ing) in the PDP's service area." such that it accommodates seasonal travelers who maintain a residence in the service area.. In many cases, 90 day mail order service and arrangements with other plans will make enrolling and disenrolling unnecessary. However, beneficiaries must have a clear understanding of how a plan will serve them while temporarily out of the service area; how when they are traveling and need emergency pharmaceutical services their plan will (or will not) reimburse for those services.

§423.44(d)(2)
Provisions in the proposed regulations to allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" create enormous opportunities for discrimination against individuals with mental illnesses, Alzheimer's, and other cognitive conditions. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and accordingly be subject to a late enrollment penalty permanently increasing their premiums. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage. Moreover, CMS lacks statutory authority to authorize PDPs to involuntarily disenroll beneficiaries. Under the MMA, section 1860D-1(b) directs the Secretary to establish a disenrollment process for PDPs using rules similar to a specific list of rules for the Medicare Advantage program. This list does not include reference to section 1851(g)(3)(B) of the Social Security Act which authorizes MA plans to disenroll beneficiaries for disruptive behavior. Thus, these proposed regulations must not be included in the final rule.

Concerns with specific provisions in this section and recommendations for beneficiary protections, which, at a minimum should be provided, are as follows:

§423.44(d)(2)(vi) Reenrollment in the PDP.
In the preamble, CMS appears to be asking for comments on whether a PDP should be allowed to refuse reenrollment of an individual who has been involuntarily disenrolled if there is no other drug plan in the area. As discussed above, it is our position that there is no statutory basis for involuntarily disenrollment. If the regulations allow this for disruptive behavior, then the plans must be required to allow reenrollment. Those individuals most likely to be subject to involuntary disenrollment will not have the resources to pay for their medications out-of-pocket. These individuals are entitled to this benefit. Disruptive behavior does not disqualify you from access to prescription drug coverage and may in fact be an indication that one is in need of medical assistance. Individuals who are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period and may therefore be subject to a late penalty and increased premium as a result. This result is unfair in light of the fact that the disruptive behavior may have resulted from denial of access to needed medications. CMS should therefore provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior, must waive the late enrollment penalty for these individuals, and the regulations must include detailed articulated protections to lessen the risks inherent in authorizing sanctions for "disruptive behavior."

§423.44(d)(2)(vii) Expedited Process.
This provision should be deleted from the final rule. The proposal to establish an expedited disenrollment process in cases where an individual's disruptive or threatening behavior has caused harm to others or prevented the plan from providing services is undefined, and provides no standards, requirements or safeguards. It allows plans to employ this mechanism on the basis of behaviors described in the broadest of terms - terms which could easily be mis-applied or applied capriciously or punitively. Thus, it would undermine all the minimal protections that would otherwise apply.

§423.46 Late enrollment penalty.
CMS should delay implementation of this section for two years. The drug benefit is a new and complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. The Medicare-endorsed prescription drug discount card program has shown that, even with significant outreach, the majority of individuals eligible for the $600 low-income subsidy have not yet enrolled. We disagree that healthy beneficiaries will not apply. We believe that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness and cognitive disabilities. Implementation of the late enrollment penalty should be delayed for individuals eligible for the low-income subsidy who may not understand that they have to apply separately for the subsidy and a drug plan, thinking that application for the subsidy is sufficient.

This section should provide that when the late enrollment penalties are implemented, there will be an opportunity for enrollees to appeal late enrollment penalties; that late enrollment penalties will be coordinated with "special enrollment periods" to ensure that individuals who take advantage of the special enrollment periods do not face late penalties; that individuals who are involuntarily disenrolled are exempt from this penalty; and that if an employer or other entity

providing drug coverage to Medicare beneficiaries fails to provide adequate or correct notice of the creditable status of that coverage or a change in status of that coverage, and that coverage is not creditable, there are no late enrollment penalties.

§423.48 Information about Part D.
Medicare beneficiaries can only exercise an informed choice about their drug plan if they have adequate information about drug plan options available to them. The information should be provided annually, in writing, and include details about the plan benefit structure, cost-sharing and tiers, formulary, pharmacy network, and appeals and exception process. In order to assure that beneficiaries have the required information, the standards should be included in regulations that are binding and enforceable, and not in guidance. Minimally, the regulations should require plans to provide premium information, including whether individuals who receive the low-income subsidy will have to pay a part of the premium and, if so, the amount they will have to pay; the benefits structure and comparative value of the plans available to them; the coinsurance or copayment amounts they will need to pay for each covered Part D drug on the formulary; the specific negotiated drug prices upon which coinsurance calculations will be based and that will be available to beneficiaries if they confront the gap in coverage; formulary structure, the actual drugs on the formulary, and how the formulary can change during the plan year; participating pharmacies, mail order options, out-of-service options; and exception, appeals and grievance processes. Plans should be required to provide this information to potential enrollees in a clear manner using a standard format that will allow beneficiaries to easily compare plans. Plans should be required to provide information on negotiated prices in an easily accessible format.

The regulations should also include specific requirements for plans and states, as well as outline activities CMS will undertake, to ensure that every effort will be made to reach dual eligibles. By summer 2005 CMS and the states should launch a concerted outreach and assistance campaign for dual eligibles to alert them about the need to enroll in a Part D plan and to help them make appropriate choices. The outreach campaign would be intended to prevent default enrollment. In addition, as early as possible, and no later than October15, 2005 (assuming information is available), CMS or the states should mail standardized, easy-to-understand notices to dual eligibles that, among other things: inform them of their eligibility to receive the low income drug benefit if they enroll in a PDP or MA-PD; list choices of health plans (clearly denoting those that meet the benefit premium assistance limit) and contact information for each plan; explain that individuals will be randomly enrolled in a prescription drug plan beginning November 15 (or, if different, the appropriate date) if they fail to opt out or enroll in a plan themselves; explain how they may change their drug plans if they wish at any time; and inform them of where in their community they can go to get help with enrollment. These notices should be tested for readability by focus groups and experts. If the states are required to provide this information, CMS should reimburse 100 percent of the states' costs.

§423.50 Approval of marketing material and enrollment forms.
The marketing rules for the PDPs and MA-PDPs should be developed in the historical context of other Medicare programs. From selective marketing to outright fraud, Medicare programs historically have been afflicted with marketing abuses and scams. We urge that CMS be vigilant to identify and prohibit these problematic areas and practices as it develops final regulations.

§423.50 (e) Standards for PDP marketing.
Telemarketing should expressly be prohibited. Door-to-door solicitation is prohibited under this section and telemarketing presents many of the same dangers. The regulations should specifically prohibit prescription drug plans from initiating telephone or e-mail contact with potential enrollees, unless the potential enrollee requests contact through such means in response to a direct mail or other advertisement.

In the Preamble, CMS asked for comments on whether it would be advisable to permit prescription drug plan sponsors to market and provide additional products (such as financial services, long term care insurance, credit cards) in conjunction with Medicare prescription drug plan services. CMS should not allow plans to market other services, nor should it seek to encourage other entities, such as financial institutions, to participate as PDPs. The potential for abuse—both cherry picking of healthier beneficiaries into plans and avoidance of financial services to less healthy individuals—is enormous. CMS also asked for comments on the applicability of MA marketing requirements for PDP marketing. PDP marketing requirements should be at least as restrictive as MA marketing because of the high potential both for confusion and for individuals to be directed to—and locked-into—plans that do not best meet their needs. Beneficiaries look to providers for balanced, unbiased information, and they should be able to rely on the information that these sources provide. However, if providers or pharmacies are allowed to market plans, there is the potential for aggressive marketing of certain PDPs, regardless of whether or not that PDP is the best for the beneficiary. The adverse consequences of making a bad selection based on promotion from a trusted source are high.

§423.56 Procedures to determine and document creditable status of prescription drug coverage.

§423.56 (e) Notification.
It is essential that beneficiaries understand whether they have creditable coverage. Failure to understand the issue of creditable coverage can lead to a lifetime of higher Part D premiums. CMS must set forth specific requirements that plans provide information to Medicare beneficiaries enrolled in those plans clearly stating whether or not the coverage they have is creditable. Minimally, in 2005, information on whether coverage is creditable or not should be provided in more than one mailing, and included in such documents as quarterly retiree income statements, medical billing correspondence, etc. After 2005, CMS should develop standard notices, through its Beneficiary Notice Initiative, to be used. In years after 2006, when creditable status changes, special notification is needed to insure that beneficiaries know as soon as the decision is made to reduce coverage, so they can begin shopping for a PDP and avoid a lifetime of premium penalties. Because this is such important notification, it should be sent by registered mail, or e-mail with proof of receipt. Additionally where beneficiaries are not adequately informed by an employer or other entity that their coverage is not creditable, CMS should take action on behalf of all the individuals of that employer or other entity to provide a special enrollment period (SEP). Each individual adversely impacted by the failure of the employer or other entity to inform adequately should not have to apply or appeal for a SEP.

Subpart C-Benefits and Beneficiary Protections

§423.100 Definitions.
"Dispensing fee" should be broadly framed, in order to permit the payment of costs associated with home infusion therapy. Of the options provided in the preamble to the proposed rule, we support option 3. We do not believe that a narrowly crafted definition of dispensing fee is appropriate because the conference report at § 1860D-2(d)(1)(B) references negotiated prices in a manner that indicates that Congress intends to define negotiated prices in a way that arrives at the most accurate prices when considering a variety of both concessions and fees. Since the antibiotics, chemotherapy, pain management, parenteral nutrition and immune globulin and other drugs that are administered through home infusion are indisputably covered Part D drugs, and equipment, supplies and services are integral to the administration of home infusion therapies, costs associated with such administration should be included in the definition of dispensing fee, in order to arrive at the most accurate determination of the negotiated price. Option 1 makes an arbitrary and inappropriate distinction between costs associated with dispensing a covered Part D drug and associated costs for the delivery and administration of a covered Part D drug, and option 2 does not capture all the true costs associated with dispensing a covered Part D drug.

"Long-term care facility" should explicitly include ICF/MRs and assisted living facilities.
We recommend that the final rule include a definition of "long-term care facility" that explicitly includes intermediate care facilities for persons with mental retardation and related conditions (ICF/MRs) and assisted living facilities. This is important because many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

§423.104 Requirements related to qualified prescription drug coverage.
The final rule defines "person" so that family members can pay for covered Part D cost-sharing. The law precludes contributions from employer sponsored health plans from being counted as incurred costs and counting toward the deductible or out of pocket limit. Contributions from one employer-sponsored benefit should not receive differential treatment over contributions from another type of employer-sponsored benefit. Contributions from employer-sponsored group health coverage should be counted as an incurred cost, similar to contributions from HSAs, HRAs, and FSAs. The final rule should also count cost-sharing subsidies from AIDS Drug Assistance Programs (ADAPs) as incurred costs. The regulations also specifically state that state-appropriated dollars spent by ADAPs cannot be counted as incurred costs. It is discriminatory and unacceptable to single out state dollars used to provide medications to people living with HIV/AIDS and not allow them to count as incurred costs, while at the same time allowing state dollars paid by State Pharmaceutical Assistance Programs' (SPAPs)to count as incurred costs.

§423.104(e)(2)(ii) Establishing limits on tiered copayments.
The final rule should not allow Part D plans to apply tiered co-payments without limits. Rather, it must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs.

§423.104(h) Negotiated prices.(1) Access to negotiated prices.
No plan should be allowed to impose 100% cost-sharing for any drug. Such cost-sharing should be considered as per se discrimination against the group or groups of individuals who require that prescription.

§423.120 Access to covered Part D drugs.

§423.120(a) Assuring Pharmacy Access.
Pharmacy access standards must be met in each local service area, rather than by permitting plans to apply them across a multi-region or national service area. Permitting plans to meet the access standards across more than one local service area could cause individuals in some local service areas to not have convenient access to a local pharmacy. Also, only retail pharmacies should be counted for the purpose of meeting pharmacy access standards. It would undermine the principle that Medicare beneficiaries will have convenient access to a local pharmacy if the access standards could be met by counting pharmacies that serve only specific populations and which are not available to all parts of the general public. The final rule should require prescription drug plans to offer to contract with Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (I/T/U) pharmacies and make available a standard contract. Should the final rule not contain this requirement and in situations where an I/T/U pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy. The final rule should also require prescription drug plans to offer to contract with all LTC pharmacies and make available a standard contract. Over 80% of nursing home beds are in facilities that require the resident to use a long-term care pharmacy. Should the final rule not contain this requirement and in situations where a LTC pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy. Furthermore, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through higher cost-sharing for out-of-network access.

§1860D-11(e)(2)(D) authority to review plan designs to ensure that they do not substantially discourage enrollment by certain Part D eligible individuals.
CMS should use the authority provided under section 1860D-11(e)(2)(D) to review plan designs, as part of the bid negotiation process, to ensure that they are not likely to substantially discourage enrollment by certain Part D eligible individuals. Previous experience with Medicare+Choice plans shows that private insurers use a variety of techniques to discourage both initial and continued enrollment in a plan by enrollees with more costly health care needs. For example, Medicare+Choice plans have offset reduced cost-sharing for doctors visits with increased cost sharing for services such as skilled nursing facility care, home health care, hospital coinsurance, and cost sharing for covered chemotherapy drugs that are utilized by people with chronic and acute care needs. CMS should thus analyze formularies, cost-sharing tiers and cost-sharing levels, and how cost-sharing (including both tiers and levels) is applied to assure that people with the most costly prescriptions are not required to pay a greater percentage of the cost of those drugs. CMS also needs to assure that a variety of drugs are included in a

formulary at the preferred cost-sharing tier to treat chronic conditions and conditions that require more costly treatments. As stated above, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through higher cost-sharing for out-of-network access.

§423.120(a)(6) Level playing field between mail-order and network pharmacies.
The final rule should ensure that beneficiary out-of-pocket costs used for the purchase of covered Part D drugs count as incurred costs. A key principle of the MMA is that Medicare beneficiaries have convenient access to a local pharmacy. This principle is undermined by permitting plans to charge beneficiaries the cost differential for receiving an extended supply of a covered Part D drug through a network retail pharmacy versus a network mail-order pharmacy. However, notwithstanding this objection, the final rule should permit the cost differential charged to beneficiaries to count as an incurred cost.

§423.120(b) Formulary requirements.
We do not believe it is appropriate for the final rule to constrain prescribers' capacity to prescribe drugs for off-label uses. By not permitting a class to exist in the USP model guidelines solely because all commonly used medications are being used for off-label indications could lead plans to deny coverage for off-label uses. Off-label prescribing has become a common-and accepted-practice across the field of medicine. For example no drugs that are currently used in the treatment of lupus (a serious, life-threatening auto-immune disorder) have the treatment of lupus as an on-label indication. For the treatment of mania, certain anti-convulsants and calcium channel blockers have proven effective and certain anti-convulsants have proven effective for treatment of bipolar disorder, although these uses are not FDA-approved on-label indications. We thus oppose any provisions in the final rule that place new limits on the ability of prescribers to prescribe drugs for off-label uses-or that legitimize the denial of coverage for covered Part D drugs simply because they are used for an off-label indication.
We support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must be protected from tiered cost-sharing that could to these defined populations must be made available at the preferred level of cost-sharing for each drug. We recommend that this treatment apply to at least the following overlapping special populations: dual eligibles, institutionalized populations, persons with life-threatening conditions, and persons with pharmacologically complex conditions.

We recommend that if the final rule limits the notice requirements to persons directly affected by the change, then plans must be required to provide notice in writing, mailed directly to beneficiary, 90 days prior to the change, and the notice must inform the beneficiary of their right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary. We also recommend that the final rule place strict limits on mid-year formulary changes, requiring plans to justify a decision to remove drugs from a formulary such as the availability of new clinical evidence indicating that a particular covered Part D drug is unsafe or contraindicated for a specific use or when all manufacturers discontinue supplying a particular

covered Part D drug in the United States. Should the final rule fail to effect such a restriction, plans should be required to continue dispensing all discontinued drugs until the end of the plan year for all persons currently taking a discontinued drug as part of an ongoing treatment regimen.

§423.124 Special rules for access to covered Part D drugs at out of network pharmacies.
The final rule must establish requirements on plans to dispense a temporary supply of a drug (wherever a prescription is presented, irrespective of whether or not it is at a network pharmacy) in cases of emergency. If the emergency situation involves a coverage dispute, the plan must dispense refills until such time as the prescription expires or the coverage dispute is resolved, through either a plan decision to provide coverage for the drug or through completion of the appeal process. This requirement must also specify that a temporary supply must be dispensed even in cases where beneficiaries are unable to pay applicable cost-sharing.

The final rule should also limit out-of-network cost-sharing to no more than the difference between the maximum price charged to any in-network Part D plan in which the pharmacy participates and the in-network price. While we recommend that this limitation apply in all circumstances, at a minimum, it must be applied through the final rule, to the scenarios described in the preamble to the proposed rule.

§423.128 Dissemination of plan information.

§423.128 (d) Provision of specific information.
It is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center. The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program.

§423.128(e) Claims Information.
In addition to the required explanation of benefits elements in the proposed regulation, the explanation of benefits should also include information about relevant requirements for accessing the exceptions, grievance and appeals processes.

Subpart J-Coordination Under Part D With Other Prescription Drug Coverage

§423.464(e) Coordination with State Pharmaceutical Assistance Programs (SPAPs).

SPAPs and new SPAPs must be able to help beneficiaries 'fill in the donut,' and we appreciate CMS's efforts to coordinate this assistance. To assure that beneficiaries are receiving seamless coverage and not facing undue out of pocket expenses, an exchange of data between the PDP and the SPAP is necessary. This should include (but not be limited to) an exchange of eligibility files, exchange of claims payment and information about the drugs on the PDPs formulary and any changes to it. Also, AIDS Drug Assistance Programs (ADAPs) should be recognized as

State Pharmacy Assistance Programs and allowed to wrap around the Medicare Part D drug benefit.

Subpart M-Grievances, Coverage Determination, and Appeals

The proposed regulations fail to meet the requirements of the Due Process Clause of the Fifth Amendment to the United States Constitution. As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid recipients whose prescription requests are not being honored currently receive a 72-hour supply of medications pending the initial coverage request. They are entitled to notice, face-to-face hearings, and aid paid pending an appeal if their request is denied and they file their appeal within a specified time frame. All state Medicaid appeals processes are completed more expeditiously than Medicare appeals. The appeals process as described in Subpart M does not accord dual eligibles and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity for a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes. While we recognize that the most efficient means of protecting enrollees, amending MMA to provide for an appeals process similar to Medicaid, is beyond the authority of CMS, CMS can take steps in the final regulations to improve notice and the opportunity for speedy review.

Sections 1860D-4(f), (g), and (h) require that Part D plan sponsors establish grievance, coverage determination and reconsideration, and appeals processes in accordance with Sections 1852(f), (g) of the Social Security Act. As will be discussed in more detail below, CMS has failed to comply with the language of those provisions. Overall, the incredibly onerous exceptions process does not comply with the statutory requirements or meet the basic elements of due process. In addition, CMS, in implementing Section 1852(c) and in settlement of *Grijalva v. Shalala*, 153 F.3d 1115 (9th Cir, 1998), *vacated and remanded*, 526 U.S. 1096 (1999), adopted 42 C.F.R. §422.626, which establishes the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review for Part D. CMS needs to incorporate a similar process for Part D in order to establish a process in accordance with Section 1852(c). A similar fast-track process would also be more in keeping with due process requirements.

As a general comment, this entire subpart needs to be made much simpler. To have two tracks, depending on (1) whether one personally pays for a drug and files an appeal or (2) does not obtain the drug and files an appeal, is far too complicated. The time frames, paperwork, and processes should be simplified into one course of action that beneficiaries may hope to understand.

§423.560 Definitions.

This section defines "appeal" to exclude grievance and exceptions processes, and defines “authorized representative” as an individual authorized by an enrollee to deal with appeals. The definition of “authorized representative” needs to clarify that a doctor or representative, including a State Prescription Drug Plan (since the SPAP may be at risk in the event of PDP

actions) can be an authorized representative, and that authorized representatives can deal with exceptions and grievances as well as appeals.

§423.562 General provisions.

§423.562(b)(5)(iii)

Reconsideration by an Independent Review Entity (IRE) should be automatic, as in the Medicare+Choice plans

§423.562(c)(1)

This subsection precludes an enrollee who has no further liability to pay for prescription drugs from appealing. However, it is important to be able to appeal formulary changes. A comprehensive change in this limitation is essential to protect the health of beneficiaries. At a minimum, SPAPs should be able to appeal on behalf of an enrollee and the section should clarify that a low-income institutionalized individual can appeal a determination, even if she has no co-payment responsibilities.

§423.566 Coverage determinations.

§423.566(b) Actions that are coverage determinations.

This subsection needs to clarify further what constitutes a coverage determination. The proposed definition does not include in the list of coverage determinations from which an appeal can be taken a determination by the PDP that a drug is not a covered drug under Part D. An enrollee should be entitled to appeal to determine whether, in fact, a drug the plan claims is not covered under Part D is so covered. The definition should also clarify that denials of enrollment in a Part D plan, involuntary disenrollment from a Part D plan, and the imposition of a late enrollment penalty are coverage determinations subject to the appeals process. Finally, the regulation should state that the presentation of a prescription to the pharmacy constitutes a coverage determination. If the pharmacy does not dispense the prescription, then the request for coverage should be deemed denied, and the enrollee should be entitled to notice and to request a re-determination. Without such clarification, enrollees will not be informed of their rights, and the appeals process will become meaningless.

§423.568, Standard timeframes and notice requirements for coverage determinations.

§423.568(a) Timeframe for requests for drug benefits.

The plan should be required to provide oral notice as soon as it determines that it will extend the deadline for considering whether it will cover a drug, including notice of the right to request an expedited grievance. The oral notice should be followed-up in writing.

§423.568(b) Timeframe for requests for payment.

This section should be eliminated. There should be no distinction in time frames when an enrollee requests payment.

§423.568(c), Written notice for PDP sponsor denials.

Who gives notice? The proposed regulations place the responsibility for providing notice of a coverage determination on the plan sponsor. This presumes a situation in which the person presents a prescription, the pharmacy contacts the plan, and then the plan takes 14 days to decide whether or not to cover a drug. In reality, the pharmacy, in most instances, tells the enrollee that the plan will not cover the drug. Without notice provided by the pharmacy, most enrollees will not know to tell the pharmacy to submit the prescription anyway so they can get a notice from which to appeal. They also may not know or understand their right to seek expedited consideration of the initial coverage determination, or an exception if the drug is not on the formulary or on too high a tier. If the enrollee pays out of pocket and then seeks reimbursement from the plan, she will not be eligible for expedited consideration.

The regulations should require the plan sponsor to develop a notice explaining the right to seek a redetermination, and to ask for expedited review. The pharmacy should be required to give the notice to the enrollee. Any potential burden of such a requirement is reduced by the need to maintain electronic communications between the pharmacies and the plans in order to keep up-to-date with formularies, coinsurance, and calculations of an enrollee's out-of-pocket expenses.

The proposed regulations talk about using "approved notice language in a readable and understandable form." The regulations need to be more specific, including information about what is required to use the exceptions process. We suggest that notice should

Include information about exceptions and appeal rights immediately upon denial (including upon determination that a drug is not covered on formulary and including denials issued by the pharmacist), explain why coverage was denied and provide options in addition to the appeal procedures for obtaining necessary medications;

Include clinical or scientific basis for denial; and

Be available in multiple languages and note the availability of language services.

In addition, all notices need to be available in alternate formats to accommodate people with disabilities, and in languages other than English where a portion of the population is not English speaking. The requirements of plans and the rights of beneficiaries in this area must be spelled out in much more detail. There is also an overarching need to consider literacy problems and encourage simplicity.

§423.568(e) Effect of failure to provide timely notice.
It is nowhere spelled out how the beneficiary is apprised of this right.

§423.570 Expediting certain coverage determinations.

§423.570(a) Request for expedited determination.
CMS requests comments on who should be able to request determinations and re-determinations. An authorized representative should be able to request expedited consideration just as the authorized representative may request a coverage determination. In emergency situations, enrollees with mental health concerns and other vulnerable individuals may need someone else to act on their behalf.

§423.570(c) How the PDP sponsor must process requests.
All coverage determinations and appeals concerning drugs, including those in which the enrollee has paid for the drug, should be treated as requests for expedited review. An enrollee would suffer adverse consequences if required to wait for the longer time periods; many people will simply go without prescribed medications pending the outcome of the review. Doubling the timeframes and disallowing expedited review in cases when enrollees pay for their drugs out-of-pocket could adversely affect the health of those who forego other necessities like food and heat in order to pay for their medicine.

At a minimum, all requests for exceptions should be automatically given expedited consideration. Where someone seeks expedited review of a request to continue a drug that is no longer on the formulary, the plan should be required to process the request in 24 hours under the provision that requires an expedited review to be completed as fast as the beneficiary's condition requires. The enrollee should be given a 72-hour supply of the medicine, which is renewable if the plan decides to take longer than 72 hours. The medicine should be treated as an on-formulary drug.

If requests for an exception are not automatically treated as a request for expedited review, the rules should state that the doctor's certificate requesting expedited review and requesting an exception should be one and the same.

§423.570(d)(2)
A beneficiary should not have to wait for a written notice to learn of the right to file an expedited grievance and the right to resubmit a request with prescribing physician support.

§423.572 Timeframes and notice requirements for expedited coverage determinations.

§423.572 (b) Extensions of timeframe.
The timeframe (of 72 hours) can be extended by the plan up to 14 days on showing that an extension is in the interests of the enrollee. The regulations should be modified to read best interest of the enrollee and define interests of the enrollee to include those situations in which the drug plan seeks additional information to substantiate the enrollee's request, or when the enrollee requests additional time to gather supporting information. The regulations should also require the plan to inform the enrollee of the extension immediately, both orally and in writing, rather than "by the expiration of extension." Also, the written notice should include more than just the reasons for the delay.

There should be no extended time period for requests for payment of drugs already received. This imposes extreme hardship on low-income beneficiaries and those with multiple prescriptions who may choose to unnecessarily spend money on their medications because of the uncertainty and length of the appeals process rather than spend the money on other urgent necessities of life.
It is not clear from the proposed regulations what notice a beneficiary will receive when sometime during the year a plan changes its formulary and the drug(s) it covers. The statute says plans must make the change in information available on the internet, the Preamble discusses a

mailed notice, and the draft regulation simply says 'notice.' A change in formulary, or a change in the tiering of a drug on the formulary should be clearly explained to a beneficiary taking that drug which has been changed. That notice should be written notice and the receipt of that notice should serve as a trigger for the beneficiary's legal rights.

§423.572(d) Content of the notice of expedited determination.
See §423.568(c) comments above.

§423.572(e) Effect of failure to provide a timely notice.
How does a beneficiary know s/he can appeal the lack of timely notice?

§423.578 Exceptions process.
The proposed regulations do not explain how an enrollee will get notice about the exceptions process and/or that a drug is not included on the formulary. The only notice requirement is found in §423.120(b), which requires the plan sponsor to provide at least 30 days notice to CMS, affected enrollees, pharmacies, pharmacist and authorized prescribers before removing a drug or changing a drug's preferred or tiered status. Although the preamble talks about written, mailed notice, and the statute requires posting on the Internet, the regulatory language merely says that notice must be given.

To meet basic due process requirements concerning termination of benefits, the notice of the change must be in writing and must include an explanation of how to use the exceptions process, including the requirements for a doctor's certificate, the right to a hearing, and the reasons why a drug is not included on or removed from the formulary, or why the tier is changing, and the evidence required to establish an exception.

Proposed section §423.120(b) provides insufficient time for the notice, given the substantial burden placed on the enrollee to either get a new prescription or to gather the medical evidence. Many beneficiaries will not be able to get a doctor's appointment within 30 days, and many will not be able to change drugs without a medical evaluation. The final regulations should state that notice must be provided 90 days in advance of the change.

In addition, the exception process section should include a subsection on notice that (1) refers to §§423.120(b) and (2) requires plan sponsors to develop a notice that explains the exceptions process, the situations in which someone may seek an exception, and the information that is required to support an exception request, which the pharmacy will give to an enrollee who requests coverage for a non-formulary drug or requests to be assessed a lower cost-sharing amount.

§423.578 (a)(2).
This subsection fails to meet the statutory requirement that the Secretary establish guidelines for an exception process. The plan statutory language is not permissive; it does not say that plans may establish additional criteria if they wish. It says that the Secretary is to establish criteria and the plans are to abide by them. Plans should have no discretion whatsoever. The fact that they may establish differing tiered structures is not relevant to the statutory right to request an

exception to whatever structure they devise. In fact, the flexibility accorded to plans is why beneficiaries need strong guidelines to protect their interests.

Where the proposed regulations include guidance for criteria, the criteria listed exceed the scope of the statute. The proposed regulations list a "limited number of elements that must be included in any sponsor's exception criteria," but this list includes criteria that do not apply based on the statutory provision that states an exception applies if a physician determines that a preferred drug would not be as effective or would have adverse effects or both.

The proposed rules also fail to provide adequate guidance to physicians concerning whether the standard requiring the doctor to certify that a preferred drug would not be as effective or would cause adverse effects has been met.

The final regulation should require that the lowest co-pay that applies should apply to drugs for which an enrollee has won an exception to the tiered cost-sharing structure. That's the whole point of this process - to infuse some equity upon a showing that none of the other medications covered are as effective or may cause harm.

The final rule should also include the following omitted criteria: regulations permitting continued access to a drug at given price when there is a mid-year formulary change, and regulations requiring sponsors to give enrollees an opportunity to request exceptions to a plan's tiered cost-sharing structure other than on a case-by-case basis.

§423.578(b) Request for exceptions involving a nonformulary drug.
This subsection fails to meet the statutory requirement that the Secretary establish guidelines for an exception process. In the preamble, CMS states that "[r]equiring sponsors to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied" and will help ensure these formularies "are based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs ." However, the proposed regulations give drug plans complete discretion in determining the criteria they will use to determine exceptions requests. In addition, independent review entities "would not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." By failing to adequately define the criteria plans may use to consider exceptions requests or provide any meaningful oversight over these criteria, these proposed regulations would not ensure that formularies are based on scientific evidence and would not establish a transparent process. The regulations as written subvert CMS's stated goals.

The proposed rules set an impossibly high bar for receiving an exception by requiring prescribing physicians to produce clinical evidence and medical and scientific evidence to demonstrate that the on-formulary drug is likely to be ineffective or have adverse effects on the beneficiary. Clinical trials generally do not include older people, people with disabilities and people with co-morbidities. While some such evidence does exist, it has not been developed for all drugs and conditions. However, a physician may have extensive experience treating these kinds of patients with the condition or illness at issue and this experience should be given at least

equal weight in making such determinations. In fact, the statutory standard requires deference to the doctor's determination that all on-formulary medications would not be effective or cause adverse consequences. This required deference is not reflected in the proposed rules. It is also important that the final rules recognize the existence of individual differences in reactions to the same drug and that exceptions be available to someone who can not tolerate or who does not benefit from a drug even though that drug is beneficial to most people.

The NPRM proposes to authorize plans to require a long list of information in the written certification from the prescribing physician that an off-formulary drug is needed. This list is overly long and repetitive and may encourage drug plans to establish burdensome paperwork requirements as a hurdle to prevent physicians and consumers from following through on an exceptions request. Moreover, this proposed rule also leaves the required contents entirely up to the plan's discretion by including the catch-all phrase - "any other information reasonably necessary". The requirements for this written certification should be standardized to facilitate use of the exceptions process by providers and consumers. These standards would also help achieve CMS's stated goal of establishing a transparent process.

An important provision was left out of the requirements for receiving a dosing exception. The proposed rule states that in order to receive an exception, the physician must demonstrate that the number of doses available is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. This rule must also allow exceptions if the prescribing physician demonstrates that the number of doses available would cause an adverse reaction or harm to the enrollee - as provided in the proposed rules for other kinds of exceptions requests.

The final regulation should clarify that formulary use includes not just dose restriction, but the format of the dosage (liquid vs capsule, etc.) and packaging, such as bubble wraps for long-term care facility residents.

§423.578(c)(2) When a sponsor does not make a timely decision.
The regulation provides for a one month's supply of a drug, but only if the plan does not act timely on an exceptions determination. If the request for an exception is not given expedited treatment, the sponsor can take two weeks to issue a decision, meaning the enrollee would wait two weeks before getting the supply of medicine. Even if the exception is treated as a request for expedited review, the enrollee would still have to wait 72 hours (unless s/he could show the decision needed to be made more quickly because of her/his condition.) Most people wait to the last minute to refill a prescription, often because of drug plan and pharmacy restrictions.

It is also unclear how an enrollee knows about these rights when a sponsor does not make a timely decision.

The enrollee should be entitled to a one month's supply upon presenting the request for a refill and upon presenting a new prescription for a non-formulary drug. Plans should be required to make exception determinations and notify the enrollee in 24 hours as required under Medicaid for prior authorization determinations. 42 U.S.C. §1386r-8(d)(5)(A).

We cannot overemphasize the importance of drug coverage and ensuring no gaps in the intake of medication. In mental health and HIV/AIDS, for example, it is essential that medications be available quickly and without interruption. In the HIV/AIDS sector, for example, consistent research proves that the risk of drug resistance and resulting treatment failure significantly increases with each missed dose of therapy.

423.578(c)(3), When an exception request is approved.
The lowest coinsurance amount should apply anytime an enrollee wins an exception through this process because the drug at issues has been determined medically necessary with no on-formulary drug as a suitable alternative. The exception for the non-formulary drug thus meets the criteria for an exception to the tiered cost-sharing structure as well.

The regulation needs to clearly set forth the requirement that notice be provided when a decision is made on an exception request. The notice should explain that the decision is a coverage determination and explain the appeal rights that are available.

We commend CMS for specifying that, once an exception request is granted, a plan sponsor may not require the enrollee to keep requesting exceptions in order to continue receiving the drug. However, we are concerned that the "exception" to this protection which allows the plan to discontinue a drug if safety considerations arise, is too broad. The final regulation should be revised to permit reversal of a previously granted exception only if the FDA determines that the drug is no longer safe for treating the enrollee's disease or medical condition.

We are concerned that the timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed provisions raise similar concerns. It is extremely unfair to require longer time frames if a beneficiary has paid out of pocket for a needed medication when their alternative would be to wait two weeks to a month for a determination or an emergency one-month supply of the needed drug. Beneficiaries' health and safety may well be at risk if they are forced to forego other necessities because of the added, and most likely very significant, expense of paying out of pocket for their medicines. Although the proposed regulations include some provisions for an emergency supply of medications while a plan is considering an exceptions request, it is unreasonable and bad health policy to make beneficiaries wait two to four weeks before the drug plan must provide an emergency supply. In addition, plans should be required to demonstrate that an extension of the standard time frame for exceptions determinations is in the best interest of the enrollee and the final rule must charge independent review entities with exercising oversight over these extensions. Plans should be required to make determinations regarding exceptions requests and notify the enrollee of these determinations in 24 hours as required under Medicaid for determinations regarding prior authorization requests (42 U.S.C. 1396r-8(d)(5)(A)).

§423.580 Right to a redetermination
The proposed regulations only authorize an enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) to request a redetermination or an expedited redetermination. The enrollee's authorized representative must also be allowed to request a redetermination and an expedited redetermination. Since the proposed regulations would allow an enrollee's authorized

representative to file a request for Determinations and Exceptions, it does not make sense to not allow an enrollee's representative to pursue a claim further through the redetermination, reconsideration, and higher levels of appeal. In fact, the proposed regulations define an authorized representative as an individual authorized to act on behalf of an enrollee "in dealing with any of the levels of the appeals process".

§423.584 Expediting certain re-determinations.
The regulations need to describe in detail the notice responsibilities for both standard and expedited re-determinations, including what must be provided in the notice. This is crucial, given that the next level of review to the IRE is not automatic, as it is with Medicare Advantage plans. The notice should explain the reason for the denial, including the medical and scientific evidence relied upon, the right to request review, or expedited review, to the IRE, including timeframes and the right to submit evidence in person and orally.

§423.584(a) Who may request an expedited redetermination.
See §423.580 regarding allowing an individual's authorized representative to request an expedited re-determination.

§423.584(d)(2).
The information in the letter should also be provided orally. The enrollee should not have to wait three days for this information.

§423.586 Opportunity to submit evidence.
The regulations should establish clear criteria for informing the enrollee and the physician that they can submit evidence in person, as well as clear procedures for in-person review.

§423.590 Timeframes and responsibility for making redeterminations.
The regulation should be amended so that a plan can only extend the timeframe for a re-determination if requested to do so by the enrollee, or if the plan can demonstrate that the extension is in the best interest of the enrollee (for example, the plan needs to obtain additional information to support the enrollee's request). As previously stated, all re-determination requests, and particularly those involving exceptions, should be treated as expedited, and plans should not be given more time to resolve re-determination requests involving payment requests.

§§423.590(c) Effect of failure to meet timeframe for standard redetermination and (e) Failure to meet timeframe for expedited redetermination.
Again, how does enrollee know this and know what to do?

§423.600 Reconsideration by an independent review entity (IRE).
CMS needs to clarify in the final regulations that the role of the IRE is to provide independent, de novo review, especially in regard to the exceptions process. The preamble states that "…The IRE's review would focus on whether the PDP had properly applied its formulary exceptions criteria for the individual in question…..the IRE will not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." If the IRE does not review all the

evidence and issue a reconsideration decision based on its own analysis, then enrollees will be denied independent review, and the requirements of due process will not have been met.

Further, because, as noted above, CMS is required by the statute to set standards for the exceptions process, the IRE must have authority to determine whether the PDP's exceptions criteria comply with the statute. Otherwise, enrollees will have no mechanism for review of arbitrary and improper standards.

Since the Part D process is supposed to follow the MA process, the regulations should follow the MA regulations and require that denials automatically be sent to the IRE for reconsideration. The regulations as written create a barrier to the first level of independent review for enrollees who have difficulty following the complicated process. We dispute CMS's statement in the preamble that many of the drug appeals will involve small monetary amounts. Rather, most will involve medications for chronic conditions that enrollees take on an on-going basis; the yearly sum of the cost-sharing will be quite substantial, especially considering the income level of most people with Medicare. In addition, by requiring the enrollee to file a request for ALJ review, the first truly independent review available, CMS can satisfy the statutory requirement that the enrollee files the appeal.

If the final regulations continue to place the burden of requesting a reconsideration on the enrollee, they need to clarify that an authorized representative can act on the enrollee's behalf. Again, without such clarification, enrollees who lack the capacity to file a reconsideration request will be denied their due process rights. In addition, the prescribing doctor should also be permitted to request a reconsideration, especially since the enrollee needs the doctor's statement in order to request IRE review of an unfavorable exception request.

Finally, the enrollee should be allowed to request a reconsideration orally, especially where the request is for an expedited review.

§423.600(b).
We are pleased that CMS is requiring the IRE to solicit the view of the treating physician. We believe the IRE should also be required to solicit the view of the enrollee. However, because in our experience the MA independent contractor is often reluctant and unwilling to accept the views of and evidence from the beneficiary, the final regulation needs to be more specific. The regulation needs to specify how this will occur, including contact by telephone, email, or face-to-face meeting.

§§423.600(d).
The regulations need to establish a set timeframe by which the IRE must issue its decision in order for this process to be transparent. Enrollees will have no knowledge of the contract between CMS and the IRE and thus will not know how long they will have to wait for a reconsideration decision. Also, if contractual, the time frame can change with each new contract, putting enrollees at greater risk of adverse health consequences from being denied needed medicines. The regulation should also state that an enrollee may appeal to an ALJ if the IRE fails to act within the regulatory time frame and how the enrollee will be apprised of this right.

§423.602 Notice of reconsideration determination by the independent review entity.
The language concerning what the notice must entail is ambiguous. The notice must "inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under 423.610." Does this mean that the notice tells you that you can go to an ALJ, but only if your claim is large enough? Or does this mean the IRE only has to tell you about your right to an ALJ hearing if your claim meets the threshold amount? The latter interpretation is problematic for several reasons, including the fact that you can aggregate claims. The final regulation should state that the notice must inform the enrollee of his or her right to an ALJ hearing, and the procedure for requesting such a hearing, including the dollar amount required to request a hearing.

§423.610 Right to an ALJ Hearing.
Congress recognized the special needs of the low income, and how even small copayment amounts can cause many lower income individuals to forgo filling prescriptions. We urge CMS to provide exceptions to the ALJ threshold requirements for those receiving the Medicare subsidy. For example, the amount at controversy for a lower-income individual could be deemed to be the amount that would be at controversy if the individual were a non-subsidy eligible individual receiving the standard benefit.

It is unclear what §423.610(c) intends when it says, "Two or more appeals may be aggregated by the enrollee… if (I) the appeals have previously been reconsidered by an IRE…" Does this mean that an enrollee will have to file a new appeal each month for a prescription to treat an on-going chronic condition? Such a requirement would be unduly burdensome for enrollees, drug plans, the IRE, and the ALJs. The final regulation needs to clarify that when the plan denies coverage, in order to satisfy the jurisdictional amount an enrollee should be able to add up the cost of the medicine for a year, if the medicine treats an on-going chronic condition, or for the number of refills authorized if the underlying condition is not chronic.

Subsection (ii) says the request for the hearing must list all of the appeals to be aggregated and must be filed within 60 days after all of the IRE reconsideration determinations being appealed have been received. If you are consolidating appeals, and the first denial is in April and the last one you need to get to the jurisdictional amount is in August, will you still be timely? Or does it have to be 60 days from the first denial in April?

§423.612 Request for an ALJ Hearing.
The regulation should specify that, if an appeal is filed with the PDP, the PDP must submit the file to the IRE within 24 hours of receipt of the request, and the IRE must transmit the file to the ALJ within 24 hours. Our experience is that, without set time frames, some current reviewing entities take long periods of time, adding to the delay in the processing and resolution of ALJ appeals.

The regulations also need to require the IRE to include all of the information in the file, such as doctor's statements, statements by the enrollee, and any other evidence submitted by the enrollee, including information not relied upon in making its decision. It has been our experience that

contracting entities, including MA plans, often omit evidence submitted by the enrollee when transferring a file to the ALJ or other level of review.

§§423.634, Reopening and revising determinations and decisions and 423.638 How a PDP sponsor must effectuate expedited redeterminations or reconsidered redeterminations.
Subsection (c) in both of these draft regulations allows the PDP to take up to 60 days to implement a reversal by the IRE, an ALJ, or higher. That's totally unacceptable, since further delays may cause increased health consequences to people who have foregone medication pending appeal. Favorable decisions should be implemented in the same 72 hour time period as reversals at earlier levels of review.

Subpart P - Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§432.772 Definitions.
"Family size." We support defining family members as relatives in the household receiving at least half of their support from the applicant or applicant's spouse. In order to minimize burdens on beneficiaries, the regulations should specify that applicants will be able to self-attest to the status of dependents, without providing further documentation.

"Full subsidy eligible individuals." The definition should refer to the language of §§423.773(b) and(c), in order to avoid ambiguity.

"Income." The definition should make clear that income not actually owned by the applicant, even if his or her name is on the check, should not be counted.

"Institutionalized individual." The definition should include those individuals eligible for home and community based services under a Medicaid waiver (see, e.g., definition of "institutionalized spouse" at 42 U.S.C. § 1396r-5(h)(1)(A)), since those individuals must meet the acuity standards for Medicaid coverage in a nursing facility, and should include individuals in ICF-MRs and individuals in any institution in which they are entitled to a personal needs allowance.

The definition should not include the language "for whom payment is made by Medicaid throughout the month" since an individual could conceivably be a full benefit dual eligible recently returned from a hospital stay whose nursing facility stay would be paid for by Medicare Part A for the entire month. Even though in that month all their drugs are likely to be paid for by Medicare Part A, as a practical matter, for continuity and minimum disruption, they should not lose their status as an "institutionalized individual." The same reasoning should apply to a full benefit dual eligible individual who might be hospitalized during an entire month, during which their entire stay would also be paid for by Medicare Part A.

"Personal representative." The portion of the definition that permits an individual "acting responsibly" on behalf of an applicant needs further clarification as to who would determine that the individual is acting responsibly and what circumstances would constitute a per se conflict of interest.

"Resources." We support the limitation of countable resources to liquid assets. However the definitions of liquid assets and what it means to be able to be converted into cash in 20 days need to be clarified. The final rule should include a specific list of countable resources to promote clarity for state and beneficiaries. Resources should not include burial plots, burial funds or life insurance of any value, nor should it include any officially designated retirement account, such as an IRA, 401(k), 403(b) etc. Alternatively, the respective exclusions for the value of life insurance and burial funds should be increased to a reasonable amount, such as $10,000 per asset. Most potential low-income beneficiaries have assets below this level.

Excluding these resources will ease the application process for consumers and eligibility workers, as well as reduce administrative costs by reducing the time and effort required to verify assets. This is consistent with both Congress's and CMS's intent. Resource assessments should not include any consideration of transferred assets, as would otherwise be required under SSI rules.

We note that a current draft of the SSA application for the low-income subsidy inquires whether an applicant has life insurance with a face value of $1,500 or more. CMS must ensure that any proposed SSA application is harmonized with these rules on assets and income. As noted above, life insurance should not count towards assets, and this question should be eliminated.

§423.773 Requirements for eligibility.
We support the proposal to make dual eligibles (both full dual eligibles and those in Medicare Savings Programs (MSPs)) automatically eligible for the low-income subsidy. As we explain below, however, we believe a great deal more specificity is needed in this section. We are particularly concerned that the proposed rule leaves room for ambiguity regarding these beneficiaries' status. We believe that the proposed eligibility rules for partial dual eligibles will result in inequities and confusion. In addition, the draft regulations do not adequately explain how low-income beneficiaries are to be notified about their eligibility, nor do they explain how prescription drug plans are to determine which beneficiaries are enrolled in the low-income subsidy. The proposed rules also do not adequately protect low-income beneficiaries whose enrollment is delayed or is processed erroneously.

§423.773(a) Subsidy eligible individual.
Although the statute defines a subsidy eligible individual as one enrolled in a Part D plan, the requirement in Subpart S that states take applications for the low-income subsidy beginning July 1, 2005, before Part D plans are available to be enrolled in makes it clear that CMS believes people should be able to apply for the low-income subsidy without being enrolled in a Part D plan. This is actually imperative, as otherwise, an individual would be forced to pay a plan premium that the subsidy, in fact, pays for them. The subsidy eligibility determination would be done "conditionally" - conditioned upon the individual enrolling in a Part D plan. The regulations should reflect this reality and clearly direct both SSA and state Medicaid programs determining eligibility that the individual can both apply and be determined subsidy eligible before she or he has enrolled in a plan

§423.773(b) Full subsidy eligible individual.

The indexing of resources should indicate that rounding is always up to the next multiple of $10.

§423.773(c) Individuals treated as full subsidy eligible.
This section should conform to Subpart S § 423.904(c)(3) which requires states to notify all deemed subsidy eligible individuals of their subsidy eligibility. It should specify that the notice must be given by July 1, 2005 for those individuals eligible at that time. For those who subsequently become eligible, notice should be given at the same time the individual is notified of their eligibility for the benefit that qualifies them to be treated as a full subsidy individual. The notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. For those who will lose Medicaid coverage January 1, 2006, the notice should explain their appeal rights as well. Individuals should also be told of their right to appeal the level of subsidy to which they are entitled.

Section 209(b) states and non-1634 states must coordinate with the Social Security Administration to determine how to provide notice to SSI recipients who are not receiving Medicaid and who therefore do not appear on the state's Medicaid rolls.

§423.773 states that both full benefit dual eligibles and MSP beneficiaries are eligible for the low income subsidy, but it does not explicitly state that these beneficiaries are automatically enrolled in the subsidy program. The regulations should be absolutely clear that an individual treated as full subsidy does not have to take any further action with respect to the subsidy (i.e., make application or in any other way verify their status), but only to enroll in a Part D plan. This will help smooth the transition from Medicaid drug coverage for dual eligibles, and should improve participation for others.

§423.773(c)(3).
We support the decision reflected in this proposed subsection to deem MSP beneficiaries automatically eligible for the low-income subsidy. We are concerned, however, that inequities and confusion among beneficiaries may result because SSA will not apply the more generous income and asset MSP eligibility rules in place in some states (for example, Alabama, Arizona, Delaware, and Mississippi, which have eliminated consideration of assets for MSPs). Eligibility requirements should be the same for all subsidy-eligible individuals in a state, regardless of where and how they apply. Under the proposed regulations, in states that have adopted less restrictive income and asset methodology, people whose assets or income are slightly above the limits set in § 423.773 would be enrolled in a less generous subsidy, or have their application rejected entirely, if they apply directly through SSA, because SSA will apply the national guidelines proposed in §423.773. However, the same people would have their application accepted if they applied through their states' Medicaid offices, were screened and then enrolled in an MSP, and were then automatically eligible for the low-income subsidy.

To resolve this problem, we propose that SSA apply state-specific income and asset eligibility rules in determining eligibility for the low-income subsidy, an option discussed, though rejected, in the preamble. This means that for applicants from states that have eliminated the asset test or

increased disregards under §1902®)(2) for MSP eligibility, SSA should apply the state's rules to determine eligibility. This option is permitted under §1860D-14(a)(3)(E)(iv) of the statute.

Alternatively, the regulations should provide that subsidy applicants who appear to have excess assets or incomes would either be screened by SSA for eligibility in an MSP program, or have their applications forwarded to the state Medicaid agency to be screened for MSP eligibility. States would be precluded from requiring beneficiaries to resubmit information, such as income and asset levels, that they have already provided to SSA. Applicants would be enrolled in the appropriate MSP program, and then be enrolled in the appropriate low-income subsidy under proposed § 423.773(c). Adopting this policy, which is not precluded by statute, will ensure that all subsidy applicants are treated equitably, as well as increase participation in MSPs.

As part of this alternative policy, the low-income subsidy application should allow an applicant to opt out of screening and enrollment for an MSP, as some applicants may not wish to participate in an MSP. Under §1860D-14(a)(3)(v)(II) of the statute, beneficiaries who are determined eligible for MSPs may be enrolled in the low-income subsidy. There is no requirement that beneficiaries actually enroll in an MSP. Therefore, applicants who meet eligibility requirements for an MSP, but who decline to enroll in the program, should still be automatically eligible for the low-income subsidy.

Because enrollment in an MSP can affect the amount of assistance a beneficiary may receive through other public assistance program, such as Section 8 housing vouchers or food stamps, there will be a profound need for beneficiary counseling during the enrollment process. We recommend that CMS plan for this need by making funds available to local agencies, including state health insurance assistance programs (SHIPs), and other community-based organizations.

This draft regulation states that a state Medicaid agency must notify full benefit dual eligibles that they are eligible for the low-income subsidy and should enroll in a Part D plan. The regulations do not state, however, when this notice should be issued, or what the notice should say. Consistent with our comments above and those accompanying 423.904(c)(3), the notification should be sent to beneficiaries on or near July 1, 2005, when states will have made the automatic eligibility determinations.

We also suggest that CMS develop model notices based on input from beneficiaries, which would explain the purpose of new subsidy simply and clearly. The notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. It should also explain as simply as possible what level of subsidy the beneficiary will receive, and the beneficiary's appeal rights if she believes the subsidy level is in error.

The draft regulation fails to address eligibility issues for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) state. These beneficiaries should be informed of their likely eligibility for a low-income Medicare subsidy and given an opportunity to enroll. When they have met their spenddown, they should be informed of their entitlement to a lower co-payment, if applicable, as a deemed subsidy eligible.

Our recommendations for redeterminations of these beneficiaries are discussed below, in §423.774.

§423.773(d) Other subsidy eligible individuals.
The indexing of resources should indicate that rounding is always up to the next multiple of $10.

§423.774 Eligibility determinations, redeterminations, and applications.

§423.774(a) Determinations of whether an individual is a subsidy eligible individual.
This subsection provides that determinations of eligibility for the subsidy are to be made by state Medicaid agencies or by SSA, depending on where an individual applies. We believe that in order to ensure prompt enrollment in both the subsidy and ultimately in a plan, the regulations should specify that a determination notice must be sent to the applicant no later than 30 days after the application is filed. Because determinations for the low-income subsidy should be a simple process, very little time should be required to render a decision. Both SSA and states should be required to notify CMS with 24 hours of a individual being determined eligible for the subsidy.

§423.774(b) Effective date of initial eligibility determination.
In order to avoid delays in the ability of beneficiaries to use their subsidy benefits while their application is pending, the final rule should offer beneficiaries the option of applying through a presumptive eligibility system. Such a system would be especially helpful to beneficiaries who have enrolled in a Part D plan but are not yet receiving the low-income subsidy. Applicants can complete a short form at a provider's office or other location in which they declare their family size, income and assets. If their income and assets are below the relevant eligibility levels, they are found presumptively eligible. Applicants may still be required to complete a full application within a prescribed period of time (typically 30 to 60 days) if additional information is required. In the meantime, however, beneficiaries are given temporary cards that they can present to health care providers and receive services immediately. Experience has shown that the error rate for these enrollment systems is very low. In the rare cases where beneficiaries are later found ineligible, they and their providers are held harmless for the benefits they receive during the presumptive eligibility period.

Applicants for the low-income subsidy could be found presumptively eligible at state Medicaid offices, SSA offices, pharmacies, or other providers. If the low-income subsidy application form is simple enough, applicants could complete the form itself and self-attest to their income and assets. If they appear to be eligible, they would be enrolled in the appropriate subsidy while their application is processed. They would receive some form of temporary certification stating that they have been presumptively enrolled, which their pharmacy would accept while their application is processed. Such a system would encourage beneficiaries to apply, as they would be able to see the benefits of the system immediately.

§423.774(c) Redetermination and appeals of low-income subsidy eligibility.
There should be a provision for prompt reconsideration of a subsidy eligibility determination, for beneficiaries who believe they have either been erroneously denied eligibility or approved for the

wrong subsidy category. The provisions applying the appeal rules of state Medicaid plans or SSA do not provide for a prompt reconsideration process. Because obtaining prescription drugs is so vital, and especially because low-income beneficiaries are unable to pay the costs of their prescription drugs out of their own pockets, a quick reconsideration process is essential.

The draft regulation refers to redeterminations and appeals under the state Medicaid plan. This is inadequate, as frequent redeterminations in place in some states will cause some beneficiaries to drop out of the program. To maximize enrollment, the rule should establish that all determinations are for one year, per the Secretary's authority under the statute. We also urge CMS to adopt an annual, passive, and simple redetermination for all beneficiaries, whether they have enrolled through SSA or states. Should it be necessary, the Secretary should direct the Commissioner of SSA to create such a system. Under a passive redetermination system, beneficiaries would be sent a statement of the relevant information on file and asked to respond only if any of that information had changed over the year. If they do not respond, their coverage would continue unchanged for another year.

If states are not required to adopt passive redeterminations, we urge that redeterminations be made as they are under the state's MSP programs, or under the most passive, simplified redetermination process used for any category of coverage under the state plan.

§423.774(d), Application requirements.
This section should make clear to both states and SSA that no documents should be required of the individual as long as the applicant authorizes the agency to verify information from financial and other institutions. Documentation production should be only the absolute last resort.

Also, as we mentioned in our comments to §423.773 above, the proposed rule does not address eligibility determinations and recertification periods for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) state. Once beneficiaries become deemed subsidy eligible individuals by completing their spenddown, they should retain that status for a full year, until their next redetermination for the low-income subsidy, regardless of whether they go off Medicaid. Otherwise, individuals who go in and out of medically needy status, depending on the length of their state's budget period, will have extremely confusing changes regarding their Medicare low-income drug subsidy.

§423.800 Administration of Subsidy.

§423.800(a), Notification of eligibility for low-income subsidy.
We are concerned that there is no provision in §423.800(a) specifying a time period by which CMS must notify a plan that an enrollee is eligible for a subsidy. This is an essential step in the process, because without the subsidy, prohibitive costs will prevent low-income beneficiaries from using their Part D benefits. We propose that CMS be required to inform Part D plans of beneficiaries' enrollment in the subsidy no later than 24 hours after the application for the subsidy is approved. As this will likely be an electronic notification, it should not be burdensome. It is vital that plans know which beneficiaries are enrolled in the subsidy, so that these low-income beneficiaries do not have to pay the full cost of their prescriptions while their subsidy application is process.

§23.800(e), Reimbursement for cost sharing paid before notification of eligibility for low-income subsidy.
The draft reimbursement provisions are inadequate to protect low-income beneficiaries. The proposed regulation would require plans to reimburse low-income beneficiaries for excess copayment and premium amounts made after the effective date of the subsidy application. This is not a realistic solution to the problem facing beneficiaries who have prescription drug needs before their Part D plans are notified that the beneficiaries are subsidy-eligible and need to have their records adjusted accordingly. Low-income beneficiaries will not be able to afford to pay these costs out of their own pockets with the expectation of being reimbursed later. Instead, these beneficiaries will forego prescription drug coverage until their plan processes their subsidy, making the first month or more of their subsidy period meaningless.

Adoption of a presumptive eligibility system recommended above would alleviate this problem. As an additional alternative, the regulations should provide that beneficiaries may present their notice of approval for the subsidy to their pharmacy when they seek prescription drugs. Pharmacies should accept this notice as adequate to relieve the beneficiary from making a co-payment, and instead seek reimbursement for the beneficiary's plan.

Subpart S - Special Rules for States - Eligibility Determinations for Subsidies and General Payment Provisions

§423.904 Eligibility determinations for low-income subsidies.

§423.904(a) General Rule.
This subsection should cross reference the entire Subpart P, or, at a minimum the definitions included in §423.772.

§423.904(b) Notification to CMS.
The rule should direct states to notify CMS of eligibility determinations within 24 hours of making them, as we previously recommended with respect to SSA determinations.

§423.904(c) Screening for eligibility for Medicare cost-sharing and enrollment under the State plan.
The proposed regulation regarding states' obligations to screen subsidy applicants and offer them enrollment in Medicare Savings Programs ("MSPs") are inadequate. In particular, the regulation should specify what "offer enrollment" means. We believe an applicant must be offered the opportunity to enroll during the same visit or contact (in office, by phone, or by mail), without providing any further documentation or completing any additional forms. Only if enrollment is easy and convenient will Congress's intent of increasing participation in MSPs be accomplished. Furthermore, because under the current rules, enrollment in an MSP may be the only entry into the subsidy for some beneficiaries, a quick and easy application for MSP programs is essential. As written, the regulation would permit states to say they have "offered enrollment" simply if they tell applicants that they might be eligible for an MSP and may return another time to complete another application form if they wish to apply. Such an outcome would defeat the

purpose of the screen and enroll provision included in the new §1935(a)(3) established in §103(a) of the statute. Instead, as proposed in our comments to Subpart P, the low-income subsidy application should include an "opt-out" provision, under which qualified applicants would be enrolled in an MSP unless they affirmatively decline to do so. This provision would explain that enrollment in an MSP may be another way to qualify for the low-income subsidy.

As we explained in our comments to Subpart P, because enrollment in an MSP may affect receipt of other public benefits, there is a tremendous need for good quality counseling of beneficiaries. In addition, in order to ensure that enrollment requirements between MSPs and the low-income subsidy are aligned, states should not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective and can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP.

In the interest of further aligning eligibility rules for MSPs and the low-income subsidy and easing administrative burdens, we suggest that CMS direct states to apply the definitions of resources used in Subpart P, §423.772, in making their resource determinations for MSP applicants.

In addition, should CMS adopt a policy, as has been discussed publicly, under which most subsidy applications to state Medicaid agencies would be forwarded to SSA for the actual eligibility determination, the regulations should be clear that the screening for MSP eligibility must take place prior to the processing of the applications to SSA. Potential beneficiaries should not have to wait to be screened and offered enrollment in MSPs. Furthermore, an individual cannot be told, by either SSA or the state that she or he is ineligible for the low-income subsidy until MSP eligibility has been determined (if the individual wishes). It would be incredibly confusing for an individual to receive a notice from SSA that she is ineligible for a subsidy, have her MSP eligibility determined by the state, then receive a notice from the state that she is eligible for both MSP and the subsidy. Whatever the mechanics, the individual must be told that MSPs are a route to subsidy eligibility.

Finally, as we discussed in our comments to §423.773, SSA should also screen subsidy applicants for eligibility in MSPs as well, and develop a system with states to enroll eligible beneficiaries. Applicants should not miss out on the opportunity to enroll in MSPs because they apply through SSA rather than state Medicaid offices. The same concerns about beneficiary education and estate recovery discussed above apply to enrollment through SSA.

The regulations should also ensure that beneficiaries are screened for eligibility for full Medicaid and offered enrollment if they qualify, consistent with 42 C.F.R. §435.404. Ideally, all subsidy applicants would be screened for Medicaid, and offered enrollment if they qualify. Because the importance of maintaining a simple application process for the subsidy is paramount, CMS may wish to consider using a simple screening process based on information obtained through the subsidy application. This screening would trigger a follow-up with applicants who appear to be eligible for full Medicaid.

Many Medicare beneficiaries who are eligible for a low-income subsidy under the Part D Program will also be eligible for other important benefits. Some of these benefits, such as food stamps, are also administered by states and have eligibility rules that very closely correspond with the new eligibility rules for the Part D subsidies. Historically participation by seniors and people with disabilities in these programs has been low, despite the fact that the benefits that low-income Medicare beneficiaries would be able to receive could help them struggle less to make ends meet every month. The Part D enrollment process offers an historic opportunity to connect Medicare beneficiaries to these other programs.

Beyond saying that applications may be filed either with a State's Medicaid program or with SSA, the proposed rule has very little detail about how the application process is likely to work. We urge CMS to specify that the new eligibility process should dovetail with other programs so that low-income Medicare beneficiaries can be enrolled as seamlessly as possible in all the state- or SSA-administered benefits for which they qualify

423.904(d)(3)(ii), Cost-effectiveness of information verification.
This section should be modified to permit states to use the verification process established by the Social Security Administration to verify the income and assets of people who apply for a Part D subsidy through a state Medicaid agency.

PART 403-SPECIAL PROGRAMS AND PROJECTS

Subpart B-Medicare Supplemental Policies

Disclosure notices advising consumers of their statutory rights must be short, simple, easy to understand, and address as few issues as possible. The proposed disclosure notice concerning Medigap policies H, I, and J included in the Preamble is too long, provides unnecessary information, and includes information that may not be accurate for all beneficiaries. We suggest that the letter be modified as follows:

Delete the information about Medicare Part D at the beginning of the disclosure notice;
Delete statements about the value of Part D benefits, which are irrelevant to the issue of changes to Medigap;
Delete the second statement about the need to notify the Medigap issuer if a person later enrolls in Medicare Part D. This information is repetitive; and

Delete the information concerning enrollment issues about Medicare Part D which is unrelated to whether a Medigap policy provides creditable coverage.

In addition, we encourage CMS to develop a different notice for people who will have creditable coverage as their options will be different from those of people whose Medigap policies are not deemed to provided creditable coverage. The specific information this group of beneficiaries will need about their creditable coverage, and any required action, will vary depending on whether their coverage is employer sponsored retiree coverage, a Medigap Plan J, a pre-standard Medigap plan, or a Medigap with a rider or an innovative benefit.

The discussion in the Preamble to the Regulation beginning with Subpart T 4(c)(iii) references the difficulty of determining creditable coverage and the inability to even make that determination in advance of a final rule to implement Part D. We expect there will be confusion on this issue and that mistakes may be made by issuers in applying an actuarial test to groups of policies issued all over the country. We expect additional confusion due to the proposal to modify the definition of Medicare Supplement (Medigap) policies in §403.205 to include riders and freestanding benefits for prescription drugs. We are requesting two remedies for Medicare beneficiaries who are initially notified of creditable coverage when the coverage is no longer or never was creditable: a Special Enrollment Period in Part D and a guaranteed issue right to a Medigap policy without prescription drug benefits. We are also requesting the extension of the right to a guaranteed issue policy to Dual Eligibles who lose their eligibility to Medicaid benefits.

Thank you for the opportunity to submit comments on the proposed rule. We hope that this will not be the final opportunity to do so.

Very truly yours,

Diane F Paulson
Senior Attorney
Medicare Advocacy Project, Greater Boston Legal Services

Linda Landry
Disability Law Center

Deborah Thomson
Massachusetts Law Reform Institute

CMS-4068-P-1258

Submitter : Dr. Eddie Rowe **Date & Time:** 10/04/2004 08:10:27

Organization : Rowe's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

BENEFICIARY ACCESS TO COMMUNITY RETAIL PHARMACIES:
I am concerned about the proposed rul regarding the pharmacy access standard. Under the proposed regulation, each prescription drug benefit plan is allowed to apply the Department of Defense's TRICARE standards on the local (37664)level rather than 'on average' in a regional service area.

To address the situation where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level (no pharmacy in the zip code), the regulation should require that the access standard be the greater of the TRICARE standard or the access equal to that available to a member of the general public living in that zip code.

Requiring plans to meet the standard on a local level is the only way to ensure patients equal and convenient access to their chosen pharmacies.

PROPOSED REGULATION CREATES NETWORKS SMALLER THAN TRICARE:
The proposed regulation also allows plans to create 'preferred' pharmacies and 'non-preferred' pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one 'preferred' pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only 'preferred ' pharmacies shoud count when evaluation whether a plan has met the required TRICARE access standards. The Dept. of Defense network of pharmacies meets the Tricare access standards and has uniform cost sharing for all these network pharmacies. CMS shoould require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan's standards terms should be allowed to provide the same copays to the patient population.

EQUAL ACCESS TO RETAIL AND MAIL ORDER PHARMACIES FOR MEDICARE BENEFICIARIES:
I believe it was the intent of Congress to assure Medicare beneficiaries are able to obtain covered prescriptions drugs and medication therapy management services from the pharmacy provider of their coice. As such, plans must permit beneficiaries to obtain covered outpatient drugs and medication therapy management services at any community retail pharmacy in the plan's network, in the same amount, scope, and duration that the plan offers through mail order pharmacies. According to the proposed regulation, the only difference a beneficiary would have to pay between retail and mail order prescriptions should be directly related to the difference in the service costs, not the cost of the drug product. Under Medicare Part D, all rebates, discounts or other price concessions shoould be credited equally to reduce the cost of prescription drugs no matter where they are dispensed. The benefits from these arrangements shoould be required to be used to directly benefit the Medicare beneficiary in terms of lower cost prescriptions.

Pharmacists are also the ideal health care professionals to provide Medication Therapy Management Program and determine which services each beneficiary needs.

I, also, know that the local pharmacist is the most accessible healthcare provider a Medicare beneficiary has. I have even gone to patients homes to help them with their medications because they couldn't understand the physician's instructions, so how could they possibly understand a mail-order pharmacist on the telephone.

In conclusion, I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.

Sincerely,
Eddie Rowe, DPh.
Rowe's Pharmacy

CMS-4068-P-1259

Submitter : Mr. Michael Starkowski **Date & Time:** 10/04/2004 08:10:44

Organization : State of Ct. DSS

Category : State Government

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

The state of Ct is submitting comments on the entire range of issues not just sections 1-10.

CMS-4068-P-1259-Attach-1.doc

STATE OF CONNECTICUT

File Code: CMS-4068-P

October 4, 2004

Dr. Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) is historic legislation that presents opportunities and challenges for Connecticut. As a state with representation on the State Pharmaceutical Assistance Transition Commission (SPATC) authorized by that law, we are pleased to have been a part of the communication process between the Centers for Medicare and Medicaid Services and certain states that will be impacted by the new Medicare pharmaceutical benefit. We have not repeated all of the recommendations made by the Commission in these comments. However, we want to note that the State of Connecticut supports all of the recommendations outlined by the Commission.

While the SPATC process was certainly a helpful forum for presenting comments of importance to Connecticut, the impact of the Medicare Modernization Act extends beyond the interests of state pharmaceutical assistance programs to include issues relevant to the Medicaid program and to state retirees. The State of Connecticut believes that there are important threshold issues in the rule related to SPAPs. Therefore, we have repeated some of the SPATC comments here to underline the critical nature of these areas.

Accordingly, attached please find comments from the State of Connecticut regarding CMS's proposed rule for implementing the Medicare prescription drug benefit. If you have any questions about our comments, please contact Paul Potamianos at 860-418-6272 (paul.potamianos@po.state.ct.us) or David Parrella at 860-424-5116 (david.parrella@po.state.ct.us).

Sincerely,

Marc S. Ryan
Secretary
Office of Policy and Management

Patricia A. Wilson-Coker, JD, MSW
Commissioner
Department of Social Services

Attachment

A. General Provisions

Section 423.4. Definitions. *PDP Sponsor.* Section 1860D-41(13) of the Act defines a PDP sponsor as a "nongovernmental entity," which is operationalized at Section 423.4 of the proposed rule (p. 46810). We ask that CMS be flexible in its interpretation of the Act and its definition of nongovernmental entity so that states can comply with the law while at the same time allowing for creation of state-sponsored nongovernmental entities or selection of one entity as PDP sponsor for our Medicaid dual-eligible and SPAP populations. Not only would this approach minimize client confusion and ensure continuity of care (since we are familiar with both the medical and pharmaceutical histories of our clients), but it would resolve issues of data-sharing, client notification and client enrollment.

Section 423.6 (p. 46636 of the preamble). Cost-Sharing in beneficiary education and enrollment. It is unclear whether PDPs or MA-PD plans can pass along education and information costs in the form of user fees to states. To the extent that there are education and information costs, these should be borne by CMS and/or PDPs or MA-PD plans, not states.

Section 423.112 (p. 46636 of the preamble). Establishment of prescription drug plan service areas. Because the MMA allows for up to 50 state regions, and because Connecticut is an SPAP state, we believe that CMS should establish PDP regions in a way that allows Connecticut to be its own region. This is of importance to Connecticut because of the need to coordinate between our SPAP and the PDP or MA-PD plans. The needs and concerns of smaller states (especially states with SPAPs) could be subsumed by larger states with different integration needs. Allowing Connecticut to be its own region will help ensure that all PDPs or MA-PD plans will be responsive to meeting Connecticut's needs, and will help maintain continuity of care for Connecticut's vulnerable populations.

Section 423.34(d) (pp. 46638-46640 of the preamble). Enrollment process. *Enrollment requirement for full benefit dual eligibles.* The preamble proposes that full benefit dual eligibles be given until May 15, 2006, to establish initial enrollment before the auto-enrollment process begins. Under this proposal, some full benefit dual eligibles will not be covered by Part D until after May 15, 2006, which would mean either that those individuals have no prescription coverage or that states will be forced to continue coverage through their Medicaid programs for that time period, but without receiving FFP for those Medicaid costs. Indeed, states will incur costs for full benefit duals who do not enroll until May 15, 2006, even beyond that date, since we do not have the administrative and programmatic ability to ensure that those individuals are immediately enrolled in a Part D plan and are accessing Part D prescription drug benefits. States should not be penalized by the fact that many full benefit dual eligibles will likely not be enrolled prior to January 1, 2006; rather, states should be able to receive FFP for prescription costs for duals until initial enrollment is accomplished and individuals are able to access their Part D benefits.

To best address this situation, we believe CMS should implement an auto-enrollment process whereby full benefit dual eligibles are automatically enrolled in a default plan effective January

1, 2006, unless the individual elects to enroll in a different plan prior to that date. In addition, in order for states to implement the most effective, best integrated wrap around program, and to minimize disruption to clients, states should be able to auto-enroll dual eligibles into a preferred PDP (similar to the drug discount card).

Under the rule, a full benefit dual who fails to enroll would be automatically enrolled in a PDP that has a monthly beneficiary premium equal to or below the subsidy amount for low income beneficiaries. While the regulation is clear that states can wrap around for beneficiaries, it is not clear whether a state can elect to enroll a dual (or perhaps SPAP recipient) in a higher premium plan if the state paid the difference and determined it to be cost effective compared to what the state's wrap around cost would otherwise be. In contrast, if a dual elects a higher premium plan as the regulation allows, the beneficiary would cover the cost of the difference (see page 46639 of the preamble). CMS should clarify that there is no obligation for states to cover the differential for duals who enroll in a plan with a premium higher than the premium subsidy benchmark level.

The proposed regulation provides for auto-enrollment for any dual eligible who has not enrolled in a Part D PDP by the end of the individual's enrollment period or upon becoming dual eligible after an initial enrollment period. While the preamble states that full benefit dual eligibles may choose to change enrollment, we believe that they should not be able to disenroll from one plan and enroll in another in a way that would create a break in coverage since this could potentially result in no prescription coverage at all or, for those states that choose to wrap around, it could force states to cover prescription costs through Medicaid at 100% state cost. Such scenarios conflict with CMS's stated rationale for auto-enrollment, which is to ensure that full-benefit dual eligibles receive outpatient drug coverage under Part D (see p. 46638 of the preamble).

If CMS does allow for a break in Part D coverage, protocols need to be in place for the coordination of and payment for drug benefits for any time period that a Medicaid dual eligible is not actually enrolled in a PDP or MA-PD plan. In addition, states need to be notified whenever a dual eligible disenrolls so that state Medicaid programs will know that the individual is no longer covered under Part D. The exposure to state Medicaid programs and SPAPs is significant as many states that choose to wrap around dual eligibles' Part D coverage will find themselves covering 100% of the prescription costs for those dual eligibles that decline enrollment or disenroll from a Part D plan.

Section 423.34 (p. 46639 of the preamble). Enrollment process. CMS is requesting comments on the most appropriate method and entity to perform auto-enrollment of dual eligibles. If the state assumes responsibility for the auto-enrollment of dual eligibles, then the rule should be amended to include an FFP provision. Since Medicare is a federal benefit, we believe that states should be fully reimbursed at 100% of their costs.

B. Eligibility and Enrollment

Section 423.36(a) (p. 46639 of the preamble). Enrollment periods. *Initial Enrollment Period for Part D—Basic Rule*. States with large SPAPs need time to develop and implement a

wraparound. Indeed efforts in this regard are complicated by the fact that many states with SPAPs will also be seeking to integrate their dual eligible populations into their programs to wraparound a dual eligible's minimal Part D costs. In effect, this creates a need to administer two wraparounds. To the degree that CMS will not announce PDP and MA-PD plans until late 2005 and with enrollment not expected until the beginning of November 2005, it is unlikely that all SPAPs will be ready to integrate their programs with the new Part D benefit. In addition, with the late rollout of Part D, there will be little time to educate consumers and help them understand the Part D benefit and its impact on them. If individual SPAPs are not ready to wrap around the federally subsidized drug benefits, SPAP states should have the option to obtain a lump sum transitional payment in FFY 2006 for SPAP recipients or elect to continue under the drug discount card program for SPAP recipients. It is assumed that non-SPAP residents would be enrolled in the nationwide program.

Left open in the preamble (see page 46727) is who will enroll beneficiaries into the Part D benefit. Section 423.774 (page 46855) of the regulation indicates that states may play a role in determining subsidy eligibility for Medicaid duals, but it is unclear if states will be required to or have the flexibility to assume the eligibility and enrollment for both Medicaid duals and SPAP beneficiaries in Part D. Many states would argue that this is the most efficacious way of enrolling beneficiaries. The regulation also leaves open the prospect that states may be the best entities to handle auto enrollment issues for duals that do not enroll in Part D voluntarily. It is noted that states could provide the best and most timely and accurate Medicaid data for determination in these instances.

But, if states are to assume the exclusive role or part of the role in the eligibility and enrollment process, states should be compensated for that cost. States should be offered the opportunity to count all administrative costs, including the costs of determining eligibility and enrollment in Part D plans as eligible Medicaid expenses, whether the beneficiary is enrolled in Medicaid or an SPAP. Consideration should be given to an enhanced reimbursement rate common to all states.

Section 423.48 (p. 46642 of the preamble). Information about Part D. CMS intends to provide information to beneficiaries in advance of initial and annual enrollment periods that would help promote informed beneficiary decisions. However, it could be very confusing for beneficiaries to receive a notice from CMS about monthly premiums and cost sharing requirements, for example, if the beneficiary is also covered by an SPAP or an employer sponsored plan that elects to wrap around the Part D coverage. Connecticut's intention is to ensure that there is no change in benefits or costs to clients of our SPAP or state retirees as a result of Part D, so a notice from CMS about cost-sharing or premiums that the state intends to cover will generate a great deal of confusion on the part of this elderly and disabled population. As an alternative, we believe that notices to beneficiaries covered by SPAPs or covered by a state employee health plan should be coordinated with states so that beneficiary confusion is minimized.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections

Section 423.100 (p. 46646 of the preamble). Definitions. *Covered Part D drug.* It is unclear whether an over-the-counter (OTC) drug currently covered under Medicaid is still subject to FFP

once Part D is implemented. The rule suggests that covered Part D drugs are prescription-only with minor exceptions and must be Medicaid-covered. We believe that dual eligibles should still be able to get non-prescription drug coverage through Medicaid (with associated FFP to the state) because these items are not covered under Part D. It is not a good use of public dollars to have Medicare pay for a more expensive product plus a dispensing fee when a cheaper product is available and is something the client wants. Such a policy could result in doctors prescribing a prescription medication instead of an OTC product so that the client can have it paid for by Medicare.

Section 423.100 (pp. 46648 – 46649 of the preamble). Definitions. *Long-term care facility.* CMS requests comments on how long-term care facilities should be defined in this section and, specifically, whether intermediate care facilities for the mentally retarded should be designated as long-term care facilities. Currently, the rule suggests that the only entities to be defined as long-term care facilities would be skilled nursing or nursing facilities. The CMS justification is that only those facilities are bound to Medicare conditions of participation that result in exclusive contracts with long-term care pharmacies. CMS appears to be willing to reconsider its position on ICF/MRs if evidence is provided that such facilities have pharmacy contracts like long-term care facilities. While ICF/MRs generally may not contract with long-term care pharmacies, it is the case that many state-run ICF/MRs tend to have separate and distinct contracts with pharmacies that are sensitive to the unique needs of these residents. As well, the preamble notes that Medicare does have special coverage related to mentally retarded individuals and that these individuals will need to be assured access to Part D drugs.

We believe ICF/MRs should be designated long-term care facilities for the following reasons:

- Many of these clients have similar health conditions as those in skilled nursing facilities.
- Contracting arrangements are similar to long-term care facilities to respond to residents' unique needs.
- The special coverage in Medicare for the mentally retarded may be better protected through this designation.
- CMS has indicated that it may exempt special needs populations from cost-sharing and formulary restrictions. Residence in a designated long-term care facility would be an appropriate criterion for inclusion in a special needs group, as discussed elsewhere in our comments. Therefore, it is important to define long-term care facilities to include all facilities where individuals live due to health related reasons and also face barriers to their access to pharmacies and drugs due to their living circumstances.

In addition to ICF/MRs, we believe that the regulation should also include group homes under a 1915(c) home and community-based waiver as long-term care facilities for the reasons outlined above. The populations in these facilities are substantially similar to those in ICF/MRs and often are included in state contracts for pharmacy services for ICF/MRs.

Section 423.100 (p. 46651 of the preamble). Definitions. *Incurred costs.* For persons eligible for both ADAP and Medicare, we believe that ADAP expenditures or, alternatively, at least state expenditures for prescription assistance to persons with HIV/AIDS, should count as "creditable"

coverage and should be added to the list of forms of "creditable" coverage under Section 423.56 of the proposed rule (p. 46644 of the preamble). Contrary to the assertion by CMS in the preamble at pages 46650-46651, state funds used to provide prescription assistance to individuals with HIV/AIDS are no different from SPAP expenditures and should count toward that beneficiary's out of pocket costs. We believe that 1860D-24 of the Act gives the Secretary the discretion to define "insurance or otherwise" as described in 1860D-2 in a way that is consistent with our recommendation. The definition of "incurred costs" in Section 423.100 of the proposed rule should therefore be revised accordingly.

Section 423.100. Definitions, or Section 423.104. Requirements related to qualified prescription drug coverage. Since plans can define a one month supply differently (e.g., 30, 31 or 32 days), the proposed rule should establish a consistent definition of supply limits. Without such a definition, one payor may reject a claim saying the refill is too soon, when another would pay. Ensuring a consistent definition will minimize the impact on SPAPs and employer sponsored wrap-around plans, which are likely at risk for covering any charges for early refills.

Section 423.104(h)(1) (p. 46654 of the preamble). Requirements related to qualified prescription drug coverage. *Access to negotiated prices.* The general understanding, based on the language in this section, is that, for a formulary drug, the negotiated PDP or MA-PD plan price will hold through the "donut hole" period and for a non-formulary drug, the SPAP will pay under their pricing structure. Thus, even though it is the SPAP not the PDP or MA-PD plan covering the expense of a formulary drug, the rebate would go to the PDP or MA-PD plan since it is their negotiated rate that is being used and which was most likely developed based on a claims volume that includes the "donut hole" period. By forcing the SPAPs to integrate their programs with all of the plans (see page 46697 of the preamble), there is a disincentive for the states to wraparound. In addition, states lose any bargaining power with manufacturers with regard to rebates if states can no longer guarantee a certain volume or as large a volume. In effect, SPAP costs could now increase during the "donut hole" for a given client as the state no longer has the ability to reduce ultimate costs through significant rebates from a drug manufacturer as the rebate is already being paid to a PDP or MA-PD plan even though the PDP or MA-PD plan is not covering the actual costs of the drugs during the "donut hole." The law and regulation are clear that PDPs and MA-PD plans have to make the discounted price available to beneficiaries even during the "donut hole" period. We recommend that, for states that need the volume to maintain rebates, they be allowed the option of covering prescription costs under their own arrangements (i.e., under existing reimbursement policies and manufacturer rebate agreements), during the "donut hole" period. While a PDP or MA-PD plan may lose some volume discount, states need the leverage.

Section 423.104(h)(3) (p. 46654 of the preamble). Requirements related to qualified prescription drug coverage. *Negotiated prices. Disclosure.* States must have access to the price concession data that CMS says will be required reporting from the PDPs and MA-PD plans despite confidentiality issues. Because states are at risk of losing discounts in both Medicaid and SPAPs, this data will help states determine the financial impact of wrapping around Part D for these populations.

Section 423.112 (p. 46655 of the preamble). Establishment of prescription drug plan service areas. Because the MMA allows for up to 50 state regions, and because Connecticut is an SPAP state, we believe that CMS should establish PDP regions in a way that allows Connecticut to be its own region. This is of importance to Connecticut because of the need to coordinate between our SPAP and the PDP or MA-PD plans. The needs and concerns of smaller states (especially states with SPAPs) could be subsumed by larger states with different integration needs. Allowing Connecticut to be its own region will help ensure that any PDP or MA-PD plans will be responsive to meeting Connecticut's needs, and maintaining continuity of care for Connecticut's vulnerable populations.

Section 423.120(a) (pp. 46658 - 46659 of the preamble). Access to covered Part D drugs. *Assuring pharmacy access.* The proposed rule distinguishes between preferred and non-preferred network pharmacies, where a non-preferred pharmacy is a network pharmacy that offers Part D enrollees higher cost-sharing for covered Part D drugs than a preferred pharmacy. As noted in the preamble, cost sharing can vary not only based on the type of drug or formulary tier, but also on a particular pharmacy's status within the plan's pharmacy network. This adds yet another level of complexity to the plan, especially as SPAPs or employer sponsored plans try to wrap around and coordinate with multiple PDPs and MA-PD plans. Further, while the proposed rule appears to guarantee beneficiaries wide access to pharmacies, a PDP or MA-PD plan could still meet these access requirements but in effect have a very small preferred network that discourages enrollment of certain populations as well as enrollment from certain geographic areas. On page 46659 of the preamble, CMS says it will review the design of proposed plans to ensure that such plans do not "substantially discourage" enrollment. This is important as the current rule does not ensure adequate access to preferred pharmacies and could be used by PDPs or MA-PD plans to shift certain costs back to SPAPs or employer sponsored plans that choose to wrap around the Part D benefit. To maximize access, CMS should establish clear guidelines to ensure the broadest network of preferred pharmacies throughout a PDP's or MA-PD plan's coverage area. We believe this could best be achieved by requiring plans to meet network access standards using preferred pharmacies. In addition, the rule should mandate that CMS approve changes to a PDP's or MA-PD plan's network annually, as well as any substantive midyear changes in plan networks.

Section 423.120. Access to covered Part D drugs. The MMA does not appear to address the issue of continuity of benefits with respect to dual eligibles. Since the existing provisions in Title XIX have not been repealed, CMS will need to clarify whether state Medicaid programs continue to be bound by the requirement to provide non-formulary drugs as dual eligibles transition to Medicare Part D. Similarly, if there is an appeal of a formulary decision, we believe that Medicare should pay for the cost of the requested prescription pending resolution of the appeal, so that Medicaid is not responsible for continuing coverage at 100% state cost.

Section 423.120 (p. 46661 of the preamble). Access to covered Part D drugs. CMS is requesting comments on special needs populations and any special treatment needed for such populations as it relates to flexibility and cost containment in the program. The preamble recognizes the unique health needs of such populations and notes that open formularies are the norm for clients in long-term care facilities. Section 423.782(a)(2)(ii) also exempts individuals in long-term care facilities from cost-sharing.

Skilled nursing facility residents and residents of ICF/MRs appear to be deemed institutionalized under the Act and would be free of cost-sharing requirements. That may not be the case for residents of 1915(c) waiver group homes and other similar facilities for persons with mental illness or mental retardation. Because these special needs populations have substantially similar financial status and health needs as residents of skilled nursing facilities and ICF/MRs, we believe that all of these populations should be treated equally.

While residents of ICF/MRs and group homes and other facilities may have some income disregarded (those in nursing homes do not), their income is still extremely limited. The personal needs allowances (PNAs) in skilled nursing facilities are generally well below $100 in most states, and need only be $30 per month according to federal Medicaid law. These PNAs must cover personal incidentals as well as co-pays and non-formulary drugs. If not deemed institutionalized or otherwise freed of cost-sharing, a medically fragile individual subject to cost-sharing and with multiple prescriptions could not afford even the minor cost-sharing under Part D.

The financial wherewithal of all special needs populations, including those in skilled nursing facilities and ICF/MRs otherwise free of cost-sharing, may not be able to afford their medications or have true access to them if formulary restrictions apply. Formulary restrictions could force such special needs individuals to utilize the majority or all of their monthly income on medications if a needed drug is not on a formulary, and must be purchased out-of-pocket while pursuing an appeal. Indeed, in some cases, their PNA would not be adequate to cover the out-of-pocket cost, resulting in a break in therapy. Furthermore, few of these individuals have the cognitive abilities to deal with appealing a formulary denial and it would be an enormous burden for their group home or case manager to have to navigate the appeals process on behalf of numerous clients.

CMS clearly recognizes in the preamble that such populations may need special treatment because they are more sensitive to and less tolerant of many medications. Also noted is that most long-term care pharmacies have open formularies to respond to this fact. In general, the existence of any formulary restrictions and cost-sharing could easily lead to greater medical costs for non-drug benefits for these exceedingly medically fragile populations. Research published by the Center for Health System Change has documented that barriers to access for drugs for the Medicaid population, including co-payments and prior authorization, have led to reduced adherence to medically necessary drug regimens. Failure to properly comply with medication therapy results in exacerbations of chronic and acute illnesses that, at a minimum, bring these patients back to the physician and, at worst, puts them in a hospital or other institutional setting.

We believe strongly that all special needs populations must be exempt from formulary restrictions and cost-sharing. Formulary exceptions and exemptions from cost-sharing are important for the following groups:

- Residents of skilled nursing facilities and other like entities.
- Residents of ICF/MR facilities.
- Residents of 1915(c) waiver group homes.

- Residents of state-run group homes that operate similarly to 1915(c) waiver group homes but have not technically met federal Medicaid qualifications.
- Those with chronic mental illness, whether they qualified for federal SSI or not. These individuals often are required to have less-than-30-day supplies of prescription drugs because of suicidal tendencies or the need for close monitoring. Formularies and cost-sharing for this population would complicate the already major challenge of drug adherence for many of these individuals, whose very illnesses make it difficult to adapt to change. Furthermore, paying out of pocket for denied drugs would force these individuals to exhaust the vast majority of their income each month. States that have implemented even nominal co-pays on Medicaid recipients have at least anecdotally found that such co-pays have dissuaded the mentally ill from filling prescriptions. This was the case even when Medicaid beneficiaries were told that federal law dictated that the drug could not be withheld due to lack of payment of co-pays. Thus, we know that financial barriers for this population result in under-treatment and consequently larger costs for non-drug services.
- Those with other chronic health conditions, such as HIV/AIDS. These beneficiaries often have multiple prescriptions due to the complex nature of their conditions. As such, they would be unable to afford cost-sharing or the additional financial implications of being subjected to a restrictive formulary.
- Beneficiaries who are otherwise on Medicaid community-based waivers (to avoid institutionalization) and therefore have very limited incomes should also be considered to be free of cost-sharing and certain formulary restrictions. This would apply to individuals on home and community-based waivers for the elderly and disabled or those on Katie Beckett waivers.

Section 423.120 (see also section 423.124) (p. 46657 of the preamble). Access to covered Part D drugs. CMS is seeking comments regarding whether plans should be required to contract with long-term care pharmacies. Section 1860D-4(b)(1)(C)(iv) of the law gives the Secretary discretion to require plans to contract with long-term care pharmacies. We would recommend that section 423.120 of the rule be modified to include access to all long-term care pharmacies.

Section 423.120 (p. 46659 of the preamble). Access to covered Part D drugs. The proposed regulation provides for fairly stringent rules to ensure that beneficiaries have access to medically necessary drugs. While section 1860D-4(b)(3)(A) of the Act requires that the formulary be "developed and reviewed" by a P&T committee, it is CMS' interpretation that the P&T committee may establish and change drugs on a formulary and that the committee's decision is binding on the plan. Section 423.120 of the regulation, however, requires only that a PDP's and MA-PD plan's formulary be reviewed by a P&T committee. The regulation should be amended to adopt CMS' intent about the binding nature of the P&T committee's decisions.

Section 423.120(a)(6) (p. 46649 of the preamble). Access to covered Part D drugs. *Level playing field between mail-order, and network pharmacies.* The proposed rule provides that those who choose an extended supply of a Part D drug through a retail pharmacy would be responsible for the differential between the retail pharmacy's negotiated price and the network's mail-order

negotiated price. We are concerned about this policy because, if that amount is greater than the amount the SPAPs or employer sponsored wrap-around plans would have paid for the extended supply, then costs are being shifted to the states.

CMS is seeking comments on their proposal that this price differential be counted as an incurred cost against the annual out-of-pocket threshold. We support this position and recommend that the rule clearly state that this differential counts towards out-of-pocket expenditures.

Section 423.120(b)(2) (p. 46660 of the preamble). Access to covered Part D drugs. *Inclusion of drugs in all therapeutic categories and classes.* There is a requirement that PDPs and MA-PD plans have at least two drugs in each class as well as have generics available. The regulations are not clear, however, whether generics can be one of the two drugs. We believe two brands plus a generic (when available) should be the minimum requirement.

Section 423.120(b)(5) (p. 46819 of the preamble). Access to covered Part D drugs. *Provision of notice regarding formulary changes.* Section 1860D-4(b)(3)(E) of the Act states: "Any removal of a covered Part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists." Of concern is that CMS has interpreted "appropriate notice" to mean 30 days. Specifically, section 423.120 (page 46819) of the proposed rule reads: "A PDP sponsor or MA organization offering an MA–PD plan must provide at least 30 days notice to CMS, affected enrollees, authorized prescribers, pharmacies, and pharmacists prior to removing a covered Part D drug from its plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug." CMS may maintain that any arbitrary change is unlikely as it has a requirement for all formulary changes to go through a P&T committee that meets specifications and the approval of CMS. The issue is not that changes might be made arbitrarily, but it simply does not allow enough time for the SPAPs to respond to or integrate the formulary change in their programs. Therefore we recommend that, at a minimum, PDPs be required to grandfather-in coverage of a deleted drug for anyone who was taking the medication prior to the deletion, unless the deletion is due to the new availability of a generic substitute or due to the FDA's removal of the drug from the market due to safety reasons. This should not be construed as prohibiting a PDP from asking physicians to voluntarily switch their patients to less costly drugs, in a therapeutic substitution initiative. In the alternative, we believe that any formulary change should require 90 day notice to all beneficiaries as well as SPAPs and state retiree plans.

Section 423.120(b)(5) (p. 46661 of the preamble). Access to covered Part D drugs. *Provision of notice regarding formulary changes.* CMS proposes that PDPs and MA-PD plans only inform those taking a drug affected by a formulary change of such a change. We believe that all beneficiaries and all parties, including SPAPs and state retiree plans, should be notified of formulary changes.

Section 423.124 (p. 46662 of the preamble). Special rules for access to covered Part D drugs at out-of-network pharmacies. In the preamble, CMS details four scenarios where out of network access would be guaranteed. A fifth scenario for out-of-network access should be added that specifically identifies those retirees who reside in different parts of the country during the year

("snowbirds") and are outside of the service area, (e.g., they reside for several months at a time in Connecticut and in Florida). Regional plans may not be sufficient for snowbirds. Even if a plan's service area does cover both areas of the country where the snowbird resides, the plan may not use the same contracting pharmacies in the dual locations, thereby subjecting the retiree to pay higher costs from out-of-network pharmacies during a portion of the year. This is an important consideration for employers who currently have (or are required to have per union agreements or otherwise) prescription drug coverage that is nationwide or covers entire regions of the country and are deciding whether to switch to a plan that has Medicare Part D as the primary payer for prescription coverage.

D. Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

Section 423.153 (p. 46667 of the preamble). Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste. CMS requests comments regarding a proposed requirement that cost-savings strategies be under the direction and oversight of a Pharmacy and Therapeutics Committee. We support this proposal.

Section 423.153 (p. 46670 of the preamble). Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste. For states to run successful disease management programs, it is important that they retain the ability to access prescription history for dual eligibles. In addition, in order to minimize prescription abuse by clients who are in lock-in status, states need the ability to continue to track a client's prescription history. The exchange of data between PDPs / MA-PD plans and states is critical. Limiting the number of plans (see our comments in Subpart J) would facilitate integration and allow the state to better coordinate care.

Section 423.153(c). Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste. *Data Sharing/ Quality Assurance.* To ensure an effective drug benefit program, quality assurance and evaluation are essential. In particular, SPAPs and state retiree plans must have access to data to evaluate program performance. As a result, we believe CMS should share Medicare evaluation data with SPAPs and state retiree plans to allow states to make decisions regarding ongoing quality improvements. We also believe CMS should issue an annual report assessing the effectiveness of the Part D drug benefit program. The report should include detailed information on claim denials; exceptions and appeals and their outcomes; the turnaround times for PDP processing of prior authorization requests, exception requests, and re-determination requests; and, the percent of the total negotiated drug costs paid by the PDP versus the beneficiary, SPAP, or state retiree plan.

F. Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation

Sections 423.104 and 423.272 (p. 46681 of the preamble). Review and negotiation of bid and approval of plans submitted by potential PDP sponsors or MA organizations planning to offer MA–PD plans. The general understanding, based on section 423.104 of the proposed rule and page 46654 of the preamble, is that, for a formulary drug, the negotiated PDP or MA-PD plan price will hold through the "donut hole" period and for a non-formulary drug, the SPAP will pay under their pricing structure. Thus, even though it is the SPAP not the PDP or MA-PD plan covering the expense of a formulary drug, the rebate would go to the PDP or MA-PD plan since it is their negotiated rate that is being used and which was most likely developed based on a claims volume that includes the "donut hole" period. By forcing the SPAPs to integrate their programs with all of the plans (see page 46697 of the preamble), there is a disincentive for the states to wraparound. In addition, states lose any bargaining power with manufacturers with regard to rebates if states can no longer guarantee a certain volume or as large a volume. In effect, SPAP costs could now increase during the "donut hole" for a given client as the state no longer has the ability to reduce ultimate costs through significant rebates from a drug manufacturer as the rebate is already being paid to a PDP or MA-PD plan even though the PDP or MA-PD plan is not covering the actual costs of the drugs during the "donut hole." The law and regulation are clear that PDPs and MA-PD plans have to make the discounted price available to beneficiaries even during the "donut hole" period. We recommend that, for states that need the volume to maintain rebates, they be allowed the option of covering prescription costs under their own arrangements (i.e., under existing reimbursement policies and manufacturer rebate agreements), during the "donut hole" period. While a PDP or MA-PD plan may lose some volume discount, states need the leverage.

Section 423.272 (p. 46681 of the preamble). Review and negotiation of bid and approval of plans submitted by potential PDP sponsors or MA organizations planning to offer MA–PD plans. This section allows CMS to reject any bid if it finds that it will "substantially discourage enrollment by certain Part D eligible individuals." In the preamble, CMS asks for comments on how to evaluate the proposed formularies in bid proposals. We believe a reasonable formulary should assure that 90% of patients with any particular diagnosis could find their medication on the formulary. CMS should therefore establish a formulary evaluation criterion that would trigger a much more detailed evaluation of the adequacy of the formulary if a drug plan failed to offer enough medication choices to assure that 90% of the beneficiaries will be able to continue on their current therapies. A formulary that requires vast numbers of elderly to switch or appeal will result in the potential for numerous interruptions in drug therapy that result in other medical cost and quality problems. It will also result in significant costs for SPAPs that will wrap around Part D by picking up the costs of drugs that are denied as non-formulary drugs.

Section 423.293(a) (p. 46685 of the preamble). Collection of monthly beneficiary premiums. *General rule.* The regulation allows for payment of premiums directly to PDPs or MA-PD plans. Because CMS will have the most up-to-date information about which plan a beneficiary is enrolled in, SPAPs should pay premiums directly to CMS. One mechanism that could be used is to parallel the existing programs whereby states pay QMB and SLMB cost-sharing to the federal government through Medicaid reimbursement withholds.

The regulation also allows for the collection of beneficiary premiums through withholding from Social Security checks. However, in the case where an SPAP state wishes to wrap its SPAP

benefit around the Part D benefit, such withholding is inappropriate. Once again, we want the option of paying premiums directly to CMS. Such payments could be made similar to the way Medicare buy-in payments are made for dual eligibles. With state payment of premiums, we would want to ensure that there are beneficiary protections to prevent disenrollment of the beneficiary if a federal-state payment dispute arises.

G. Payments to PDP Sponsors and MA Organizations Offering MA-PD Plans for All Medicare Beneficiaries for Qualifies Prescription Drug Coverage

Section 423.336 (p. 46693 of the preamble). Risk-sharing Arrangements. *Plan spending below target*. In the preamble, CMS writes "if plan spending fell below the target, plans would share the savings with the government." Because states are contributing toward the cost of running the Part D program through the clawback, any savings that accrue to "the government" should be shared with states.

I. Organization Compliance With State Law and Preemption by Federal Law

No comments.

J. Coordination Under Part D Plans With Other Prescription Drug Coverage

Section 423.464(a) (p. 46700 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *General rule*. This section addresses the data sharing that should occur with SPAPs as to coordination of benefits, calculation of out-of-pocket requirements, etc. In our view, the regulation is weak with respect to safeguarding states' needs for coordination because it says that PDPs "must permit" SPAPs to coordinate with PDPs. We believe that the rule should be modified to read that PDPs and MA-PD plans "are required to coordinate with SPAPs." We also believe that, once the initial coordination is in place, language requiring ongoing coordination needs to be added to the rule. In addition, we believe explicit language in the contracts of PDPs and MA-PD plans (see section 423.505 of the rule) must be included to ensure the proper data sharing and coordination, especially if PDPs and MA-PD plans are responsible for TrOOP calculation, as opposed to a separate vendor contracted by CMS. We have offered additional comments under Subpart K, below, regarding contractual language that would help effectuate the requirement for PDPs and MA-PD plans to coordinate with SPAPs.

Section 423.464(a). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *General rule*. While this section of the regulation requires PDPs and MA-PD plans to permit SPAPs to coordinate with plans, the detail is insufficient to address the significant continuity of care concerns raised by SPAP plans on behalf of their beneficiaries. The regulation needs to be stronger on the requirements of PDPs and MA-PD plans to share data and enter into agreements regarding continuity of care and coordination of such things as prior authorization, generic substitution and formulary changes. The regulation should make clear that PDPs and MA-PD plans are required to work with SPAPs and give some deference to the controls,

processes, and limitations (e.g., preferred drug list, prior authorization and generic substitution decisions) already established by SPAPs. We recommend that state rules addressing patient access to drugs should govern PDPs and MA-PD plans. To protect continuity of care, procedures should be put in place before the January 2006 start date to mandate dialogue concerning SPAP clients that have already been prior authorized for certain brand drugs.

Section 423.464(e)(ii) (p. 46697 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Non-discrimination.* Section 1860D-3 of the Act requires the Secretary to ensure that each Part D eligible individual has a choice of at least two qualifying plans or, if necessary, the opportunity to enroll in a fallback prescription drug plan. Section 1860D-23(b)(2) prohibits SPAPs from working with a subset of plans available in the region (the so-called "anti-discrimination" requirement), which means that SPAPs must coordinate with multiple plans. Section 426.464(e)(1)(ii) operationalizes the Act by requiring SPAPs to provide assistance "to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls." Section J of the preamble (page 46697) states:

> "We are interpreting the nondiscrimination language to mean that SPAPs, if they offer premium assistance or supplemental assistance on Part D cost sharing, must offer equal assistance by all PDPs or MA–PD plans available in the State and may not steer beneficiaries to one plan or another through benefit design or otherwise. State programs cannot, for example, use the threat of withholding SPAP enrollees to negotiate coverage, premium or formulary changes with PDPs or MA–PD plans. Violations of the non-discrimination rule will jeopardize the program's special status with respect to true out-of-pocket costs. That is, a State program that discriminates does not qualify under the definition of an SPAP, and consequently, its contributions to cost sharing do not count toward the out-of-pocket limit."

CMS indicated in an 8/4/04 conference call that the actual operational details were not yet defined. For administrative ease, efficiency and cost effectiveness, states need the ability to limit the number of PDPs with which they need to coordinate to one or two. The states need to have ways to ratchet down their costs, especially in light of no guarantee of reimbursement for ongoing administrative costs, the strong likelihood of a loss of drug rebate dollars in SPAP and Medicaid programs, and the ongoing "donut hole" costs to states. More to the point, continuity of care can be maximized (and costs to the state and federal governments minimized) if states have the ability to work with one or two preferred PDPs. Further, many SPAPs will be providing some form of wrap around coverage or will be subsidizing a plan's premiums. As a result, it is essential that SPAPs be given the opportunity to steer their beneficiaries away from those PDPs requiring disproportionately high premiums without providing any clear benefits to their enrollees. The language in section 423.464 of the regulations should be broadened to allow states to contract with one or two PDPs as long as the contracts are competitively bid and limiting the number of PDPs would be in the best interest of state SPAP clients because the state clearly defined what it was looking for during the bidding process. We believe that states would still be able to meet the anti-discrimination test with this process. As an alternative, states should be allowed to design a wrap around and limit enrollment of its SPAP and dual-eligible clients in those plans that agree to the state's contractual requirements. As a further alternative, states should have the right to auto-enroll any SPAP clients who are required as a condition of enrollment in an SPAP to enroll in Part D but fail to do so (or duals that either refuse to enroll voluntarily or disenroll from Part D) in a state's preferred PDP vendor(s). Indeed, section 423.34

of the regulation refers to states potentially doing an automatic and random enrollment function with regard to duals that do not voluntarily enroll. We believe that allowing states to enroll SPAP clients and dual eligibles in default plans, but then allowing those enrollees to choose another PDP if they do not want to be in the default plan, will meet the test of anti-discrimination.

Section 423.464(f)(3) (pp. 46696-46700 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Imposition of fees.* While SPAPs are not required to coordinate with PDPs (see page 46701 of the preamble), section 423.464(a) of the regulation says PDPs "must permit" SPAPs to coordinate with PDPs and MA-PD plans. The rule allows Part D plans to impose fees on SPAPs for required coordination, including enrollment, claims processing, payment of premiums, and administrative processes (see page 46700 of the preamble). Because no funding is provided to states for this coordination, such fees should not be imposed on the states. While 1860D-11(j) of the Act says that fees unrelated to the cost of coordination are not to be imposed, we believe that CMS has the authority to interpret this language to prevent unnecessary and unreasonable fees from being charged at all. Instead, CMS should establish a baseline requirement of coordination that is applicable nationwide, with any costs related to that coordination factored into a plan's bid and paid by CMS. Only extraordinary costs related to a state's unique situation that are beyond the scope of normal, reasonable national-standard coordination requirements should be borne by the state, and even then we seek the ability to negotiate such costs in concert with CMS before plan contracts are executed. Additionally, it is important that the regulations and the PDP and MA-PD plan contracts signed with CMS be clear and specific on the level of coordination that PDPs and MA-PD plans must have with SPAPs, and that any state-specific requirements be included in the contracts executed by CMS and the plans. Without these protections, there is absolutely no incentive for plans to negotiate in good faith with states, and states could be subjected to unreasonable and excessive fees as a result of needing to coordinate SPAP and retiree coverage with the plans. (We have made related comments on contract protections in Subpart K.)

Section 423.464(f)(ii) (pp. 46698 – 46699 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Employer Options*. If employers pick an option that requires their retirees to enroll in Part D with Medicare as the primary payer, the final rule should contain special access and financial protections to safeguard those employers with significant numbers of "snowbird" retirees. As discussed in our comments on Subpart C, above, this segment of the retiree population has access issues that must be addressed. This is particularly important because there is still uncertainty over how many plans that currently offer nationwide drug discount cards will participate in Part D due to the notion of presumed risk.

Section 423.464(d) (p. 46701 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Cost Management Tools.* Section 423.464(d) of the proposed rule and section 1860D-24(c)(1) of the Act allow PDPs and MA-PD plans to continue to use cost-containment strategies even as they relate to SPAPs or other drug plans providing wrap-around or supplemental coverage. CMS seeks comments in the preamble on how CMS "can ensure that wrap-around coverage offered by SPAPs and other insurers does not undermine or eliminate the cost management tools established by Part D plans." The greater concern may be how to ensure that Part D plans are not incentivized to cost shift to SPAPs and state retiree plans. If states are

paying for coverage for SPAP enrollees who are also Medicare Part D beneficiaries (regardless of whether the PDP or MA-PD plan is directly providing the additional benefits under contract with the SPAP or whether the SPAP is coordinating such wrap around coverage with the PDP or MA-PD plan), we believe CMS should help support state laws and policies regarding SPAP coverage. States are as interested in cost management as CMS—but we are also mindful of the impact on vulnerable populations and the need to ensure continuity of care. The rule makes no attempt to prevent PDPs and MA-PD plans from controlling or overruling SPAP decision-making when coverage is paid for by SPAPs, particularly in the "donut hole." Section 423.464(d) of the rule should be modified to require that PDPs and MA-PD plans accede to SPAP rules where SPAPs are paying for beneficiary coverage.

Section 423.464(e)(2) (p. 46702 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Special treatment under out of pocket rule*. CMS indicates it is interested in comments on whether SPAPs should be required to provide feedback on how much TrOOP they have paid. Because PDPs know how much of the claim they have paid and because beneficiary and SPAP expenditures both count as TrOOP costs, it is irrelevant how much of that claim is SPAP related. There are enough administrative and coordination requirements in MMA without imposing more. The rule should be modified by deleting the phrase "collect information on and" from Section 423.464(e)(2). PDPs should count any non-PDP costs for SPAP enrollees as out of pocket for purposes of TrOOP calculation.

Section 423.464(e)(2) (pp. 46706 and 46789 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Tracking TrOOP*. CMS seeks comments on whether a single, central entity or multiple PDPs are best suited to tracking TrOOP. Because of coordination requirements with SPAPs, we recommend that one central entity (CMS) maintain a data system rather than having multiple PDPs maintaining separate systems.

K. Proposed Application Procedures and Contracts With PDP Sponsors

Section 423.505. Contract Provisions. (cross reference Section 423.464. Coordination of Benefits). Section 423.464 of the rule and page 46700 of the preamble address the data sharing that will occur with SPAPs as to coordination of benefits, calculation of out-of-pocket requirements, etc. See our comments under Subpart J, above, regarding strengthening the rule by requiring PDPs to coordinate with SPAPs. CMS has proposed no specific contractual language for PDPs and MA-PD plans that would describe the required coordination. Section 423.505 of the proposed regulation only states that PDPs would need to "comply with the coordination requirements…in subpart J". In order to implement this requirement, we believe explicit language in section 423.505 of the rule as well as in the contracts of PDPs and MA-PD plans must be included to ensure the proper data sharing and coordination, especially if PDPs and MA-PD plans are responsible as opposed to a separate vendor contracted by CMS.

Section 423.505. Contract Provisions. (cross reference Section 423.464. Coordination of Benefits). *Fees*. CMS has proposed no specific contractual language for PDPs and MA-PD plans that would prevent unreasonable or excessive fees from being imposed (see comments to Section 423.464 under Subpart J). Section 423.505 of the proposed regulation only states that

PDPs would need to "comply with the coordination requirements…in subpart J". Because no funding is provided to states for coordination, such fees should not be imposed on the states. While 1860D-11(j) of the Act says that fees unrelated to the cost of coordination are not to be imposed, we believe that CMS has the authority to interpret this language to prevent fees from being charged at all, or at a minimum the imposition of unnecessary and unreasonable fees. Instead, CMS should establish a baseline requirement of coordination that is applicable nationwide, with any costs related to that coordination factored into a plan's bid and paid by CMS. Only extraordinary costs related to a state's unique situation that are beyond the scope of normal, reasonable, national-standard coordination requirements should be borne by the state, and even then we seek the ability to negotiate such costs in concert with CMS before plan contracts are executed. Additionally, it is important that the regulations and the PDP and MA-PD plan contracts signed with CMS be clear and specific on the level of coordination that PDPs and MA-PD plans must have with SPAPs, and that any state-specific requirements be included in the contracts executed by CMS and the plans. Without these protections, there is absolutely no incentive for plans to negotiate in good faith with states, and states could be subjected to unreasonable and excessive fees as a result of needing to coordinate SPAP and retiree coverage with the plans. (We have made related comments on contract protections in Subpart J.)

Sections 423.509 and 423.510. Termination of contract by PDP or CMS. Currently, SPAPs are not among the parties specifically delineated as requiring notification by either PDPs or CMS. Given the significant impact Part D plans will have on SPAPs and state retirees, states must be included as parties to be notified of the termination of PDP contracts. At a minimum, SPAPs should be allowed greater notice than to the public in order to coordinate coverage as well as current and future enrollment. Sections 423.507 through 423.510 of the proposed rule should be amended to include timely notification to SPAPs and state retiree plans of termination of a PDP contract. (Similar notification requirements should be imposed by CMS on MA-PD plans.)

L. Effect of Change of Ownership or Leasing of Facilities During Term of Contract

Sections 423.551(c) and 423.552(a)(1) (pp. 46716-46717 of the preamble). Advance Notice Requirement. Currently, states are not among the parties specifically delineated as requiring notification by either PDPs or CMS. Given the significant impact Part D plans will have on SPAPs and state retirees, states must be included as parties to be notified of changes in ownership. To ensure continuity of care and minimize disruption of coordinated benefits, the advanced notification requirements in sections 423.551 and 423.552 of the proposed rule should be amended to include states, especially SPAP states.

M. Grievances, Coverage, Reconsiderations, and Appeals

Section 423.562. General Provisions. (cross-reference Section 423.44 (p, 46641 of the preamble). Disenrollment by the PDP). Section 423.44 of the proposed rule allows for the disenrollment of beneficiaries whose behavior is "disruptive, unruly, abusive, uncooperative or threatening." Because of the special needs of the dual eligibles, as well as the elderly and disabled served under our SPAP, an adequate appeals process needs to be established as well as

provisions to ensure that there will be no lapse in coverage since lack of coverage would threaten their health needs.

Sections 423.560 to 423.638. To protect continuity of care, procedures should be put in place before the January 2006 start date to mandate dialogue between states and PDPs and MA-PD plans concerning SPAP clients that have already been prior authorized for certain brand drugs. In Connecticut, atypical antipsychotic drugs are exempt from prior authorization for clients currently on them – only newly prescribed atypical antipsychotics that have at least three A-rated generics available for substitution are required to get prior authorization, and then for initial scripts only. The regulation should be modified to ensure that PDPs honor the existing prior authorization and generic substitution decisions made by SPAPs. This will help maintain continuity of care.

Section 423.560. Definitions, and Section 423.562. General Provisions. *SPAPs as Authorized Representatives, and Data Sharing*. While the definition of an authorized representative under section 423.560 could be interpreted to include an SPAP acting on behalf of an SPAP client, the regulation should be clarified. For both administrative and programmatic reasons, it is important that SPAPs be allowed to be the authorized representatives for SPAP clients.

For example, regarding step therapy, SPAPs may have claims history to show that the PDPs and MA-PD plans preferred drug was previously tried. PDPs and MA-PD plans should be required to coordinate with SPAPs and share claims history because SPAPs may have the longest and most complete clinical history. This is especially important because people may change PDPs and MA-PD plans every year, but the SPAP will remain consistent.

SPAPs and PDPs / MA-PD plans need to coordinate or at least share clinical criteria for prior authorization and also generic substitution. It is important both to avoid having two entities undertake prior authorization but also to protect continuity of care.

It will be confusing for SPAPs that have full benefit plans to know whether they should pay under their wrap-around when a PDP or MA-PD plan denies coverage. For example, when denials occur for a DUR reason, how will an SPAP know not to pay for a contraindicated drug? Certainly, SPAPs will want to continue with their own DUR programs to both protect their clients as well as prevent unnecessary costs. This will be challenging if the PDP or MA-PD plan and SPAP DUR programs don't have the same system edits.

Again, the rule must be clarified to ensure that the definition of "authorized representative" includes SPAPs and retiree plans acting on behalf of a beneficiary. We also recommend that CMS add requirements to Section 423.562 to ensure that PDPs are required to share data with SPAPs, at no cost to SPAPs, to ensure coverage is coordinated to promote continuity of care.

Section 423.566 (pp. 46718-46721 of the preamble). Coverage determinations. A phase-in period for formulary denials by PDPs and MA-PD plans for new enrollees is needed. This would ensure that new enrollees don't first discover that they aren't covered for a drug when they have run out and are seeking a refill – leaving them no time to pursue a switch or to appeal. This is especially important for individuals taking multiple drugs who may discover that more

than one medication needs to be switched. Good clinical practice calls for not switching multiple drugs at once, but rather doing them one at a time, so that it is clear which drug is causing side effects, if any show up. An exception should automatically be granted any time an individual is running into more than one denial for non-formulary drugs. Otherwise, SPAPs and employer sponsored wrap-around plans will wind up paying for all of these denials.

Section 423.568(a). Standard timeframe and notice requirements for coverage determinations. The proposed rule allows PDPs up to 14 days to issue a decision on the request for an exception. This timeframe, however, is far too lengthy and is inconsistent with current industry practice as well as Medicaid standards. If adopted, this standard could put vulnerable populations, particularly those with chronic illnesses, at significant risk. PDPs should be required to render a decision on a request for an exception within 48 to 72 hours. While an exception request is pending, the beneficiary should receive the requested prescription (at a minimum, a 3-day supply if a 48-72 hour timeframe for PDP review of exception requests is adopted).

Section 423.578. Exceptions process. We have a number of recommendations regarding the proposed exceptions process. First, the final regulation must ensure that exceptions processes dovetail with SPAP prior authorization processes. Second, SPAPs must be allowed to be authorized representatives for the individual during the exception appeal. Third, while an exception is pending for dual eligibles, Medicare should pick up the full cost of the requested prescription until a decision is rendered so that states are not forced to pick up the costs as a potential Medicaid and SPAP continuity of care issue. This is particularly important because of restrictions on limiting Medicaid state plan services for the dual eligible population. Fourth, PDPs should be required to grandfather-in coverage of a deleted drug for anyone who was taking the medication prior to the deletion, unless the deletion is due to the new availability of a generic substitute or due to the FDA's removal of the drug from the market due to safety reasons. This should not be construed, however, as prohibiting a PDP from asking physicians to voluntarily switch their patients to less costly drugs as part of a therapeutic substitution initiative. Finally, we urge inclusion of language to guarantee access to lower co-pays when midyear increases are made by the PDPs.

Section 423.600 (p. 46722 of the preamble). Reconsideration by an Independent review entity (IRE). Connecticut supports the proposal for establishing an independent review entity for reconsideration of PDP redeterminations.

Sections 423.560 to 423.638. Grievances, Coverage Determinations, and Appeals. As an alternative to the dispute resolution framework presented in the proposed rule, we offer a potential retrospective dispute settlement framework. Under this alternative, a drug is authorized in favor of continuity of care while the dispute resolution process takes place. The system could be modeled after several Medicare demonstration programs operating in states dealing with home care coverage in the Medicare and Medicaid programs.

N. Medicare Contract Determinations and Appeals

No comments.

O. Intermediate Sanctions

No comments.

P. Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Section 423.772 (pp. 46725-46726 of the preamble). Definitions. *Family Size.* In addition to applicant and his/her spouse, the household includes "individuals who are related to the applicant or applicants…and who are dependent on the applicant or the applicant's spouse for at least one-half of their financial support." As the preamble indicates, this rule is dissimilar to the SSI as well as eligibility determination rules for Transitional Assistance under the current drug discount card program. By requiring the consideration of a household member other than a spouse, complexity is added to the process, increasing the administrative burden on states performing eligibility determinations for low income subsidy individuals. It is also very different than how eligibility is determined for our SPAP, and as such, it increases the administrative burden involved in wrapping around the Part D benefit. The rule should be changed to have greater consistency with existing government programs.

Section 423.772. Definitions. *Resources*. The proposed rule at Section 423.773 includes resource limits (also known commonly as "asset limits") for "full subsidy eligible" and "other low-income subsidy" eligible individuals. The definition for resources under Section 423.772 of "other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act" is problematic because it is vague. It is not clear how this 20-day liquidation rule should be interpreted. The regulation should provide a specific list of instruments and asset types that are excluded. For example, cash surrender value of life insurance should be totally excluded. Providing a clear list of excluded "non-liquid" resources will foster uniform eligibility determination and ease the administrative burden for SPAPs.

Section 423.772. Definitions. *Institutionalized individual.* (cross reference Section 423.782. Cost-sharing subsidy.) While institutionalized persons have no cost sharing for covered Part D drugs covered under their PDP or MA-PD plans, the definition of "institutionalized" is problematic. Individuals in residential care homes, group homes, etc. are vulnerable populations and their care is typically paid for or subsidized by states and the federal government. The imposition of cost-sharing on these individuals could have the unintended effect of encouraging institutionalization in order to provide prescription coverage under Part D. The incentive should be for the client to choose the community option, not the institutional option. Community settings such as residential care homes and group homes should be included in the definition of "institutionalized individual."

Section 423.782(a)(2)(ii) (p. 46729). Cost-sharing subsidy. *Full subsidy eligible individuals.* Consistent with the MMA statute, this section rules out any cost-sharing for institutionalized beneficiaries, although page 46729 of the preamble may not completely comport with the outlined section. The preamble refers to 1902(q)(1)(B) of the Social Security Act:

(B) In this subsection, the term "institutionalized individual or couple" means an individual or married couple—

(i) who is an inpatient (or who are inpatients) in a medical institution or nursing facility for which payments are made under this title throughout a month, and

(ii) who is or are determined to be eligible for medical assistance under the State plan.

It would appear that the SSA section above does define ICF/MRs as institutions, so those clients would not be subject to cost sharing. It is less clear whether individuals in 1915(c) waiver group homes, assisted living facilities, residential care homes, boarding homes and other such entities would be defined also as "medical institutions." For the reasons outlined in our comments on special needs populations (section 423.120), we strongly believe that all of these individuals need to be exempt from cost-sharing. Thus, the proposed rule should be clarified to include in the definition of "institutionalized beneficiary" all individuals in 1915(c) waiver group homes, assisted living facilities, residential care homes, boarding homes and other such therapeutic residential facilities.

Q. Guaranteeing Access to a Choice of Coverage (Qualifying Plans and Fallback Plans)

See our comments under Subpart J regarding nondiscrimination and use of preferred plans.

Section 423.855 (p. 46638 of the preamble). Definitions. *Eligible Fallback Entity or Fallback Entity*. If the fallback option must be implemented because not enough PDPs or MA-PD plans express interest in serving in a state, the definition of an eligible fallback entity should be modified so that an SPAP can serve as the fallback plan for SPAP clients (and all others would go to the Part D fallback provider).

R. Payments to Sponsors of Retiree Prescription Drug Plans

Section 423.884 (pp. 46741 – 46743 of the preamble). Requirements for qualified retiree prescription drug plans. *Definition of Actuarial Equivalence.* CMS' concern over windfalls, though justifiable, could drive sponsors from participating in the subsidy or worse yet drive them to drop their employer-sponsored drug coverage completely. CMS is so concerned that employers could impose the full cost of the benefit package on employees through employee premiums or contribute a smaller amount toward the financing of the package and still be eligible for subsidy, that they don't realize their proposed requirements to qualify for the subsidy are too stringent for most employers.

Three tests for actuarial equivalency have been proposed. Option 1 is the creditable coverage gross test or one prong approach. Option 2 proposes to limit the amount of the retiree drug subsidy so that it could not exceed the amount paid by plan sponsors on behalf of their retirees. Option 3 proposes a two- prong gross and net test that employers must satisfy. We do not support the proposals under Options 2 and 3 as they contradict the intent of the MMA to slow the decline in employer-sponsored retiree insurance. In addition, CMS stated in the preamble that, "we have questions about the adequacy of the legal basis" for the proposed policies in Options 2 and 3. If

a limit on the subsidy is imposed, there is no incentive for employers that offer a retiree drug benefit that exceeds the proposed Part D coverage to continue to provide high-quality prescription drug coverage to their Medicare eligible retirees. The two-prong approach under Option 3 places an undue burden on employers by requiring them to meet both tests in order to qualify for the subsidy. The unnecessary burden of meeting the net test may force employers to not apply for the subsidy, discontinue its coverage and make Medicare Part D the primary payer for its retiree drug costs.

For all these reasons stated above, we believe the gross test for actuarial equivalency proposed as Option 1 is more than sufficient. It meets the policy goal established by Congress in that it will minimize the administrative burdens on employers. By minimizing the administrative burdens, more employers will retain their sponsored drug coverage for its retirees and thereby fulfill two other goals of Congress to maximize the number of retirees retaining employer-sponsored drug coverage and minimize the costs to the government of providing retiree drug subsidies.

Section 423.888 (pp. 46745 – 46746 of the preamble). Payment methods, including provision of necessary information. *Plan Year versus Coverage Year Issues.* Cost threshold and cost limits are calculated for plan years that end in 2006 yet the subsidy amount for a qualifying covered retiree is based on coverage year (calendar year). Connecticut is a state that has a July 1 through June 30 plan year. As such we would encounter the situation identified where for the plan year July 1, 2006 through June 30, 2007, our actuarial attestation would be due on April 1, 2006. However, the cost threshold and cost limit for 2007 would most likely not be calculated. This is a major issue for employers. How can employers provide evidence of actuarial equivalency without knowing the cost limit and cost threshold that will be in place during the plan year? It is unreasonable and unrealistic to expect that this can be done.

A second aspect of this issue is specific to the first year of implementation. How should CMS handle plan years that begin in 2005 with respect to the subsidy payment? The options are to: 1) start counting gross costs for prescriptions filled after January 1, 2006; 2) determine a subsidy amount as if the sponsor were authorized to receive subsidy payments for the entire plan year and then prorate this amount based on the number of plan year months that fall in 2006; or 3) determine subsidy amounts on a monthly basis as if the sponsor were authorized to receive subsidy payments for the entire plan year but would then pay only the amounts for the plan year months that fall in 2006. Of the three options presented the preference is for either Option 1 or Option 3. Because our plan year begins July 1, 2005, the same results would be achieved under either scenario.

Section 423.888 (pp. 46746 – 46748 of the preamble). Payment methods, including provision of necessary information. *Payment Methodology.* The proposal is for CMS to make monthly payments with adjustments for over/under payments to subsequent periodic payments and a final reconciliation 45 days after the end of the calendar year. This requires plan sponsors to certify by the 15th of the following month the total amount by which actual drug spending exceeds the cost threshold and yet remains below the cost limit. CMS based this method on the assumption that plan sponsors use PBMs and PBMs routinely adjudicate claims on a real-time basis with very limited claims or payment lags. This may be true, but what does a sponsor do if it can't get the data in a timely fashion from the plan? The State of Connecticut utilizes the services of one PBM

for the collection of prescription claims data for all employees, including retirees. The prescription benefits are on a fully insured basis with employees contributing a set dollar amount for a co-payment. The state has encountered problems with respect to receiving timely information from the PBM. The expectation to require sponsors to certify the prior month's amounts by the 15th is idealistic and is a goal that the state would be unlikely to meet. A more realistic goal would be to allow sponsors to certify within the range of 45 – 60 days after the end of the month.

Section 423.888 (p. 46748 of the preamble). Payment methods, including provision of necessary information. *Data Collection*. Of the options proposed, we recommend the first option that requires the sponsor (or group health plan designated by the sponsor) to submit the aggregate total of all allowable drug costs of all of the qualifying covered retirees in the plan for the time period in question. This choice does not place excessive burdens on the employer and is the most protective of the retiree's privacy. CMS states that this option may be the most problematic in terms of assuring the accuracy of the subsidy payment but we disagree. Even though the aggregate cost submitted to CMS would not be broken down to each qualifying retiree, the sponsor (or group health plan) must maintain the claims data to support and verify its submission for audit purposes for at least six years after the end of the plan year.

The remaining options require a sponsor (or group health plan) to submit the aggregate allowable costs for each qualifying covered retiree. Even if this data is required for only the first two years as proposed in one option, there are still privacy issues. Therefore the remaining options are not recommended as they impinge on a retiree's privacy. This infringement is to the point where the submission of costs broken down to each retiree does not appear to comply with the government's own HIPAA requirements.

S. Special Rules for States—Eligibility Determinations for Low-Income Subsidies, and General Payment Provisions

Section 423.904 (p. 46751 of the preamble). Eligibility determinations for low-income subsidies. (See also Section 423.744 (p. 46727 of the preamble)). We request clarification of the language on page 46751 of the preamble regarding eligibility determinations for low-income subsidies being conducted "consistent with the manner and frequency" that Medicaid determinations and redeterminations are conducted. While Section 1860D-14(a)(3) of the Act and the proposed rule at Section 423.774(a) say that eligibility determinations for low-income subsidies are made "by the State under its State plan under title XIX if the individual applies with the Medicaid agency," this is inconsistent with the language on page 46751 of the preamble. Also, if a state were to consider using a contractor for the eligibility determination and redetermination process, we would want costs associated with the contractor to be eligible for FFP.

The state is seeking clarification as to whether CMS would approve a State Plan Amendment that eliminates prescription drugs as a covered benefit for full duals (because of the availability of the Part D benefit), without violating equal amount, scope and duration requirements. In other words, can states limit pharmaceutical coverage in Medicaid to non-duals? Without this ability, states will be faced with providing prescription drug coverage for dual eligible Medicaid

recipients who decline enrollment or disenroll at 100% state cost. If CMS will not approve such an amendment, the state will be open to coverage at 100% state cost of Part D non-formulary drugs pending the outcome of an appeal.

Section 423.906(a) (p. 46751 of the preamble). General payment provisions. *Regular Federal matching*. The proposed rule indicates that states could receive the regular federal match for administrative costs in determining subsidy eligibility and for notification. However, the preamble also indicates that states would be responsible for periodic redeterminations. We therefore believe that the rule should be modified to clarify that FFP for redeterminations is permitted.

In addition, ongoing financial support should be provided for states' operational and administrative costs once transitional grants end in/after FFY 06. Specifically, in addition to the provision that allows states to gain federal financial participation on their administrative costs associated with determining a dual eligible's subsidy, states and SPAPs should be eligible to count the following as eligible reimbursement costs in the Medicaid program: costs of enrolling dual eligibles in the Part D program; enrollment and eligibility costs of SPAP recipients in the part D program; and all administrative costs associated with administering a wraparound for both dual eligible and SPAP recipients.

Section 423.910. Requirements. If Connecticut determines that it is in their best interest – from both a financial and continuity of care standpoint – to run their own prescription drug program for their dual eligibles at 100% state cost (e.g., through our SPAP), can we waive the auto-enrollment process for dual eligibles? It appears that under this scenario, the state would not be subject to the phase-down state contributions provisions.

Section 423.910(b)(1) (p. 46752 of the preamble). Requirements. *State contribution payment. Calculation of payment*. The 2003 base year is artificially high because it fails to account for changes in utilization and pricing that were implemented through Connecticut law to bring down pharmacy costs in the Medicaid program for dual eligibles (e.g., MAC pricing, prior authorization, generic substitution, dispensing fee changes, preferred drug list and supplemental rebates). We believe that the law (Section 1935(b), page 2157 of MMA) gives the Secretary the discretion to make adjustments to the 2003 base. In determining the gross per capita Medicaid expenditures for prescription drugs, the Secretary shall "use data from the Medicaid Statistical Information System (MSIS) and other available data" (emphasis added). We believe the Secretary could use actuarial analyses or other data to evaluate the changes to state drug expenditures (as described above) to consider adjustments to the 2003 baseline. We ask that you consider this and adjust the proposed rule accordingly.

Section 423.910(b)(2) (p. 46752 of the preamble). Requirements. *State contribution payment. Method of payment.* The rule specifies that state payments for the "phased-down state contribution" would be made in a manner similar to the mechanism by which states pay Medicare Part B premiums for dual eligibles. If Connecticut can make its contribution in the same manner as we are currently doing for our dual eligibles, this methodology is acceptable. If the Secretary were to require that we submit a check or make an electronic transfer payment,

there would be significant implications for Connecticut's constitutional and statutory expenditure cap.

T. Part D Provisions Affecting Physician Self-Referral, Cost-Based HMO, PACE, and Medigap Requirements

No comments.

CMS-4068-P-1260

Submitter : Ms. c c **Date & Time:** 10/04/2004 08:10:46

Organization : c

Category : Individual

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
DEPARTMENT FOR REGULATIONS & DEVELOPMENT

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Submitter : Mrs. Tammy Higgins **Date & Time:** 10/04/2004 08:10:07

Organization : Horizon Healthcare

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attached

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
DEPARTMENT FOR REGULATIONS & DEVELOPMENT

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CMS-4068-P-1232

Submitter : Kathryn Kuhn **Date & Time:** 10/04/2004 08:10:23

Organization : National Community Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

See Attachment

CMS-4068-P-1232-Attach-1.doc

National
COMMUNITY
PHARMACISTS
Association

Formerly NARD, the National Association of Retail Druggists

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October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Proposed Rule—Medicare Program; Medicare Prescription Drug Benefit (CMS-4068-P)

To Whom It May Concern:

On behalf of the National Community Pharmacists Association (NCPA), I would like to submit the following comments regarding CMS-4068-P.

We support the use of a facilitator (FAC) in the processing of TrOOP and COB claims. Without a FAC, the burden placed on PDPs and claims processors could be exponential due to the complex nature of these claims (i.e., from reversals, resubmissions, etc.).

While we favor the FAC model, we also have some concerns with respect to using a prominent switch company (e.g., NDCHealth or another single entity) as a FAC. Our concerns primarily revolve around the net effect on pricing and freedom of choice with regards to switch companies.

1) Pricing - Today, the majority of pharmacy transactions are single switch transactions (provider - payer - provider). A small percentage of transactions require multiple switches (e.g., COB). The FAC model inherently involves a multitude of multiple switches to various payers, thus theoretically increasing the cost associated with full processing of a claim. Our concern for pharmacy, in general, is the fees associated with these complex processes. One common concern in the industry with respect to the Medicare Drug Program is the decreasing margins at the pharmacy level. While this logic is debatable, adding a higher switching fee for these types of complex claims would only add more fuel to the fire and continue to further decrease pharmacy margins.

2) Switch Providers - The fact that NDC is eyeing the opportunity to serve as a FAC concerns us as well. NDC is well known in the industry as the leader in claims switching (however, competitors such as eRx and WebMD continue to gain ground in this area). Our concern with placing a prominent switch company in the role as a FAC is the potential for an unfair advantage in the switch marketplace. This could result in decreased competition and create an environment susceptible to price increases for general claims switching services. Provisions would need to be made to allow equal access to the FAC by all switching companies so that no one switch provider would be placed at an economic disadvantage. In addition, measures should be taken to prevent any switch company serving as a FAC from creating a monopolistic environment.

The National Community Pharmacists Association (NCPA) represents the nation's community pharmacists, including the owners of 24,000 pharmacies. The nation's independent pharmacies, independent pharmacy franchises, and independent chains represent a $78 billion marketplace, dispensing nearly half of the nation's retail prescription medicines.

Thank you for the opportunity to provide these comments. Please feel free to contact me if I can provide you with any further assistance concerning this issue.

Sincerely,

Kathryn F. Kuhn, R.Ph.
Senior Vice President, Pharmacy Programs

CMS-4068-P-1233

Submitter : Ms. Lisa M. Getson **Date & Time:** 10/04/2004 08:10:17

Organization : Apria Healthcare

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

Please refer to Apria Healthcare's formal comments on this subject as found in the attached Word file.

CMS-4068-P-1233-Attach-1.doc

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Re: Comments on CMS-4068-P
The Proposed Rule for the Medicare Prescription Drug Benefit

Dear Dr. McClellan:

On behalf of Apria Healthcare Inc., I am pleased to submit these comments regarding the proposed rule to implement the new Medicare Part D prescription drug benefit. Specifically, these comments pertain to the recent notice published in the *Federal Register* on August 3, 2004.[1]

Apria is a leading provider of integrated home care services and products. Apria offers a full range of home infusion drug therapy, as well as home medical equipment and home respiratory therapy. Through 30 wholly-owned, licensed and JCAHO-accredited infusion pharmacies, Apria serves adult and pediatric patients with a wide range of infectious diseases, nutritional disorders, cancer and chronic illnesses such as Lou Gehrig's Disease and multiple sclerosis. Aside from the thousands of people covered by private managed care organizations who benefit from Apria's home infusion services, the company also cares for a significant number of elderly patients throughout the United States who have complex medical problems and multiple co-morbidities who require home infusion therapy and are covered by Medicare Advantage (MA. formerly Medicare+Choice) plans.

These comments are divided into the following sections:

I. General
II. Dispensing Fees for Home Infusion Drug Therapy
III. Contracting with Home Infusion Drug Pharmacies
IV. Formulary Development

[1] Medicare Program; Medicare Prescription Drug Benefit; 69 *Fed. Reg.* 46632 (Aug. 3, 2004).

I. General

We wish to commend CMS for engaging in the research necessary to understand many of the unique characteristics of home infusion drug therapy. These findings are reflected in the preamble of the proposed rule, which summarizes the various services and functions that are required to provide home infusion drug therapy safely and effectively in the home care setting.

We applaud CMS for recognizing in the proposed rule the clinical and cost benefits of home infusion drug therapy, as well as the essential role this area of therapy plays in the private sector health system and under Medicare managed care programs. The proposed regulation describes an interpretation of the Part D benefit that would include the essential services, supplies and equipment that are integral to the provision of infusion drug therapy provided in the home (see discussion of "Dispensing Fee Option 3" below).

If Dispensing Fee Option 3 is adopted in the final regulation, as we recommend, then the Medicare fee-for-service program can offer coverage of home infusion drug therapy comparable to what private sector health plans and Medicare Advantage plans have offered for years. In doing so, Medicare would realize the significant system-wide savings that come from the provision of infusion drug therapy in the most cost-effective setting.

A. Home infusion drug therapy provides an opportunity for Medicare Part D to replicate the success achieved by private sector health plans and Medicare Advantage plans.

Currently, many of the infusion drug therapies used commonly in the private sector, such as antibiotic therapy used in the treatment of severe infections, are not covered under the Medicare Part B durable medical equipment (DME) benefit. Coverage under the DME benefit is based on the use of an item of DME – in this case, an infusion pump − and extends only to a few designated drugs, most of which are used in the treatment of cancer and intractable pain. As a result, Medicare beneficiaries who could have received infusion drug therapy at home have been forced into far more costly settings, such as acute care hospitals, hospital outpatient departments, hospital emergency rooms and long term care facilities.

In contrast to the limited coverage that exists under Medicare Part B, Medicare coverage of home infusion therapy has worked well under Part C with the Medicare Advantage plans. Many if not most Medicare Advantage plans provide coverage for a broad range of home infusion therapies and related services as a <u>medical</u> benefit. Examples include Aetna US Healthcare, Humana Health Plans, PacifiCare's Secure Horizons plans and Presbyterian Salud in New Mexico. Clearly, these plans would not provide this optional coverage unless they were convinced that coverage of home infusion therapy in the home setting is cost-effective.

For Medicare Advantage plans, home infusion has provided significant system-wide savings by enabling beneficiaries to receive infusion therapy without incurring hospital or nursing facility costs. Medicare Advantage plans cover the homecare pharmacy, nursing and other in-home services, supplies, equipment and same-day, in-home delivery/patient teaching necessary for the provision of home infusion therapy. The effectiveness of home infusion therapy under Part C, and the manner in which Medicare Advantage plans define and cover this therapy, can be a model for infusion coverage under Part D.

B. Specific requirements must be established by CMS to ensure that Medicare Part D makes use of home infusion drug therapy in the same fashion as private sector and Medicare Advantage plans.

Stand-alone Part D prescription drug plans (PDPs), in the absence of specific requirements or direction from CMS, will not embrace drug therapies such as home infusion drug therapy because the PDPs will be rewarded for contributing to system-wide savings on the drugs alone. As a result, the financial incentives that have driven private payer acceptance and use of home infusion drug therapy will not exist for stand-alone PDPs.

As a result, specific requirements and direction from CMS are necessary for the coverage of home infusion drugs to work properly. We urge CMS to ensure that the Final Rule contains provisions relating to home infusion drug therapy on the issues discussed in the remainder of these comments, including such issues as dispensing fees, pharmacy access, formulary provisions and the formatting of claims.

II. Dispensing Fees for Home Infusion Drug Therapy

A. CMS should adopt Dispensing Fee Option 3, which is the only proposed option that would adequately recognize the services and items that are necessary to provide home infusion drug therapy.

Congress' definition of prescription drugs under the statute clearly includes infusion drugs provided in the home, and the proposed rule likewise reinforces the fact that infusion drugs (other than the few drugs currently covered under Part B) are included in the Part D benefit.

However, for the coverage of home infusion drugs to be meaningful for Medicare beneficiaries, CMS also must cover the services, supplies and equipment related to the provision of these drugs. Limiting coverage to the drugs only without the services, supplies and equipment will not produce meaningful coverage of infusion drugs in outpatient settings. This is because infusion pharmacies will be unable to provide infusion drugs without adequate payment for the services, supplies and equipment.

The most appropriate mechanism for such coverage of infusion services, supplies and equipment provided under the proposed rule is the dispensing fee. In the preamble, CMS sets out three options for defining dispensing fees under the new benefit and invites comment on each.

- Option 3 comes closest to accurately recognizing the fundamental elements – including the services, supplies and equipment – that are essential for the provision of home infusion drug therapy. Option 3 is the only option that reflects the fundamental elements of home infusion drug therapy (see additional discussion in subsequent sections of these comments).

- In contrast, Option 1 only provides the perspective of retail pharmacies and does not meet the needs of Medicare beneficiaries requiring home infusion drug therapy.

- Although Option 2 captures the supplies and equipment used in the provision of home infusion drug therapy, this option falls far short of recognizing the essential professional services required to provide home infusion drug therapy because it does not recognize the professional services that are required to provide safe and effective infusion therapy in the home.

B. CMS should adopt Dispensing Fee Option 3 because it is consistent with the well-established standards of practice for home infusion drug therapy.

The major independent accreditation organizations, including the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), have established extensive, detailed standards regarding the patient management, support services, facilities, patient safety, policies, procedures and functions that must be provided by home infusion pharmacies. These standards, which address issues ranging from the requirements for sterile preparation of infusion drugs to the oversight of patient therapy, are significantly different from the standards governing traditional retail pharmacies.

Option 3 is the only dispensing fee option that adequately reflects the content of these national accreditation standards. For example, one major difference between retail pharmacies and home infusion pharmacies is the urgency surrounding the initial referral from a physician or hospital and the resulting home delivery/patient education requirements. Due to the severity of the patient's illness (such as a serious infection which has not responded to oral medications), pressures on hospitals to discharge patients as soon as possible, and stability/refrigeration requirements for many medications, home infusion pharmacy staff frequently have to deliver directly to patients' homes the same day as the referral. This is considerably more expensive than a retail pharmacy model where the patient or caregiver visits the pharmacy in person to pick up the drug. All of this must take place in conjunction with insurance verification, coordination with the nurse who will teach the patient, compounding by a home infusion pharmacist, and eventually, billing third party payors and collecting patient co-pays – all activities that are not applicable to the retail setting.

The well-established understanding of the professional services involved in providing in home infusion drug therapy is not merely an industry definition. Payers, clinicians, clinical societies, providers and accrediting organizations share a common understanding of what is involved in providing these therapies in outpatient settings.

C. CMS should adopt accreditation requirements under Dispensing Fee Option 3 as a straightforward means to protect Part D enrollees.

As the first homecare provider to seek and obtain JCAHO accreditation in the 1980s, Apria has a longstanding commitment to ensuring that the professional services and functions we provide meet a demanding set of quality standards. Apria recently completed its latest triennial survey cycle, with a successful outcome in all infusion pharmacies, respiratory and medical equipment locations. Our company has served as a pilot for innovative survey techniques developed by the JCAHO, and our management has formally served on advisory committees of the organization. Today, our quality standards meet or exceed JCAHO's requirements, which is a requirement of the over 2500 private sector managed care plans with which we contract to provide home infusion services.

In the final rule, CMS should address the qualifications of the infusion pharmacies that may provide the elements of care described under Dispensing Fee Option 3. We recommend that CMS require every pharmacy providing infusion services to be accredited as a home care pharmacy by a recognized national accrediting organization. We also recommend that every entity that provides nursing services to Part D infusion patients be either accredited as a nursing agency as an extension of their existing home infusion accreditation, or be a Medicare-certified home health agency.

Private sector plans require accreditation as a basic assurance that the pharmacists and nurses are experienced and the pharmacies are staffed properly to provide the necessary care. The quality standards required of home infusion pharmacies and nursing agencies by the accreditation organizations have become the community standard for the provision of home infusion therapy.

D. CMS should use a refined version of Dispensing Fee Option 3 to define the full scope of necessary professional infusion pharmacy services.

All infusion patients, whether or not they qualify for the home health benefit, require professional pharmacy services that again differ from those found in the retail setting. The general categories of such services are:

- Compounding medications in a sterile environment
- Dispensing
- Ongoing Clinical Monitoring
- Care Coordination with other agencies involved in patient care

- Provision of Supplies and Equipment
- Multiple Categories of Pharmacy Professional Services, such as pharmacokinetic drug monitoring or parenteral nutrition formula development
- Administrative Services
- In-home delivery, patient and caregiver education
- Third party billing
- Other Support Costs

These services are described in greater detail in a number of accreditation materials and other forums, including a document on the website of the National Home Infusion Association describing the "per diem" model.[2]

We propose a modification to Dispensing Fee Option 3 to more explicitly describe the pharmacy professional services that are needed for home drug infusion therapy. The pharmacy services referenced above in the model per diem definition (and generally described in Dispensing Fee Option 3) should be included in the dispensing fee for all Part D infusion patients. Most of these functions would be captured in the Option 3 definition of dispensing fees.

Both private payers and Medicare Advantage plans use per diem payments that are tied to the intensity level of the particular infusion therapy. For over 20 years, these plans have essentially developed resource-based relative value scales to capture the intensity, in terms of time and resources involved in providing each infusion therapy safely and effectively. Thus, the plans do not use a single per diem amount for all infusion therapies. We recommend that the PDPs follow this approach under Medicare Part D.

E. CMS can establish easily-administered safeguards to avoid any duplicate payments for nursing services

CMS raises a question in the proposed rule regarding how to ensure that the services captured in Dispensing Fee Option 3 are not reimbursed under the home health benefit or otherwise.

The potential area of concern involves the infusion patients who also qualify for the Medicare home health benefit. For this subset of infusion patients who also qualify for the home health benefit, it would be a simple matter to first determine whether a beneficiary qualifies for the home health benefit before reimbursing Part D funds for nursing services. The majority of beneficiaries who require infusion drug therapy do not qualify for the home health benefit, and their nursing services should be paid under the Part D benefit as part of the dispensing fee.

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[2] National Home Infusion Association. National Definition of Per Diem. June 2003. *Available at* www.nhianet.org/perdiemfinal.htm.

Importantly, the home health benefit does not cover any of the pharmacy services described in the preceding subsection of these comments.

By first identifying beneficiaries who qualify for the home health benefit, the nursing component, when medically necessary, should be reflected in the dispensing fee but only for beneficiaries who do not qualify under the home health benefit for nursing services. Importantly, nursing care is not included in the model per diem definition (discussed above) nor in the HCPCS "S" coding structure (discussed below) used by private payers.

Private payers typically separate out nursing from the pharmacy-related costs represented by the per diem. They share the Medicare program's natural concern about nursing costs, and these plans have concluded the best means of tracking and controlling nursing costs is to use a separate payment mechanism for nursing.

F. CMS can establish easily-administered safeguards to avoid duplicate payments under Medication Therapy Management Programs.

CMS asks for comments regarding how to ensure that the Medicare program avoids making duplicate payments if the PDPs pay for infusion-related dispensing fees as well as medication therapy management services.

Generally, the dispensing fee as defined in Dispensing Fee Option 3 will capture most of the services and functions described in our per diem model plus the nursing component, and there will not be a clear need for a separate payment to infusion pharmacies for additional medication therapy management services. We believe that the primary situation where medication therapy management services may be indicated is where an infusion pharmacy has to coordinate the activities of another pharmacy.

However, if CMS does not choose Dispensing Fee Option 3 for defining dispensing fees, then CMS should not consider the medication therapy management program as a substitute for covering the services, supplies and equipment required to provide infusion drug therapy. The limitations on the applicability of the medication therapy management program (*i.e.*, it is limited to patients with chronic conditions and multiple medications) make it a poor vehicle for capturing the clinical monitoring functions required of infusion pharmacies for all infusion patients.

III. Contracting with Home Infusion Pharmacies

A. CMS should establish separate and distinct requirements for PDPs to contract with sufficient numbers of home infusion pharmacies to ensure adequate enrollee access to home infusion drug therapy under Medicare Part D.

CMS should establish specific safeguards for home infusion pharmacies to ensure meaningful enrollee access to home infusion drug therapies. A number of important differences exist between home infusion pharmacies and traditional retail pharmacies that highlight the need to create separate requirements for the two types of pharmacies. For example–

- Home infusion pharmacies provide specific essential services that are not provided by the vast majority of retail pharmacies or mail order pharmacies.

- Home infusion pharmacies must maintain facilities, equipment and safeguards for compounding and storing sterile parenteral drug solutions, which is not common among retail pharmacies.

- Home infusion pharmacies are responsible for the care of their patients 24 hours a day, seven days a week, while retail pharmacies are not.

- Home infusion pharmacies are subject to separate state licensure, regulations and accreditation standards from retail pharmacies.

- The contracts used by private health plans for home infusion pharmacies are structured differently from the contracts used for retail pharmacies.

- The total number of traditional retail pharmacies in the United States far outweighs the total number of home infusion pharmacies.

These differences are echoed in the preamble of the proposed rule, where CMS discusses its findings regarding important distinctions between home infusion pharmacies and retail pharmacies.[3]

To ensure that Part D enrollees have sufficient access to home infusion drug therapy, CMS should adopt its proposal to establish distinct access standards for home infusion pharmacies in the Final Rule. This would be consistent with Congress' general mandate that CMS must ensure enrollees have convenient access to pharmacies, as access to a retail pharmacy does not by itself meet the needs of a beneficiary who requires infusion therapy.

B. CMS should require use of the ASC X12N 837 claims format for infusion drug therapy, consistent with CMS' recent determination, because infusion claims formats are different from retail pharmacy claims.

CMS' Office of HIPAA Standards has carefully reviewed how home infusion therapy is provided, and recently issued a Program Memorandum[4] and a Frequently Asked Question (FAQ)[5] document on the CMS website summarizing its conclusion.

[3] 69 *Federal Register* at 46648 and 46658.

For example, the FAQ document states:

> …Home infusion therapy typically has components of professional services and products that include ongoing clinical monitoring, care coordination, supplies and equipment, and the drugs and biologics administered – all provided by the home infusion therapy provider.

In a letter dated April 8, 2003, Jared Adair, director of the CMS Office of HIPAA Standards, wrote:

> …we have determined that home drug infusion therapy services are different from services provided by retail pharmacies, and that the business model for home drug infusion therapy providers is fundamentally different from a retail pharmacy for dispensing drugs…. We also acknowledge that a requirement to bill home infusion drugs using the NCPDP format would fail to meet the administrative, clinical, coordination of care, and medical necessity requirements for home drug infusion therapy claims." (emphasis added)

As a result, CMS determined that the National Council for Prescription Drugs Program (NCPDP) claim format, which is the HIPAA standard for the processing of retail pharmacy drug claims, is not appropriate for the filing of home infusion drug therapy claims. Instead, CMS instructed that home infusion claims, to be compliant with HIPAA, must be filed under the ASC X12N 837 claims format.

Please note that the description of infusion therapy as described in the FAQ tracks very closely with the language of Dispensing Option 3 in the proposed rule. We recommend that the specific wording already posted on CMS's FAQ be included as the infusion claiming requirement in Part D regulations. To do so will increase the level of administrative standardization in infusion claims transactions per the objectives of HIPAA, while also ensuring that home infusion providers and Part D payers comply with the HIPAA regulation when implementing Part D claiming transactions. If CMS does not require that Part D home infusion therapy claims be submitted on the 837, then it would open up the possibility for some Part D payers to ignore the fundamental differences of home infusion therapy from retail pharmacy and implement only NCPDP claiming—forcing infusion pharmacies to be out of compliance with HIPAA.

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[4] Centers for Medicare & Medicaid Services, Program Memorandum, Carriers, Transmittal B-03-024 (4/11/03), *available at* http://cms.hhs.gov/manuals/pm_trans/B03024.pdf.

[5] Centers for Medicare & Medicaid Services, Frequently Asked Questions (FAQs), "Are Drug Transactions Conducted by HIT Providers Retail Pharmacy Drug Claim Transactions Billed Using NCPDP Formats?" (Answer ID 1880) (3/31/03), *available at* http://questions.cms.hhs.gov.

This would deprive the PDPs and CMS of a valuable tool for tracking important patient-specific data. Consolidated 837 claiming would facilitate the consolidation of all drugs along with the professional pharmacy "per diem" services, equipment and supplies into single claims billed for infusion therapies, easily mapped into patient services utilization data bases for analysis—whereas the possibility of billing infusion drugs separately via the retail NCPDP claim format results in loss of this consolidated data for analysis.

C. CMS should recognize that infusion coding is different from retail pharmacy drug coding.

Since 2002 the Healthcare Common Procedure Coding System (HCPCS) provides approximately 80 "S" codes for home infusion therapy services. Most codes reflect a "bundled" per diem approach in which most or all of the supplies and services provided to a home infusion patient are billed under a single code. This complete system of "S" codes for home infusion therapy services is specifically designed for use by private payers, and are available for use by government payers that adopt this widely used private sector methodology for infusion coding and payment. These codes are not used in coding of retail pharmacy drug claims and are not permitted for HIPAA-compliant use on the NCPDP transaction).

Although CMS does not have a single HIPAA coding standard for drugs, we believe that the PDPs and CMS will find requiring NDC drug coding for Part D claims will provide best opportunity for patient utilization analysis and tracking of total Part D drug costs for CMS's program administration. We believe the Part D regulations should require that all claims for drugs be coded with NDC numbers.

D. Coordination of benefits.

In addition to these reasons for infusion claiming and coding consistency, the COB portion of the Part D program is also best implemented by CMS's establishing a requirement for 837 claiming and use of the established coding systems. The majority of COB will occur with commercial payers such as the Blues and other private health plans. As the private sector has already widely adopted the established coding systems described above, it will be important for CMS to require consistent coding adoption to make COB work, ensuring that the allocation of payment for services between Part D plans and other primary or secondary plans works well.

Since the private payer sector accepts home infusion therapy claims using the HIPAA-compliant X12 N 837 format, for COB to work effectively is another reason that CMS should require PDPs to use the 837 claim format for infusion claims. Because a very large majority of private infusion payers use the HIPAA-complaint *professional* 837 (837P) claim format, to make COB work we believe that CMS's Part D regulations should require PDPs to adopt the HIPAA-compliant 837P format only, excluding both the *institutional* 837 and NCPDP transaction from use.

E. CMS should clarify the any willing provider requirements with respect to home infusion drug therapy.

CMS should clarify that this access safeguard is to be applied to any willing provider of home infusion therapy meeting the infusion-specific quality standards (see below), as distinct from retail pharmacies. Such a requirement is consistent with the statutory language.[6]

In addition, for the purpose of the any willing provider requirements, CMS should clarify that prescription drug plans should have a standard contract for home infusion pharmacies.

These recommendations for the network access standards will help safeguard enrollee access by ensuring that the Medicare Part D benefit reflects common private sector practices for home infusion drug therapy. In addition, the recommended clarifications will not impose significant burdens on PDPs.

F. CMS should recognize that OBRA 1990 standards do not represent the standard of care for infusion pharmacies.

In the preamble, CMS refers to Section 54401 of the Omnibus Reconciliation Act of 1990, stating that the regulations issued pursuant to that section in 42 CFR 456.705 "describe currently accepted standards for contemporary pharmacy practice and our intent is to require plans to continue to comply with contemporary standards." CMS seeks comments on whether these standards are industry standards and whether they are appropriate for Part D.

The OBRA 1990 standards were written for retail pharmacies. The drafters of these standards did not attempt to address the standard of care for infusion pharmacies. Infusion pharmacies that are in compliance with the infusion-specific standards established by accrediting organizations meet the OBRA 1990 standards, but the OBRA 1990 standards do not reflect "contemporary pharmacy practice" for infusion pharmacies. The community standard of care for infusion pharmacies is found in the accreditation standards that are required by virtually every private health plan, as well as numerous MA plans, to participate in their provider networks.

The quality assurance standards followed by home infusion pharmacies—and as required for accreditation--far exceed the OBRA 1990 standards. Due to advances in newly-approved drugs and technology and additional laws and regulations established in the intervening years (such as HIPAA), and development of knowledge surrounding patient safety and medication management at home, the level of patient data collection, assessment and intervention in the infusion clinical model goes far above and beyond the quality standards currently used for Medicaid. Again we respectfully direct your attention to Jared Adair's April 8, 2003 comments concerning the key differences between retail and home infusion pharmacies.

[6] Social Security Act, Section 1860D-4(b)(1)(A).

IV. Formulary Development

A. CMS should mandate that PDP and MA-PD plan sponsors maintain an open formulary for infusion drugs to ensure this population of vulnerable patients has appropriate access to necessary medications.

Much of the MMA is based on the premise that Medicare can take advantage of cost-savings techniques commonly used in the private sector and still deliver quality services to Medicare beneficiaries. CMS should note that although private health plans commonly use restricted or preferred formularies for drugs delivered orally, via patch or other non-invasive methods, private plans rarely apply these formulary restrictions to infusion drugs.

As discussed in greater detail below, there are numerous clinical and operational barriers to establishing formularies for infusion drugs. As a result, with respect to infusion drugs, formularies should remain open.

B. CMS should recognize that PDPs and pharmacy and therapeutics committees are not well situated to evaluate infusion drugs.

It will be difficult for PDPs and traditional pharmacy and therapeutics committees (P&T committees) to evaluate infusion drugs in the same manner that they evaluate orally administered drugs.

P&T committees generally evaluate the relative safety, efficacy, and effectiveness of prescription drugs within a class of prescriptions drugs and make recommendations to a health plan for the development of a formulary or preferred drug list. Frequently, P&T committees focus on the "therapeutic equivalence" of different multisource drugs (*i.e.*, whether one drug will have the same desired clinical impact as another). However, such evaluations are performed in a context where the method of administering the drug is not significant.

In contrast to oral drugs, the method of administration for an infusion drug may have separate and significant clinical and cost implications. All infusion drugs require a device of some type to deliver the drug into the body, including various catheters temporarily or semi-permanently implanted in each patient depending on the anticipated duration of therapy, potential side effects of the drug and the patient's diagnosis itself. Various methods of drug delivery also exist, from IV bags hung on poles to sophisticated external or internal infusion pumps. A patient's clinical condition may determine not only what device is selected for delivery, but also what drug should be used. For instance, many patients receiving infusion therapy are at high risk of infection or complications from infection. Consequently, a physician may need to choose a medication that can be prepared in advance in a pharmacy clean room and administered once a day to reduce the risk of infection from preparation in the home or multiple intravenous access device manipulations.

Similarly, in selecting a medication for a patient, a physician often needs to consider administration access type and what delivery technology will be best suited for use in a particular patient's home. If the patient is capable of managing a portable infusion pump, drugs requiring longer infusion times may become more clinically appropriate. If other technologies are used, such as IV bags hung on poles, the patient may require more frequent nursing visits to monitor the risk of infection.

The typical P&T Committee would usually not have the experience to evaluate the administration technology or professional support requirements, such as nursing visits, in reviewing infusion drugs. Furthermore, such committees do not typically make decisions considering all available treatment options throughout the continuum. Drugs considered ideal in an inpatient setting are often not desirable in the home setting and visa versa, especially where the first dose of the drug is concerned. Examples include Taxol® for ovarian cancer, Lovenox® for deep vein thromboses and certain immune globulins.

In addition, most infusion drugs must be compounded by the pharmacy. Once compounded, these drugs lose stability over time or be impacted by changes in temperature. For oral drugs, the frequency of administration or stability issues usually do not pose challenges for a P&T Committees as they try to determine therapeutic equivalence.

Ultimately, the infrastructure for protecting patient interests in formulary decisions—the traditional P&T Committee—does not have the ability to evaluate the extra-pharmacological considerations that must be taken into account for infusion treatment, including the administration device, drug stability, proximity to a compounding pharmacy, available administration access site and infection risk. Typically, these factors would be addressed by a physician or pharmacist knowledgeable about an individual's patient's circumstances and history when selecting a drug and delivery device.

C. CMS should recognize home infusion patients as a particularly vulnerable population that requires additional protection.

Patients receiving home infusion therapy are one of the truly vulnerable populations of the Medicare population, and as CMS acknowledged in the Proposed Rule,[7] the medical needs of such populations necessitate that they receive special protection under Medicare Part D. Infusion drugs are used to treat some of the most severe illnesses, including cancer, severe infections, pain and loss of gastrointestinal integrity.

Although the Medicare Part D regulations do create an appeals process for patients if their physician's choice of medication is not on formulary, patients with these compromising illnesses are the least capable of exercising an appeals right. If a patient does not have a family member or physician willing to take on the burden of being an advocate, then the patient's care could be compromised.

[7] 69 Fed. Reg. at 46661.

* * * *

We commend CMS for its initial efforts to understand and accurately define home infusion drug therapy under Medicare Part D. There is an important opportunity for the program to replicate the successes achieved by private health plans and Medicare managed care plans. There is also a risk that in the absence of sufficient direction from CMS and some targeted safeguards, the benefits of home infusion drug therapy will be lost for both beneficiaries and the overall Medicare program.

We would be pleased to provide additional assistance regarding these important issues. Please contact Lisa Getson, Apria's executive vice president, at 949-639- 2021 if you have any questions or comments.

Sincerely,

Lawrence M. Higby
President and Chief Executive Officer

CC: Herb Kuhn
Leslie Norwalk

Submitter : Ms. Janet Schalansky **Date & Time:** 10/04/2004 08:10:44

Organization : Dept. Of Social and Rehabilitation Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-4068-P-1234-Attach-1.pdf

K A N S A S

JANET SCHALANSKY, SECRETARY

SOCIAL AND REHABILITATION SERVICES

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Dear Sir or Madam:

The Kansas Department of Social and Rehabilitation Services respectfully submits the following comments regarding the proposed rule on the Medicare Prescription Drug Benefit published Tuesday, August 3, 2004. Comments are grouped under section identifiers as requested in the proposed rule.

One general comment needs to be made. Because of the statutory and regulatory requirements regarding states' responsibilities in implementing and administering activities related to Part D, it is absolutely critical that access to federal data be provided in a timely and thorough manner. Specifically Kansas requests access to online real time entitlement and enrollment information for not only Part D and subsidy eligibility but also Part A and B. This should occur through access to the Common Working File.

Subpart B - Eligibility & Enrollment

Section 423.34 - <u>Enrollment Process</u>

Because of the level of information required for the auto enrollment process and the resources needed to carry it out, the State would recommend that the Centers for Medicare & Medicaid Services (CMS) take the lead for this process. Information will need to be obtained in order to better guarantee that the person is enrolled in an appropriate plan taking into consideration their living arrangement, specific drug needs, and available participating pharmacies. CMS is in the best position to accomplish this task with information provided from the states and SSA.

Section 423.36 - <u>Initial Enrollment Period</u>

The State is concerned regarding the impact of the initial enrollment period for persons who are fully dually eligible at the time of this enrollment process. Per section 423.906, a person who is eligible for Part D and also is a full benefit dual eligible, medical assistance under Medicaid is not available for drugs that could be covered under Part D. It appears that in order to protect drug coverage from lapsing as of January 1, 2006 for current Medicaid eligibles, the individual would need to enroll by the

end of December 2005. If this is correct, the period of time to accomplish such enrollment (November 15 through December 31) is not sufficient for the number of beneficiaries who will be impacted. The State strongly recommends that an additional period of 90 days or more following January 1 be provided for Medicaid to continue paying drug claims for consumers who have not yet been able to complete the Part D enrollment process.

This same approach will likely be necessary for consumers who newly apply for full Medicaid coverage during this initial enrollment period for Part D. For example, a person who has not yet enrolled for Part D applies for Medicaid on December 20, 2005 and would qualify as a fully dual eligible. If the Medicaid application is not processed until January 15 but Part D enrollment does not take effect until February, the person would again appear to be left without drug coverage for the month of January.

On an ongoing basis, this additional Medicaid coverage period may need to be applied in certain instances involving the individual's own initial enrollment period for Part D. Persons may apply and qualify for full Medicaid coverage and be not only currently eligible but also eligible for Medicaid coverage in the three prior months. If not enrolled in Part D during this period, again the person would be left without drug coverage until that enrollment is completed.

Lastly such an extended Medicaid coverage period may need to be applied in situations where retroactive Medicare entitlement is established. Per section 423.4, a Part D eligible is defined as a person who is entitled to or enrolled in Part A and/or Part B. There will be instances in which an individual is retroactively enrolled in Parts A or B because of a delayed approval for disability benefits. Such persons may have received Medicaid during this time and had their drug costs covered. Once approved for retroactive enrollment in Parts A or B, the person would now become a retroactive full dual eligible. As the person was not enrolled in Part D during this time, any retroactive drug coverage would potentially be in violation of these regulations. The regulations would appear to require the State to fully reimburse CMS for the coverage provided, yet do not allow the beneficiary to enroll in Part D retroactively.

Because of these and similar instances, the State strongly encourages CMS to provide for either retroactive Part D enrollment and coverage or permit an interim period of Medicaid drug coverage to account for such situations.

Subpart C - Benefits & Beneficiary Protections

Section 423.100 - <u>Definitions</u>

Prescription drug coverage under Part D has been limited for institutionalized consumers so that only

those residing in skilled nursing facilities are eligible. The State disagrees with this limitation and believes that all institutional settings including ICF-MR's should be included. In addition, persons accessing long term care services through home and community based services waivers should also be included. Individuals in these living arrangements should be assured access to coverage of all drugs through Part D.

Subpart P - Premiums & Cost Sharing Subsidies for Low Income Individuals

Section 423.772 - Definitions

The definition of full benefit dual eligibles includes persons who meet a medically needy spenddown in a month. Such definition is extremely problematic as the person will go in and out of full benefit classification on an ongoing basis making continuity of drug coverage next to impossible. There is also an issue with persons who meet spenddown in a prior period but who are back in spenddown status in the current month of application. The State proposes that medically needy individuals who meet spenddown be viewed as meeting the full benefit dual definition for a continuous period of up to 12 months even though going back into spenddown status during this time.

Section 423.773 - Requirements for Eligibility

The State strongly concurs with the inclusion of QMB, SLMB, and QI 1's as full subsidy eligible without the requirement for a separate determination.

Section 423.774 - Eligibility Determinations, Redeterminations, and Applications

The regulations provide for a duplicative application and determination process in which persons may apply for low income subsidies with either the State or Social Security Administration. As the subsidy is directly tied to Medicare coverage, this process is best handled as an SSA function. However, it is understood that many low income subsidy applicants may qualify for the Medicaid Savings Programs (QMB, SLMB, QI1) and thus automatically qualify for a subsidy. The State recommends that where an application is filed with the State and the person does not qualify for a Medicaid category that would result in automatic qualification for a subsidy, the information be provided to Social Security for a determination of subsidy eligibility. This can best be done by permitting SSA to use the State's application to make the subsidy determination. This would prevent the State from expending substantial funds and resources on modifying eligibility systems to handle the subsidy determination. That determination uses income and resource rules as well as family size definitions that differ substantially from Medicaid rules applied is in most states. SSA should also handle the redetermination and appeal process for all subsidy-only consumers. Information systems also need to be developed to better share information gathered between the two entities.

There do not appear to be any provisions regarding treatment of individuals who lose subsidy eligibility, particularly those who are deemed eligible by virtue of Medicaid eligibility. Processes need to be put into place for SSA to redetermine subsidy eligibility before the subsidy is eliminated. This may occur in instances where the individual has failed to return a Medical redetermination form or in which they have moved to another state and not contacted the new state agency for continued

Medicaid coverage. Proper and timely notification is critical before the subsidy is withdrawn.

Subpart S - Special Rules for States

Section 423.910 - <u>Requirements</u>

The baseline for determining the state's contribution doesn't take into consideration deductions for recoveries received as a result of such activities as estate recovery, medical subrogation, consumer overpayment recoveries, and third party collections. The State requests such activities be included in the baseline calculation.

We appreciate the opportunity to provide comments regarding these regulations.

Sincerely,

Janet Schalansky
Secretary

JS:BM:DZP:jmm

CMS-4068-P-1235

Submitter : Ms. M. J. Terrebonne **Date & Time:** 10/04/2004 08:10:37

Organization : Department of Health and Hospitals

Category : State Government

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

With the use of formularies, Medicaid recipients who are currently stable on medication therapies may not have continuity of care should they be switched to MA-PD or PDP preferred drug therapies.
A Medicare Part D beneficiary who is a Medicaid dual eligible should not be disenrolled from a MA-PD or PDP plan for any reason. This group of individuals in most cases do not have an alternative drug plan.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Part B drug claims which are denied covergae due to therapeutic inappropriateness, drug-disease contraindication, incorrect drug dosage, duration of drug treatment or for similar reasons related to meidal necessity should not be considered a Part D drug. Consideration should be given for coverage of drugs which are denied coverage under Part B as there may be clinical reasons for the coverage of these products.

Also, while there is much interface between drug coverage under Part B and Part D, use of the NDC number should be require in Part B billing to ensure rebate collections from drug manufacturers on federal and state supplemental rebates. Continuing the use of HCPCS codes makes it difficult to invoice drug manufacturers accurately for all drugs.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Should the auto-enrollment of dual eligibles end prior to 1/1/06? The dual eligibles should have an opportunity to choose the MA-PD or PDP plan prior to an auto-enrollment period.

Submitter : Ms. Linda Hanold **Date & Time:** 10/04/2004 08:10:47

Organization : NCC MERP

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

By Electronic Mail October 4, 2004

Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014

File Code: CMS-4068-P

Dear Dr. McClellan:

On behalf of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), I would like to take this opportunity to respond to the proposed rule for Title 1 of the Medicare Prescription Drug, Improvement and Modernization Act under Section 423.153(c) that requires providers of qualified prescription drug coverage to implement a quality assurance program. This includes quality assurance measures and systems for reducing medication errors, reducing adverse drug reactions, and improving medication use.

At its September 24, 2004, meeting, the Council had the opportunity to carefully review and discuss these sections of the proposed rule and offers the following comments:

? The Council supports the inclusion of drug utilization review, patient counseling, and patient information record-keeping as part of the quality assurance program.

? The Council supports inclusion of the proposed elements for quality assurance systems including electronic prescribing, clinical decision support systems, educational interventions, use of barcodes, adverse event reporting systems, and provider/patient education.

? The Council strongly cautions the Agency against the inclusion of error rates or the comparison of error rates in future quality reporting systems. In June 2002, the Council issued a statement against the use of medication error rates as a basis for comparing health care organizations noting that medication error rates for this purpose are of no value because of differences in culture, interpretation of error definition, differences in patient populations, and methods of reporting and detection. This document may be found in Attachment A. The Council suggests that there is

more value in encouraging the reporting of errors to a central location (e.g., national databases such as USP MEDMARX SM and FDA MedWatch). When errors are reported to an objective third party, these data can be broadly disseminated to help avoid recurrence. It is the Council?s contention that using these data for comparisons is a step backward that will resurrect the punitive ?culture of blame? identified by IOM as a major obstacle to safer patient care. Such comparisons also foster under-reporting and less than full disclosure about events which prevent the understanding of the causes of error.

Finally, the Council would like to point out that the definition of medication error that is quoted in the proposal was originally developed by the Council (see Attachment B) and later adopted by the Food and Drug Administration. It is important to note, however, that medication errors are preventable adverse events; but not all adverse events are preventable. All drugs have intrinsic toxicities that are unavoidable in some patients. Also, some patients have unanticipated allergic or idiosyncratic reactions to drugs that cannot be prevented.

A roster of NCC MERP member organizations and individuals is included as Attachment C. These comments reflect the collective opinion of the Council, but not necessarily of its individual members.

Thank you for this opportunity to provide input on this important issue. If you require additional information, please do not hesitate to contact me at 630-792-5916 or lhanold@jcaho.org.

Sincerely,

Linda S. Hanold
Chair, NCC MERP, c/o USP, 12601 Twinbrook Parkway, Rockivlle, MD 20852

CMS-4068-P-1236-Attach-1.doc

CMS-4068-P-1236-Attach-3.doc

CMS-4068-P-1236-Attach-2.doc

National Coordinating Council for Medication Error Reporting and Prevention

Statement from the National Coordinating Council for Medication Error Reporting and Prevention:

USE OF MEDICATION ERROR RATES TO COMPARE HEALTH CARE ORGANIZATIONS IS OF NO VALUE

The use of medication error rates to compare health care organizations is not recommended for the following reasons:

1. Differences in *culture* among health care organizations can lead to significant differences in the reporting of medication errors. Organizations that encourage medication error reporting by providing incentives and resources to report within a non-punitive, continuous quality improvement arena will likely report more medication errors than organizations that wish to conceal errors and punish individuals who report or are involved in errors.

2. Differences in the *definition* of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors. For example, some organizations may only consider actual errors that reach the patient as errors. Other organizations also will include potential errors and errors that do not reach the patient. The latter organizations will likely collect more medication errors, and information from reports of potential errors can sometimes be more useful in prevention efforts than reports of actual errors.

3. Differences in the *patient populations* served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations. For example, tertiary care hospitals generally may serve more severely ill patients than rehabilitation hospitals. In addition, the intensity of drug therapies, the types of drugs used, and the methods of drug distribution may be substantially different in these environments, thereby leading to differences in number and types of errors.

4. Differences in the *type(s) of reporting and detection systems* for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded. Passive reporting systems, relying upon voluntary reports from staff, are known to result in far fewer medication error reports than active surveillance systems are able to detect. Also, the number of error reports can be significantly different, depending on the type of active surveillance system (e.g., direct observation versus retrospective review of medical records versus computer-based data gathering from electronic medical records and order entry systems).

The National Coordinating Council for Medication Error Reporting and Prevention believes there is no acceptable incidence rate for medication errors. Use of medication error rates to compare health care organizations is of no value. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Health care organizations should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication use system to prevent future errors, and potential patient harm. The value of medication error reports and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the health care organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

Adopted by the National Coordinating Council for Medication Error Reporting and Prevention
June 11, 2002

The definition of “medication error” as developed by the Council and adopted by the Food and Drug Administration reads as follows:

“A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.”

The following national organizations, agencies, and individuals comprise the current membership of the NCC MERP:

AARP*

American Health Care Association

American Hospital Association

American Medical Association

American Nurses Association

American Organization of Nurse Executives

American Pharmacists Association

American Society for HealthCare Risk Management

American Society of Consultant Pharmacists

American Society of Health-System Pharmacists

Department of Defense

Department of Veterans Affairs

Food and Drug Administration

Generic Pharmaceutical Association

Healthcare Distribution Management Association

Institute for Safe Medication Practices

Joint Commission on Accreditation of Healthcare Organizations

National Association of Boards of Pharmacy

National Association of Chain Drug Stores

National Council of State Boards of Nursing

National Council on Patient Information and Education

Pharmaceutical Research and Manufacturers of America

The United States Pharmacopeia

David Kotzin, R.Ph., Director, Department of Pharmacy, Greater Baltimore Medical Center

Deborah Nadzam, PhD, FAAN, Director, The Quality Institute, The Cleveland Clinic

* AARP's opinion on the MMA Regulations is reflected in its own comments to CMS.

Submitter : Karla Fultz McHenry **Date & Time:** 10/04/2004 08:10:00

Organization : Iowa Medical Society

Category : Physician

Issue Areas/Comments

Issues 11-20

SPECIAL RULES FOR STATES

The MMA clawback provisions and eligibility determination requirements for dual eligibles under Part D have the potential to impact State Medicaid budgets significantly.

CMS-4068-P-1238

Submitter : Mr. Randy DeFrehn **Date & Time:** 10/04/2004 08:10:33

Organization : NCCMP

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find the comments filed by the NCCMP

CMS-4068-P-1238-Attach-2.doc

CMS-4068-P-1238-Attach-1.doc

VIA ELECTRONIC DELIVERY

October 4, 2004

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014
http://www.cms.hhs.gov/regulations/ecomments

Dear Sirs/Madams:

These comments are filed by the National Coordinating Committee for Multiemployer Plans (NCCMP) in response to the request for public comments by the Centers for Medicare and Medicaid Services (CMS) on the proposed rule to implement the new Medicare Prescription Drug Benefit authorized in section 101 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). This proposed rule was published in the Federal Register of August 3, 2004 (69 Fed. Reg. 46632).

The NCCMP is the only national organization devoted exclusively to protecting the interests of the approximately ten million workers, retirees, and their families who rely on multiemployer plans for retirement, health and other benefits. Our purpose is to assure an environment in which multiemployer plans can continue their vital role in providing benefits to working men and women. The NCCMP is a nonprofit organization, with members, plans and plan sponsors in every major segment of the multiemployer plan universe, including in the building and construction, retail food and service, and entertainment industries.

Most multiemployer plans today provide for retiree health benefits and many of those plans include some type of coverage for prescription drugs. As is well documented, the number of retirees covered by employer-sponsored health benefit plans today and in the future has continued to shrink, primarily because of the combination of accounting rule changes that force private sector employers to recognize the long-term liability of the retiree medical benefits and the rapidly escalating cost of providing that retiree health coverage.

Although facing the same marketplace cost pressures as other plan sponsors, employers and unions who have come together through collective bargaining to establish multiemployer plans have been less likely to drastically reduce or eliminate retiree coverage, in part because active workers in those industries where multiemployer plan coverage is prevalent have been willing to forgo some portion of their compensation to continue to subsidize the health benefits of their brothers and sisters who have retired. Even so, some multiemployer plans have been forced to alter the way benefits are financed in order to remain fiscally solvent. For some multiemployer plans, the rapidly escalating costs, the demographic trends, and the contraction of

the unionized workforce have required them to seriously rethink plan design and financing issues and to take steps to reduce or eliminate retiree benefits in ways that would have been unthinkable just a few years ago.

During the legislative process surrounding the passage of the MMA, the NCCMP urged Congress to consider carefully the structure of the new prescription drug program so as to avoid creating additional burdens on employer-sponsored plans and further incentives for them to reduce or drop prescription drug coverage for Medicare-eligible retirees. Although Congress incorporated an employer subsidy provision in the final legislation for plans that provided prescription drug benefits that were at least actuarially equivalent to the standard Part D drug benefit to encourage employers to continue providing retiree drug coverage, the overall structure of the new Medicare Part D benefit seriously disadvantages retirees with employer-sponsored coverage. This is particularly true with respect to the ability of retirees to meet the out-of-pocket limits that would trigger Medicare's catastrophic coverage. We recognize that CMS cannot through regulation remedy such a serious structural flaw in the statutory framework of the MMA, but we urge CMS to use its interpretive authority to ameliorate wherever possible the disadvantageous treatment of retirees with employer-sponsored coverage.

The statutory provisions of the MMA relating to employer-sponsored retiree prescription drug coverage are largely fashioned with a corporate health plan model in mind. Under this model, the plan sponsor is the employer who controls both plan design and financing decisions with little or no input from employees, unions or retirees. As you know, the world of multiemployer plans is quite different. Under applicable labor law, these collectively bargained plans are administered by a Board of Trustees consisting of equal numbers of representatives of labor and management. Under the Employee Retirement Income Security Act of 1974 (ERISA), the Board functions as both plan sponsor and the named fiduciary of the plan (and often the plan administrator as well) and therefore no individual employer can influence the operation or design of the plan because those decisions are reserved for the Board.

We appreciate the obvious effort that CMS has made in crafting its proposed rule to recognize that not all employer-sponsored plans are the same. We share your goals of maximizing the number of retirees retaining existing drug coverage, avoiding windfalls in which retirees receive a smaller subsidy from plan sponsors than Medicare would pay on their behalf, minimizing administrative burdens on beneficiaries, employers, unions, and plans, minimizing costs to the government of providing retiree drug subsidies and staying within the budget estimates. However, we believe that some of the rules that are being considered, particularly those directed at avoiding employer windfalls, may not be as relevant to multiemployer plans as they might be in a corporate plan setting, since it is the joint Board of Trustees that controls the design and financing of the retiree health plan, not any individual employer. This provides a degree of protection against potential manipulation that may be missing in other circumstances.

We have focused our comments on a handful of key issues raised in Subpart R of the proposed rule but we hope to open a dialogue with CMS staff on these and other issues of concern. Our detailed comments follow.

Comments Related to Subpart R – Payments to Sponsors of Retiree Prescription Drug Plans:

Section 423.882 Definitions

"Group health plan"

We support the use of the same definition of group health plan as found in section 607(1) of ERISA, 29 U.S.C. 1167(1). To further clarify the ability of multiemployer plans to qualify for the subsidy, we suggest also incorporating the definition of "multiemployer plan" found in section 3(37) of ERISA, 29 U.S.C. 1002(3)(37).

"Sponsor"

Although the proposed rule refers back to the definition of plan sponsor found in section 3(16)(B) of ERISA, we suggest that CMS confirm that in the case of a multiemployer plan (i.e., a plan established or maintained jointly by more than one employer and one or more employee associations), the plan sponsor is the board of trustees.

It would also be helpful for CMS to confirm how the employer subsidy provisions for prescription drug coverage operate in the context of a multiemployer health plan.

As we understand the statutory structure and legislative history of MMA regarding the employer subsidy for retiree prescription drug coverage, Congress intended for the Board of Trustees of the multiemployer plan to be the recipient of the employer subsidy since it is the plan that finances the retiree drug benefits (i.e., employer contributions and retiree contributions are placed in trust and those amounts, together with interest accumulated in the trust, are used to pay retiree prescription drug benefits). Therefore, as the entity claiming the subsidy, the multiemployer plan, not each contributing employer, will be responsible for meeting the procedural requirements to claim the subsidy, including providing the required disclosures to the Secretary and all eligible individuals (e.g., the notice of creditable coverage). The plan will apply for the subsidy (including furnishing the actuarial attestation and the list of qualified retirees covered under the multiemployer retiree prescription drug plan who are not enrolled in Medicare Part D). Once CMS has processed the application and verified the status of qualified retirees of all contributing employers, the subsidy would be paid to the multiemployer retiree prescription drug plan and these amounts would be credited toward future contributions to prescription drug coverage, by providing funds to cover costs that would otherwise have to be met through additional contributions. This approach eases burdens on CMS and individual contributing employers, while allowing the entity that pays the retiree prescription drug benefits (the multiemployer plan) to receive the subsidy and use it to cover retiree drug costs without incurring necessary administrative costs.

We would be happy to review with you the way that multiemployer plans operate and to furnish further detail why it is essential that the plan be treated as the plan sponsor for purposes of the subsidy, rather than individual contributing employers.

Section 423.884 Requirements for qualified retiree prescription drug plans

(a) Actuarial Attestation

Under the proposed rule, plan sponsors seeking to claim a subsidy for their prescription drug coverage must annually apply for the subsidy, no later than 90 days before the beginning of the calendar or plan year for which the subsidy is sought.

Although the proposed rule requires an actuarial attestation that the prescription drug benefits provided under the retiree prescription drug plan is at least actuarial equivalent to the standard Medicare Part D benefit, little guidance is given regarding the content of this attestation. CMS should consider developing a model form for this attestation, in which the plan's actuary could describe in simple terms how the determination of actuarial equivalency was made and what assumptions were used. A useful example of this type of standardized actuarial reporting for CMS to consider is the Schedule B to the Form 5500, the annual financial report that certain ERISA-covered pension plans must file with the U.S. Department of Labor. Of course, if CMS decides to promulgate a model form, its use should be considered a safe harbor for satisfaction of the attestation requirement and plan sponsors should be free to submit their own attestations in any other format as long as the required information has been included.

We think that CMS's proposal to require that an additional attestation must be filed with CMS no later than 90 days before a material change to the drug coverage that impacts the actuarial value of the coverage is generally reasonable, but we are concerned that the 90-day requirement may not be feasible in all situations.

The question of whether the 90-day deadline is feasible is interrelated with the issue of whether this deadline ought to be related to a calendar year or the plan year. CMS has indicated that it is leaning toward the use of a calendar year approach. Although most plan sponsors use a calendar year as the plan year, many do not. Clearly there are persuasive arguments favoring the use of a calendar year which can be made, however, we believe to reduce administrative burdens on plan sponsors, CMS should adopt a plan year approach.

Establishing actuarial equivalency

Under the MMA, the federal government will pay a cash subsidy to employers and other plan sponsors (including multiemployer plans) that provide retiree prescription drug coverage that is at least equal in value to the new Medicare Part D prescription drug coverage. The subsidy would be 28 percent of a retiree's total covered drug costs between $250 and $5,000 per year, which translates to a maximum subsidy payment to a plan sponsor of $1,330 per retiree. The subsidy would be payable for each retiree covered under the employer-sponsored plan who is not enrolled in Medicare Part D.

Although the cost of providing the new drug coverage under Medicare is partially financed by the Federal government, retirees enrolled in the new Medicare Part D benefit program will still be paying a substantial amount themselves for the coverage.

The standard Medicare Part D benefit design which will be offered through stand-alone prescription drug plans (PDPs) is as follows:

- Retirees will pay a monthly premium set by the PDP (estimated to be $35 per month in 2006 when the program begins, but expected to increase as costs increase);
- The PDP decides which prescription drugs to cover, as long as the PDP's formulary meets certain statutory requirements;
- Retirees must pay the first $250 in covered drug costs out of their own pocket (the standard deductible);
- Retirees pay 25% of covered drug costs between $250 and $2,250 during the year;
- Retirees pay 100% of covered drug costs between $2,225 and $5,100 during the year;
- Retirees pay no more than 5% of covered drug costs to the extent that those costs exceed $5,100. But to be eligible for this "catastrophic" coverage, an individual retiree must pay $3,600 (in 2006) in covered drug costs. Costs covered by a third-party, such as insurance or a group health plan, would not count toward this so-called "true out-of-pocket" amount (TrOOP).

To qualify for the 28% Federal subsidy, coverage provided by the employer-sponsored retiree medical plan does not have to be identical to the standard Part D drug benefit described above; it must be at least equal in value on an actuarial basis to the Part D coverage.

The MMA defines this measurement and comparison of the values of the two benefit design "actuarial equivalence." This test makes it possible to compare the value of different benefit designs. Actuarial equivalence looks at the expected cost of a benefit for a typical person, not how much it will actually cost for any given individual. This is important because a person who has greater health care needs obviously will cost more than one who is healthier.

The term "actuarial equivalence" is not defined in the proposed rule itself. CMS will have to create a standard for determining whether an employer retiree drug benefit is actuarially equivalent to the standard Part D benefit. However, in the preamble to the proposed rule, CMS has suggested a variety of differing approaches or tests to determine whether the employer-sponsored retiree drug plan is actuarially equivalent to the standard Medicare Part D prescription drug plan. CMS has asked for public comments on which, if any, of these standards is the right one and which may not be suitable. The standard CMS ultimately chooses will determine how generous a benefit employers have to offer retirees and how big a share of the benefit employers can require retirees to pay and still qualify for the federal subsidy.

Below is a brief description of each of the standards for which CMS seeks public comment:

- Single Prong Test: Under this test, also known as the "gross value test," an employer's benefit is good enough to qualify for a federal subsidy if, on average, the total value of

the benefit is at least equal to the total value of the standard Part D benefit. It does not matter what share of the benefit, if any, the employer pays. Under this test, the employer could contribute nothing and require the retiree to pay the full cost of the plan, yet the employer would still be paid the federal subsidy.

- Single Prong/No Windfall Test: As with the test above, an employer's benefit is good enough for a subsidy if on average the total value of the benefit is at least equal to the total value of the standard Part D benefit. However, the dollar amount of the subsidy paid to the employer cannot be greater than the dollar amount the employer pays toward the retiree coverage. The employer could design the plan so that it pays nothing towards retiree drug coverage after taking the federal subsidies into account.

- Two-Prong Test: This test begins with the single prong test but applies a second test (or "prong") in which the employer would also have to show it is paying for at least a specific minimum share of the total benefit. CMS offers several examples of the level at which it could set the minimum share or amount the employer must pay under the Two-Prong Test. These include:
    - The average per person amount Medicare would expect to pay as a subsidy to employers during the year, estimated by CMS to be $611 in 2006 when the program begins.
    - The expected amount of paid claims under the standard Part D prescription drug plan minus the monthly part D premiums paid by the retiree, estimated by the Congressional Budget Office to be approximately $1,200 in 2006.
    - The after-tax value of the average per person amount Medicare would expect to pay as a subsidy to employers during the year. For employers subject to the federal corporate income tax, this would be higher than the $611 estimated subsidy payment and will vary depending on the employer's tax rate.

One of Congress's policy goals under MMA is to ensure that the subsidy is used to preserve retiree benefits and not used simply to improve the employer's bottom line or for other non-health care uses. The preamble to the proposed regulation endorses the principle that the subsidy should be passed through to the retirees to pay for retiree prescription drug benefits. In particular, the proposed regulation states:

> "The intent of the MMA retiree prescription drug subsidy provisions is to slow the decline in employer-sponsored retiree insurance. By providing a special subsidy payment to sponsors of qualifying plans, the MMA provides employers with extra incentives and flexibility to maintain prescription drug coverage for their retirees. Our intention is to make these subsidy payments as reasonably available to plan sponsors as possible. We wish to take into account as much as possible the needs and concerns of plan sponsors, consistent with necessary assurances that Federal payments are accurate and in accordance with statutory requirements, that the interests of retiree-beneficiaries are protected, and that employers do not receive ''windfalls'' consisting of subsidy payments that are not passed on to beneficiaries."[1]

[1] 69 Fed. Reg. 46737 (August 3, 2004).

The structure of multiemployer plans assures that this policy goal is met.

After carefully considering each of the proposed standards, we have the following recommendations regarding the actuarial equivalence test that we believe are consistent with CMS's goals.

- CMS should adopt the Two-Prong Test for actuarial equivalence, which requires the portion of the prescription drug plan financed by the employer to be at least equal to the portion of the Part D benefit that is financed by Medicare. Only this test is consistent with the letter and intent of the MMA to provide for alternative drug coverage that is actuarially equivalent to the standard Part D benefit. In considering the portion of the plan that is financed by the employer, earnings on employer contributions held in trust as plan assets should be included. The comparison of the employer plan to the Part D benefit should be based on the benefits provided, not the cost.

- All of the other standards described by CMS in the preamble to the proposed rules could penalize retirees covered under a retiree drug plan and should be rejected. The Single Prong Test, the Single Prong/No Windfall Test, and the two versions of the Two-Prong Test that permit the employer to limit its contribution to the average subsidy amount it would expect to be paid from Medicare could all require a retiree to pay more for drug coverage than the retiree would if he or she were covered under a Medicare Part D prescription drug plan.

- Other tests being considered by CMS would allow for even greater windfalls to an employer. The Single Prong (or Gross Value) Test would allow for enormous windfalls to employers since it would permit an employer to pay nothing toward the drug benefit and still collect federal subsidies. This option has been roundly criticized in the press, is inconsistent with the intent of Congress, and would undermine the integrity of the Medicare drug program and therefore endanger the future of the program.

- In those cases in which a plan sponsor would be prohibited from claiming the largest possible retiree drug subsidy payable under the law due to the anti-windfall protections, CMS should provide a mechanism permitting the plan sponsor to claim the larger subsidy, so long as it passes through the value of the subsidy exceeding the windfall protections to the retirees. This is very important from a multiemployer perspective.

- Where a plan is fully insured, the regulations should require the insurance carrier to provide to the plan sponsor the information necessary to apply for the subsidy.

What is a "plan"?

As CMS acknowledges, many plan sponsors provide different levels and packages of benefits to different groups of retirees. In determining whether the coverage meets the actuarial equivalency test, one must first determine what the plan is that is being compared to the standard Medicare Part D prescription drug coverage. In its proposed rule, CMS indicates that it intends

to adopt a definition of "plan" that mirrors the current approach found in the Treasury regulations regarding the health insurance continuation requirements of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). Under those regulations, all health benefits provided by the plan sponsor are presumed to be under a single plan unless plan documents indicate otherwise.

As a result, actuarial equivalence would be determined by evaluating the plan as a whole, not on a benefit structure by benefit structure basis, and if, on average the actuarial value of the drug coverage equals or exceeds the value of the standard Part D coverage, the plan would satisfy the actuarial equivalency test.

We support the use of such an approach because it is one that is already familiar to plan sponsors and it provides flexibility without sacrificing retiree protections.

(b) Sponsor application for the subsidy payment

In general we support the approach taken by CMS that requires the plan sponsor to apply for the subsidy annually. As previously noted above, in the case of a multiemployer prescription drug plan, it is the plan itself, not each contributing employer that will file the application for the subsidy payment.

Under the proposed rule, plan sponsors must submit their subsidy applications no later than 90 days prior to the beginning of the calendar year for which the subsidy is requested. In order to receive the subsidy for 2006, applications with accompanying documentations must be submitted by September 30, 2005. For plans that begin coverage in the middle of a year, the plan sponsor must submit an actuarial attestation no later than 90 days prior to the date that coverage begins. For new plans that begin prescription drug coverage after September 30, 2005, the plan sponsor must submit an actuarial attestation no later than 150 days prior to the start of the program.

CMS also proposes to require that a plan sponsor submit a new actuarial attestation no later than 90 days before the implementation of a material change to the plan's drug coverage that impacts the actuarial value of the plan. A material change is defined as "any change that potentially causes the plan to no longer meet the actuarial equivalence test."

Although we generally support the proposed structure, we have concerns about the need to apply for a subsidy in the first year of the program by September 30, 2005. We are not sure whether the Boards of Trustees of multiemployer plans or other plan sponsors will be able to determine with certainty what alternatives there may be for retiree coverage other than simply continuing to provide benefits in the same way as in the past. For instance, some multiemployer plans may want to contract with qualified prescription drug plans (PDPs) to offer a coordinated or supplemental benefit. There is no guarantee that all the PDPs that might ultimately be offered in the region will be up and running by September 30, 2005. CMS should consider allowing plan sponsors who think they will be claiming the subsidy to file their application by September

30, 2005, but allow some flexibility in revising that application during a somewhat more extended period.

In addition, as previously noted in our comments on actuarial attestations generally, we think that CMS's proposal to require an additional attestation must be filed with CMS no later than 90 days before a material change to the drug coverage that impacts the actuarial value of the coverage is generally reasonable, but we are concerned that the 90-day requirement may not be feasible in all situations.

The question of whether the 90-day deadline is feasible is interrelated with the issue of whether this deadline ought to be related to a calendar year or the plan year. CMS has indicated that it is leaning toward the use of a calendar year approach. Although most plan sponsors use a calendar year as the plan year, many do not. Clearly there are persuasive arguments favoring the use of a calendar year which can be made, however, we believe to reduce administrative burdens on plan sponsors, CMS should adopt a plan year approach.

(c) Disclosure of creditable coverage

The proposed rule requires plan sponsors to disclose to retirees (and their Medicare-eligible spouses and dependents) whether the retiree prescription drug plan is actuarially equivalent to the standard Medicare Part D drug plan and therefore whether their coverage under the employer plan is creditable coverage. CMS has asked for input on a number of issues related to this requirement.

We encourage CMS to develop a model disclosure form that plan sponsors might use. We agree with CMS that it would be useful to consider as a model the approach taken by CMS, the Department of Labor and the Department of Treasury in their joint regulations regarding notices of creditable coverage under the Health Insurance Portability and Accountability Act of 1996, although the notice must be provided in a more timely fashion that would enable retirees to enroll in Part D if their plan is not actuarially equivalent.

CMS has also asked for comments regarding whether this disclosure could be incorporated into existing disclosures made to retirees in the normal course of plan operation or whether a separate notice should be required. In particular, CMS notes:

> We are soliciting comments regarding the types of materials that could provide an appropriate vehicle for this purpose, as well as ways to ensure that the notice is conspicuous and readily identified by recipients, particularly in those instances where the coverage is not creditable. 69 Fed. Reg. 46744.

Although we normally would oppose additional separate notices as unduly burdensome and would typically encourage CMS to allow plan sponsors to incorporate disclosure into existing types of dissemination, given the importance of the choice facing retirees, the need for timely disclosure of whether or not the plan's drug coverage is actuarially equivalent, and the

potential late enrollment penalties that retirees will face if they do not enroll in Part D when they are first eligible, we support requiring a separate notice regarding creditable coverage, unless the retiree prescription drug plan finds an alternative method of incorporating the notice with existing mailings or other forms of disclosure that assures that the notice will be conspicuous and readily identified by the recipients as important.

(d) HSAs, FSAs, HRAs, and MSAs

In the Preamble to the proposed rule, CMS requests input on whether the amounts used for prescription drug expenses under health savings accounts (HSAs) and other types of individual savings arrangements, including flexible spending accounts (FSAs), health reimbursement arrangements (HRAs) and medical savings accounts (MSAs) should be treated as group health payments for purposes of counting as incurred costs for purposes of meeting the Part D out-of-pocket threshold. 69 Fed. Reg. 46650. The general rule under Section 1860D-2(b)(4)(C)(ii) of the MMA is that any costs for which the individual is reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement do not count toward incurred costs.

CMS indicates that its "strong preference" is to treat HSA amounts differently so as to allow amounts reimbursed through an HSA to count towards incurred costs. Under this interpretation, a Medicare beneficiary could withdraw funds from his or her HSA, pay Part D drug expenses, and allow these expenses to count toward the beneficiary's out-of-pocket payments. Medicare catastrophic coverage would consequently begin sooner than if these payments were not counted toward TrOOP.

We strongly oppose creating a special exception for these payments. Although the Department of Labor has established a regulatory safe harbor for certain HSAs so that they may not be treated as group health plans under the Employee Retirement Income Security Act of 1974 (ERISA),[2] not all HSAs will fall into that safe harbor and some may, in fact, be group health plans. Even under the Department's guidance this question is ultimately decided by the individual facts and circumstances of each case. There is no statutory authority for CMS to create a special rule for HSAs and it would be both illegal and inappropriate to do so. Moreover, if HHS were to create a special exception from TrOOP only for those HSAs that were not employer plans would create an enforcement problem and an administrative nightmare. Who would determine whether the HSA in question was an ERISA plan? The Department of Labor? HHS? The plan sponsor? The individual who established the HSA himself or herself? The structure of the MMA and the proposed rule places a great deal of confidence in the plan sponsor to self-police compliance. Determining whether or not an arrangement constitutes an ERISA plan has always been the purview of the Department of Labor or, ultimately, the courts through actions brought under ERISA section 502. This would create a level of complexity and administrative burden that seems unjustified and unsupportable, given CMS' goals of

[2] Department of Labor Field Assistance Bulletin 2004-1 (April 7, 2004). This can be found at: http://www.dol.gov/ebsa/regs/fab_2004-1.html.

minimizing administrative burdens on employers, unions, plans and beneficiaries and minimizing costs to the government of providing retiree prescription drug coverage.

We believe that HSA amounts should be treated as other tax-favored forms of health coverage and excluded from incurred costs. They are not "essentially analogous to a beneficiary's bank account" because individuals who establish these accounts have been given extraordinarily generous tax preferences to use this form of tax-favored savings. Individuals can deduct amounts placed in HSAs when the contributions are made "above-the-line," contributions can be made by others on behalf of an individual and deducted by the individual, even though he or she didn't make the contribution, and withdrawals from HSAs for qualified medical expenses (including prescription drug costs) are tax free. In contrast, individuals who place money in a bank account are given no special tax preferences.

CMS' desire to give HSAs special treatment is simply another example of discrimination against retirees with employer-sponsored prescription drug coverage, since HSAs can be set up by individuals without any employer involvement, although employer contributions to HSAs on behalf of employees are permitted. HSAs should be treated as all other tax-favored savings mechanisms – whether individual or employer-sponsored (including FSAs, HRAs and MSAs). In other words, payments from all four of these vehicles should be excluded from incurred costs. To do otherwise would create a substantial windfall and an unjustified double taxpayer subsidy for individuals who establish HSAs. Not only would they receive a tax subsidy for establishing such an arrangement, they would be treated more favorably than individuals who pay prescription drug expenses through salary reduction programs that are employer-sponsored. To allow HSA amounts to count toward incurred costs while barring other forms of subsidized employer coverage from doing so is just another example of the bias against retiree drug coverage provided under employer-sponsored plans that is an integral part of the structure of the MMA, notwithstanding Congress' attempt to ameliorate that bias somewhat through the offering of an employer subsidy for continuing to provide coverage.

Waivers for Plan Sponsors to contract with or become Part D Prescription Drug Plans (PDPs) or Medicare Advantage (MA-PD) plans

Plan sponsors that do not choose to provide coverage that qualifies for the subsidy or provide coverage that supplements or wraps around the Part D benefit can instead contract with or become a PDP or Medicare Advantage (MA) plan. CMS indicates that an MA-PD plan or a PDP plan may request, in writing from CMS, a waiver or modification of the Medicare Advantage or Part D requirements that hinder the design of, the offering of, or the enrollment in Medicare Advantage plans by employees or former employees receiving benefits from plans sponsored by employers, labor organizations, or multiemployer plans. MA and PDP plans that receive a waiver may restrict the enrollment to participants and beneficiaries in an employer-sponsored plan. Waivers might include restricting enrollment to the plan sponsor's retirees and offer a benefit that resembles existing active coverage. A waiver might also include authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group.

A waiver process should be established for employers and other plan sponsors to contract with or otherwise create Medicare Part D PDPs and MA-PD plans that serve employment-based populations. Waivers should be published and made easily available online. Existing waivers that were made available to Medicare+Choice plans should be catalogued and placed online so that plan sponsors can determine what requirements have already been considered for waiver.

CMS recognizes that one option available to employers under the MMA is to provide retiree prescription coverage that supplements coverage offered under a PDP or MA-PD plan. For this option to work smoothly for plan sponsors, particularly those with retirees living across the PDP and MA-PD regions to be established, CMS should take appropriate steps to encourage the development of supplemental plans by PDP and MA-PD providers. If both the Part D plan and the supplemental plan are offered a single provider, it may be easier to coordinate benefits.

In addition, a number of multiemployer plans have joined together to establish purchasing coalitions to improve their purchasing leverage for prescription drugs with pharmacy benefit managers (PBMs). We strongly urge CMS to extend waiver authority to purchasing coalitions involved with employer-sponsored plans. It is quite likely that these purchasing coalitions may be potential PDP plan sponsors, so CMS should not preclude waivers for such entities.

Conclusion

Again we appreciate your willingness to seek input from the plan sponsor community and other stakeholders in the fight to preserve employer-sponsored retiree health programs. We are especially grateful for your willingness to consider the special administrative problems of multiemployer plans because of their structural differences from plans sponsored by individual employers. Please feel free to contact me for further information. We would be pleased to meet with you to discuss these comments and any other issues on which you are seeking input. We look forward to working with you in the future.

Yours truly,

Randy DeFrehn
Executive Director

VIA ELECTRONIC DELIVERY

October 4, 2004

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014
http://www.cms.hhs.gov/regulations/ecomments

Dear Sirs/Madams:

These comments are filed by the National Coordinating Committee for Multiemployer Plans (NCCMP) in response to the request for public comments by the Centers for Medicare and Medicaid Services (CMS) on the proposed rule to implement the new Medicare Prescription Drug Benefit authorized in section 101 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). This proposed rule was published in the Federal Register of August 3, 2004 (69 Fed. Reg. 46632).

The NCCMP is the only national organization devoted exclusively to protecting the interests of the approximately ten million workers, retirees, and their families who rely on multiemployer plans for retirement, health and other benefits. Our purpose is to assure an environment in which multiemployer plans can continue their vital role in providing benefits to working men and women. The NCCMP is a nonprofit organization, with members, plans and plan sponsors in every major segment of the multiemployer plan universe, including in the building and construction, retail food and service, and entertainment industries.

Most multiemployer plans today provide for retiree health benefits and many of those plans include some type of coverage for prescription drugs. As is well documented, the number of retirees covered by employer-sponsored health benefit plans today and in the future has continued to shrink, primarily because of the combination of accounting rule changes that force private sector employers to recognize the long-term liability of the retiree medical benefits and the rapidly escalating cost of providing that retiree health coverage.

Although facing the same marketplace cost pressures as other plan sponsors, employers and unions who have come together through collective bargaining to establish multiemployer plans have been less likely to drastically reduce or eliminate retiree coverage, in part because active workers in those industries where multiemployer plan coverage is prevalent have been willing to forgo some portion of their compensation to continue to subsidize the health benefits of their brothers and sisters who have retired. Even so, some multiemployer plans have been forced to alter the way benefits are financed in order to remain fiscally solvent. For some multiemployer plans, the rapidly escalating costs, the demographic trends, and the contraction of

the unionized workforce have required them to seriously rethink plan design and financing issues and to take steps to reduce or eliminate retiree benefits in ways that would have been unthinkable just a few years ago.

During the legislative process surrounding the passage of the MMA, the NCCMP urged Congress to consider carefully the structure of the new prescription drug program so as to avoid creating additional burdens on employer-sponsored plans and further incentives for them to reduce or drop prescription drug coverage for Medicare-eligible retirees. Although Congress incorporated an employer subsidy provision in the final legislation for plans that provided prescription drug benefits that were at least actuarially equivalent to the standard Part D drug benefit to encourage employers to continue providing retiree drug coverage, the overall structure of the new Medicare Part D benefit seriously disadvantages retirees with employer-sponsored coverage. This is particularly true with respect to the ability of retirees to meet the out-of-pocket limits that would trigger Medicare's catastrophic coverage. We recognize that CMS cannot through regulation remedy such a serious structural flaw in the statutory framework of the MMA, but we urge CMS to use its interpretive authority to ameliorate wherever possible the disadvantageous treatment of retirees with employer-sponsored coverage.

The statutory provisions of the MMA relating to employer-sponsored retiree prescription drug coverage are largely fashioned with a corporate health plan model in mind. Under this model, the plan sponsor is the employer who controls both plan design and financing decisions with little or no input from employees, unions or retirees. As you know, the world of multiemployer plans is quite different. Under applicable labor law, these collectively bargained plans are administered by a Board of Trustees consisting of equal numbers of representatives of labor and management. Under the Employee Retirement Income Security Act of 1974 (ERISA), the Board functions as both plan sponsor and the named fiduciary of the plan (and often the plan administrator as well) and therefore no individual employer can influence the operation or design of the plan because those decisions are reserved for the Board.

We appreciate the obvious effort that CMS has made in crafting its proposed rule to recognize that not all employer-sponsored plans are the same. We share your goals of maximizing the number of retirees retaining existing drug coverage, avoiding windfalls in which retirees receive a smaller subsidy from plan sponsors than Medicare would pay on their behalf, minimizing administrative burdens on beneficiaries, employers, unions, and plans, minimizing costs to the government of providing retiree drug subsidies and staying within the budget estimates. However, we believe that some of the rules that are being considered, particularly those directed at avoiding employer windfalls, may not be as relevant to multiemployer plans as they might be in a corporate plan setting, since it is the joint Board of Trustees that controls the design and financing of the retiree health plan, not any individual employer. This provides a degree of protection against potential manipulation that may be missing in other circumstances.

We have focused our comments on a handful of key issues raised in Subpart R of the proposed rule but we hope to open a dialogue with CMS staff on these and other issues of concern. Our detailed comments follow.

Comments Related to Subpart R – Payments to Sponsors of Retiree Prescription Drug Plans:

Section 423.882 Definitions

"Group health plan"

We support the use of the same definition of group health plan as found in section 607(1) of ERISA, 29 U.S.C. 1167(1). To further clarify the ability of multiemployer plans to qualify for the subsidy, we suggest also incorporating the definition of "multiemployer plan" found in section 3(37) of ERISA, 29 U.S.C. 1002(3)(37).

"Sponsor"

Although the proposed rule refers back to the definition of plan sponsor found in section 3(16)(B) of ERISA, we suggest that CMS confirm that in the case of a multiemployer plan (i.e., a plan established or maintained jointly by more than one employer and one or more employee associations), the plan sponsor is the board of trustees.

It would also be helpful for CMS to confirm how the employer subsidy provisions for prescription drug coverage operate in the context of a multiemployer health plan.

As we understand the statutory structure and legislative history of MMA regarding the employer subsidy for retiree prescription drug coverage, Congress intended for the Board of Trustees of the multiemployer plan to be the recipient of the employer subsidy since it is the plan that finances the retiree drug benefits (i.e., employer contributions and retiree contributions are placed in trust and those amounts, together with interest accumulated in the trust, are used to pay retiree prescription drug benefits). Therefore, as the entity claiming the subsidy, the multiemployer plan, not each contributing employer, will be responsible for meeting the procedural requirements to claim the subsidy, including providing the required disclosures to the Secretary and all eligible individuals (e.g., the notice of creditable coverage). The plan will apply for the subsidy (including furnishing the actuarial attestation and the list of qualified retirees covered under the multiemployer retiree prescription drug plan who are not enrolled in Medicare Part D). Once CMS has processed the application and verified the status of qualified retirees of all contributing employers, the subsidy would be paid to the multiemployer retiree prescription drug plan and these amounts would be credited toward future contributions to prescription drug coverage, by providing funds to cover costs that would otherwise have to be met through additional contributions. This approach eases burdens on CMS and individual contributing employers, while allowing the entity that pays the retiree prescription drug benefits (the multiemployer plan) to receive the subsidy and use it to cover retiree drug costs without incurring necessary administrative costs.

We would be happy to review with you the way that multiemployer plans operate and to furnish further detail why it is essential that the plan be treated as the plan sponsor for purposes of the subsidy, rather than individual contributing employers.

Section 423.884 Requirements for qualified retiree prescription drug plans

(a) Actuarial Attestation

Under the proposed rule, plan sponsors seeking to claim a subsidy for their prescription drug coverage must annually apply for the subsidy, no later than 90 days before the beginning of the calendar or plan year for which the subsidy is sought.

Although the proposed rule requires an actuarial attestation that the prescription drug benefits provided under the retiree prescription drug plan is at least actuarial equivalent to the standard Medicare Part D benefit, little guidance is given regarding the content of this attestation. CMS should consider developing a model form for this attestation, in which the plan's actuary could describe in simple terms how the determination of actuarial equivalency was made and what assumptions were used. A useful example of this type of standardized actuarial reporting for CMS to consider is the Schedule B to the Form 5500, the annual financial report that certain ERISA-covered pension plans must file with the U.S. Department of Labor. Of course, if CMS decides to promulgate a model form, its use should be considered a safe harbor for satisfaction of the attestation requirement and plan sponsors should be free to submit their own attestations in any other format as long as the required information has been included.

We think that CMS's proposal to require that an additional attestation must be filed with CMS no later than 90 days before a material change to the drug coverage that impacts the actuarial value of the coverage is generally reasonable, but we are concerned that the 90-day requirement may not be feasible in all situations.

The question of whether the 90-day deadline is feasible is interrelated with the issue of whether this deadline ought to be related to a calendar year or the plan year. CMS has indicated that it is leaning toward the use of a calendar year approach. Although most plan sponsors use a calendar year as the plan year, many do not. Clearly there are persuasive arguments favoring the use of a calendar year which can be made, however, we believe to reduce administrative burdens on plan sponsors, CMS should adopt a plan year approach.

Establishing actuarial equivalency

Under the MMA, the federal government will pay a cash subsidy to employers and other plan sponsors (including multiemployer plans) that provide retiree prescription drug coverage that is at least equal in value to the new Medicare Part D prescription drug coverage. The subsidy would be 28 percent of a retiree's total covered drug costs between $250 and $5,000 per year, which translates to a maximum subsidy payment to a plan sponsor of $1,330 per retiree. The subsidy would be payable for each retiree covered under the employer-sponsored plan who is not enrolled in Medicare Part D.

Although the cost of providing the new drug coverage under Medicare is partially financed by the Federal government, retirees enrolled in the new Medicare Part D benefit program will still be paying a substantial amount themselves for the coverage.

The standard Medicare Part D benefit design which will be offered through stand-alone prescription drug plans (PDPs) is as follows:

- Retirees will pay a monthly premium set by the PDP (estimated to be $35 per month in 2006 when the program begins, but expected to increase as costs increase);
- The PDP decides which prescription drugs to cover, as long as the PDP's formulary meets certain statutory requirements;
- Retirees must pay the first $250 in covered drug costs out of their own pocket (the standard deductible);
- Retirees pay 25% of covered drug costs between $250 and $2,250 during the year;
- Retirees pay 100% of covered drug costs between $2,225 and $5,100 during the year;
- Retirees pay no more than 5% of covered drug costs to the extent that those costs exceed $5,100. But to be eligible for this "catastrophic" coverage, an individual retiree must pay $3,600 (in 2006) in covered drug costs. Costs covered by a third-party, such as insurance or a group health plan, would not count toward this so-called "true out-of-pocket" amount (TrOOP).

To qualify for the 28% Federal subsidy, coverage provided by the employer-sponsored retiree medical plan does not have to be identical to the standard Part D drug benefit described above; it must be at least equal in value on an actuarial basis to the Part D coverage.

The MMA defines this measurement and comparison of the values of the two benefit design "actuarial equivalence." This test makes it possible to compare the value of different benefit designs. Actuarial equivalence looks at the expected cost of a benefit for a typical person, not how much it will actually cost for any given individual. This is important because a person who has greater health care needs obviously will cost more than one who is healthier.

The term "actuarial equivalence" is not defined in the proposed rule itself. CMS will have to create a standard for determining whether an employer retiree drug benefit is actuarially equivalent to the standard Part D benefit. However, in the preamble to the proposed rule, CMS has suggested a variety of differing approaches or tests to determine whether the employer-sponsored retiree drug plan is actuarially equivalent to the standard Medicare Part D prescription drug plan. CMS has asked for public comments on which, if any, of these standards is the right one and which may not be suitable. The standard CMS ultimately chooses will determine how generous a benefit employers have to offer retirees and how big a share of the benefit employers can require retirees to pay and still qualify for the federal subsidy.

Below is a brief description of each of the standards for which CMS seeks public comment:

- Single Prong Test: Under this test, also known as the "gross value test," an employer's benefit is good enough to qualify for a federal subsidy if, on average, the total value of

the benefit is at least equal to the total value of the standard Part D benefit. It does not matter what share of the benefit, if any, the employer pays. Under this test, the employer could contribute nothing and require the retiree to pay the full cost of the plan, yet the employer would still be paid the federal subsidy.

- Single Prong/No Windfall Test: As with the test above, an employer's benefit is good enough for a subsidy if on average the total value of the benefit is at least equal to the total value of the standard Part D benefit. However, the dollar amount of the subsidy paid to the employer cannot be greater than the dollar amount the employer pays toward the retiree coverage. The employer could design the plan so that it pays nothing towards retiree drug coverage after taking the federal subsidies into account.

- Two-Prong Test: This test begins with the single prong test but applies a second test (or "prong") in which the employer would also have to show it is paying for at least a specific minimum share of the total benefit. CMS offers several examples of the level at which it could set the minimum share or amount the employer must pay under the Two-Prong Test. These include:
    - The average per person amount Medicare would expect to pay as a subsidy to employers during the year, estimated by CMS to be $611 in 2006 when the program begins.
    - The expected amount of paid claims under the standard Part D prescription drug plan minus the monthly part D premiums paid by the retiree, estimated by the Congressional Budget Office to be approximately $1,200 in 2006.
    - The after-tax value of the average per person amount Medicare would expect to pay as a subsidy to employers during the year. For employers subject to the federal corporate income tax, this would be higher than the $611 estimated subsidy payment and will vary depending on the employer's tax rate.

One of Congress's policy goals under MMA is to ensure that the subsidy is used to preserve retiree benefits and not used simply to improve the employer's bottom line or for other non-health care uses. The preamble to the proposed regulation endorses the principle that the subsidy should be passed through to the retirees to pay for retiree prescription drug benefits. In particular, the proposed regulation states:

> "The intent of the MMA retiree prescription drug subsidy provisions is to slow the decline in employer-sponsored retiree insurance. By providing a special subsidy payment to sponsors of qualifying plans, the MMA provides employers with extra incentives and flexibility to maintain prescription drug coverage for their retirees. Our intention is to make these subsidy payments as reasonably available to plan sponsors as possible. We wish to take into account as much as possible the needs and concerns of plan sponsors, consistent with necessary assurances that Federal payments are accurate and in accordance with statutory requirements, that the interests of retiree-beneficiaries are protected, and that employers do not receive ''windfalls'' consisting of subsidy payments that are not passed on to beneficiaries."[1]

[1] 69 Fed. Reg. 46737 (August 3, 2004).

The structure of multiemployer plans assures that this policy goal is met.

After carefully considering each of the proposed standards, we have the following recommendations regarding the actuarial equivalence test that we believe are consistent with CMS's goals.

- CMS should adopt the Two-Prong Test for actuarial equivalence, which requires the portion of the prescription drug plan financed by the employer to be at least equal to the portion of the Part D benefit that is financed by Medicare. Only this test is consistent with the letter and intent of the MMA to provide for alternative drug coverage that is actuarially equivalent to the standard Part D benefit. In considering the portion of the plan that is financed by the employer, earnings on employer contributions held in trust as plan assets should be included. The comparison of the employer plan to the Part D benefit should be based on the benefits provided, not the cost.

- All of the other standards described by CMS in the preamble to the proposed rules could penalize retirees covered under a retiree drug plan and should be rejected. The Single Prong Test, the Single Prong/No Windfall Test, and the two versions of the Two-Prong Test that permit the employer to limit its contribution to the average subsidy amount it would expect to be paid from Medicare could all require a retiree to pay more for drug coverage than the retiree would if he or she were covered under a Medicare Part D prescription drug plan.

- Other tests being considered by CMS would allow for even greater windfalls to an employer. The Single Prong (or Gross Value) Test would allow for enormous windfalls to employers since it would permit an employer to pay nothing toward the drug benefit and still collect federal subsidies. This option has been roundly criticized in the press, is inconsistent with the intent of Congress, and would undermine the integrity of the Medicare drug program and therefore endanger the future of the program.

- In those cases in which a plan sponsor would be prohibited from claiming the largest possible retiree drug subsidy payable under the law due to the anti-windfall protections, CMS should provide a mechanism permitting the plan sponsor to claim the larger subsidy, so long as it passes through the value of the subsidy exceeding the windfall protections to the retirees. This is very important from a multiemployer perspective.

- Where a plan is fully insured, the regulations should require the insurance carrier to provide to the plan sponsor the information necessary to apply for the subsidy.

What is a "plan"?

As CMS acknowledges, many plan sponsors provide different levels and packages of benefits to different groups of retirees. In determining whether the coverage meets the actuarial equivalency test, one must first determine what the plan is that is being compared to the standard Medicare Part D prescription drug coverage. In its proposed rule, CMS indicates that it intends

to adopt a definition of "plan" that mirrors the current approach found in the Treasury regulations regarding the health insurance continuation requirements of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). Under those regulations, all health benefits provided by the plan sponsor are presumed to be under a single plan unless plan documents indicate otherwise.

As a result, actuarial equivalence would be determined by evaluating the plan as a whole, not on a benefit structure by benefit structure basis, and if, on average the actuarial value of the drug coverage equals or exceeds the value of the standard Part D coverage, the plan would satisfy the actuarial equivalency test.

We support the use of such an approach because it is one that is already familiar to plan sponsors and it provides flexibility without sacrificing retiree protections.

(b) Sponsor application for the subsidy payment

In general we support the approach taken by CMS that requires the plan sponsor to apply for the subsidy annually. As previously noted above, in the case of a multiemployer prescription drug plan, it is the plan itself, not each contributing employer that will file the application for the subsidy payment.

Under the proposed rule, plan sponsors must submit their subsidy applications no later than 90 days prior to the beginning of the calendar year for which the subsidy is requested. In order to receive the subsidy for 2006, applications with accompanying documentations must be submitted by September 30, 2005. For plans that begin coverage in the middle of a year, the plan sponsor must submit an actuarial attestation no later than 90 days prior to the date that coverage begins. For new plans that begin prescription drug coverage after September 30, 2005, the plan sponsor must submit an actuarial attestation no later than 150 days prior to the start of the program.

CMS also proposes to require that a plan sponsor submit a new actuarial attestation no later than 90 days before the implementation of a material change to the plan's drug coverage that impacts the actuarial value of the plan. A material change is defined as "any change that potentially causes the plan to no longer meet the actuarial equivalence test."

Although we generally support the proposed structure, we have concerns about the need to apply for a subsidy in the first year of the program by September 30, 2005. We are not sure whether the Boards of Trustees of multiemployer plans or other plan sponsors will be able to determine with certainty what alternatives there may be for retiree coverage other than simply continuing to provide benefits in the same way as in the past. For instance, some multiemployer plans may want to contract with qualified prescription drug plans (PDPs) to offer a coordinated or supplemental benefit. There is no guarantee that all the PDPs that might ultimately be offered in the region will be up and running by September 30, 2005. CMS should consider allowing plan sponsors who think they will be claiming the subsidy to file their application by September

30, 2005, but allow some flexibility in revising that application during a somewhat more extended period.

In addition, as previously noted in our comments on actuarial attestations generally, we think that CMS's proposal to require an additional attestation must be filed with CMS no later than 90 days before a material change to the drug coverage that impacts the actuarial value of the coverage is generally reasonable, but we are concerned that the 90-day requirement may not be feasible in all situations.

The question of whether the 90-day deadline is feasible is interrelated with the issue of whether this deadline ought to be related to a calendar year or the plan year. CMS has indicated that it is leaning toward the use of a calendar year approach. Although most plan sponsors use a calendar year as the plan year, many do not. Clearly there are persuasive arguments favoring the use of a calendar year which can be made, however, we believe to reduce administrative burdens on plan sponsors, CMS should adopt a plan year approach.

(c) Disclosure of creditable coverage

The proposed rule requires plan sponsors to disclose to retirees (and their Medicare-eligible spouses and dependents) whether the retiree prescription drug plan is actuarially equivalent to the standard Medicare Part D drug plan and therefore whether their coverage under the employer plan is creditable coverage. CMS has asked for input on a number of issues related to this requirement.

We encourage CMS to develop a model disclosure form that plan sponsors might use. We agree with CMS that it would be useful to consider as a model the approach taken by CMS, the Department of Labor and the Department of Treasury in their joint regulations regarding notices of creditable coverage under the Health Insurance Portability and Accountability Act of 1996, although the notice must be provided in a more timely fashion that would enable retirees to enroll in Part D if their plan is not actuarially equivalent.

CMS has also asked for comments regarding whether this disclosure could be incorporated into existing disclosures made to retirees in the normal course of plan operation or whether a separate notice should be required. In particular, CMS notes:

> We are soliciting comments regarding the types of materials that could provide an appropriate vehicle for this purpose, as well as ways to ensure that the notice is conspicuous and readily identified by recipients, particularly in those instances where the coverage is not creditable. 69 Fed. Reg. 46744.

Although we normally would oppose additional separate notices as unduly burdensome and would typically encourage CMS to allow plan sponsors to incorporate disclosure into existing types of dissemination, given the importance of the choice facing retirees, the need for timely disclosure of whether or not the plan's drug coverage is actuarially equivalent, and the

potential late enrollment penalties that retirees will face if they do not enroll in Part D when they are first eligible, we support requiring a separate notice regarding creditable coverage, unless the retiree prescription drug plan finds an alternative method of incorporating the notice with existing mailings or other forms of disclosure that assures that the notice will be conspicuous and readily identified by the recipients as important.

(d) HSAs, FSAs, HRAs, and MSAs

In the Preamble to the proposed rule, CMS requests input on whether the amounts used for prescription drug expenses under health savings accounts (HSAs) and other types of individual savings arrangements, including flexible spending accounts (FSAs), health reimbursement arrangements (HRAs) and medical savings accounts (MSAs) should be treated as group health payments for purposes of counting as incurred costs for purposes of meeting the Part D out-of-pocket threshold. 69 Fed. Reg. 46650. The general rule under Section 1860D-2(b)(4)(C)(ii) of the MMA is that any costs for which the individual is reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement do not count toward incurred costs.

CMS indicates that its "strong preference" is to treat HSA amounts differently so as to allow amounts reimbursed through an HSA to count towards incurred costs. Under this interpretation, a Medicare beneficiary could withdraw funds from his or her HSA, pay Part D drug expenses, and allow these expenses to count toward the beneficiary's out-of-pocket payments. Medicare catastrophic coverage would consequently begin sooner than if these payments were not counted toward TrOOP.

We strongly oppose creating a special exception for these payments. Although the Department of Labor has established a regulatory safe harbor for certain HSAs so that they may not be treated as group health plans under the Employee Retirement Income Security Act of 1974 (ERISA),[2] not all HSAs will fall into that safe harbor and some may, in fact, be group health plans. Even under the Department's guidance this question is ultimately decided by the individual facts and circumstances of each case. There is no statutory authority for CMS to create a special rule for HSAs and it would be both illegal and inappropriate to do so. Moreover, if HHS were to create a special exception from TrOOP only for those HSAs that were not employer plans would create an enforcement problem and an administrative nightmare. Who would determine whether the HSA in question was an ERISA plan? The Department of Labor? HHS? The plan sponsor? The individual who established the HSA himself or herself? The structure of the MMA and the proposed rule places a great deal of confidence in the plan sponsor to self-police compliance. Determining whether or not an arrangement constitutes an ERISA plan has always been the purview of the Department of Labor or, ultimately, the courts through actions brought under ERISA section 502. This would create a level of complexity and administrative burden that seems unjustified and unsupportable, given CMS' goals of

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minimizing administrative burdens on employers, unions, plans and beneficiaries and minimizing costs to the government of providing retiree prescription drug coverage.

We believe that HSA amounts should be treated as other tax-favored forms of health coverage and excluded from incurred costs. They are not "essentially analogous to a beneficiary's bank account" because individuals who establish these accounts have been given extraordinarily generous tax preferences to use this form of tax-favored savings. Individuals can deduct amounts placed in HSAs when the contributions are made "above-the-line," contributions can be made by others on behalf of an individual and deducted by the individual, even though he or she didn't make the contribution, and withdrawals from HSAs for qualified medical expenses (including prescription drug costs) are tax free. In contrast, individuals who place money in a bank account are given no special tax preferences.

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CMS recognizes that one option available to employers under the MMA is to provide retiree prescription coverage that supplements coverage offered under a PDP or MA-PD plan. For this option to work smoothly for plan sponsors, particularly those with retirees living across the PDP and MA-PD regions to be established, CMS should take appropriate steps to encourage the development of supplemental plans by PDP and MA-PD providers. If both the Part D plan and the supplemental plan are offered a single provider, it may be easier to coordinate benefits.

In addition, a number of multiemployer plans have joined together to establish purchasing coalitions to improve their purchasing leverage for prescription drugs with pharmacy benefit managers (PBMs). We strongly urge CMS to extend waiver authority to purchasing coalitions involved with employer-sponsored plans. It is quite likely that these purchasing coalitions may be potential PDP plan sponsors, so CMS should not preclude waivers for such entities.

Conclusion

Again we appreciate your willingness to seek input from the plan sponsor community and other stakeholders in the fight to preserve employer-sponsored retiree health programs. We are especially grateful for your willingness to consider the special administrative problems of multiemployer plans because of their structural differences from plans sponsored by individual employers. Please feel free to contact me for further information. We would be pleased to meet with you to discuss these comments and any other issues on which you are seeking input. We look forward to working with you in the future.

Yours truly,

Randy DeFrehn
Executive Director

CMS-4068-P-1239

Submitter : Mr. Carlos Ortiz **Date & Time:** 10/04/2004 08:10:02

Organization : CVS/pharmacy

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

Please accept these comments on behalf of CVS/pharmacy regarding the proposed rule addressing Medicare Program: Medicare Prescription Drug Benefit, CMS 4068-P, RON-0938-AN08.

CMS-4068-P-1239-Attach-1.doc

CARLOS R. ORTIZ, R.Ph.
Vice President of Government Affairs

September 30, 2004

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Subject: Medicare Program: Medicare Prescription Drug Benefit, CMS 4068-P, RIN-0938-AN08

To Whom It May Concern:

CVS/Pharmacy is providing comments with regard to the proposed rule published August 3, 2004. This rule would implement Title I of the Medicare Modernization Act of 2003 that establishes the voluntary Medicare Part D prescription drug benefit.

CVS operates over 5,300 pharmacies in 36 states and the District of Columbia. CVS is the largest provider of out-patient prescription drugs in the United States. As such, our expectation is that CVS will be a major provider of pharmacy services to Medicare recipients under the Part D program.

Section 423.30-423.50 – Issues Relating to Eligibility and Enrollment (Subpart A)

The confusion that has surrounded the Medicare discount card demonstrates the need for clear and understandable materials for Medicare recipients. CVS would also encourage CMS to recognize the role of the pharmacist in helping recipients to understand this benefit. Some of the components of these materials would include:

- The network status of a pharmacy and whether the pharmacy is a preferred or non-preferred pharmacy.
- The eligibility status of the recipient, whether they have met their front end deductible, and whether they have reached a gap in coverage (ie. the donut hole).
- This information must be provided to the pharmacist via an on-line real time basis.
- The experience with Medicare recipients, who were eligible for the $600 Transitional Assistance and failed to enroll, shows a definite need for special attention to be directed to the Medicare/Medicaid dual eligible. CVS would encourage CMS to allow for a transitional period for these dual eligible beneficiaries. We would also encourage an automatic enrollment process for these individuals.

Section 423.100 – Definition of Covered Part D Drugs

Options for Dispensing Fees – 69 Federal Register 46647-48

Most Medicare recipients will receive their Part D benefits from private insurers or prescription benefit managers (PBMs). CVS is concerned that these entities will attempt to utilize dispensing fees usually reserved for private insurers for this program. The complexity of providing services to this population, because of issues such as coordination of benefits, gaps in coverage, determination of front end deductibles, product and patient eligibility, etc. makes this program considerably more difficult. Recent studies, including the newly enacted California Medicaid dispensing fee, showing that the dispensing fee has to be in excess of $7 to adequately reimburse pharmacies for providing these services.

Section 423.104 – Requirements relating to Qualified Precription Drug Coverage

Access to negotiated prices

Subsection(h) of this section requires pharmacies to pass through negotiated prices during coverage gaps and for non-covered formulary drugs. This requirement amounts to nothing less than price controls on retail pharmacies. While this burden is extended to retail pharmacies, no such burdens are required of pharmaceutical manufacturers, or plan sponsors. Plan sponsors should not be able to keep any "pharmacy spreads" on prescriptions. Thus, they should not be able to reimburse pharmacies at a lower rate than they are charging the plan for filling the prescription.

Section 423.120 – Access to Covered Part D Drugs

Section 423.120(a)(1)-(5) – Issues relating to access to pharmacies

The legislative history demonstrates that it was the intent of Congress to require plans to comply, at a minimum, with the Department of Defense TriCare access standards. These standards require that 90% of Medicare beneficiaries must live within 2 miles of a participating pharmacy in an urban area, 90% of recipients in a suburban area must live within a 5 mile radius of a participating pharmacy, and 70% of recipients living in rural areas they must live within a 15 mile radius of a participating pharmacy. The proposed rule should also clearly define whether these distances are geographic or driving distances.

Averaging Access Standards

The proposed rules allow plans to meet these standards by averaging. CVS believes that each plan must meet these standards in each state and in region in which they operate. Allowing them to average the access standards could create areas where Medicare recipients lack adequate accessibility to a participating pharmacy. For

example, in Pennsylvania, averaging could result in a situation where Philadelphia is more than adequately served while Pittsburgh is not.

Creating "Preferred Pharmacy" Network

The proposed rule also allows plans to use this averaging methodology when creating networks of "preferred pharmacies" and "non-preferred pharmacies". By utilizing this method, the plan could create a higher cost non-preferred network that meets the TriCare access standards and at the same time create a lower cost preferred network that does not meet the standard. The proposed rule should be changed to require that all networks meet the TriCare access standard.

Section 423.120(a)(4) – Contracting Terms with Pharmacies and Prohibition of Transferring Insurance Risk

This section and Congress clearly prohibited plans from requiring pharmacies to accept insurance risk as a condition of participation. The proposed rule defines insurance risk as "risk that is commonly assumed by insured licensed by a state". It further states that it should not include payment variations due to performance based measures. Although these performance based incentives are common in the market place, they are usually in addition to the basic reimbursement. They represent additional payments for meeting certain objectives and there are no deductions from the basic payment, if these objectives are not met.

The final rule should prohibit plans from utilizing a variation of the system detailed above to require pharmacies to accept any contractual terms that would require them to accept lower payment rates if a plan experiences cost over runs. The plans should also cleanly identify to the pharmacy the pricing source that they will use for payment.

Section 423.120(a)(6) – Level playing field between mail order and network pharmacies

The Legislative Record shows that it was the intent of Congress to allow community pharmacies to provide a 90-day supply with no artificial cost sharing that would "coerce" recipients to obtain their maintenance medication from a mail order entity. Thus, the only additional cost to the recipient should be the difference in the negotiated price for the covered drug at the network pharmacy and the mail order pharmacy. With this in mind, the definition of "negotiated price" should reflect the price to the plan net any rebates, discounts or other price concessions paid to the plan for a similar drug quantity obtained from either the retail pharmacy or the mail order pharmacy. These price concessions should be applied directly to reducing the cost of the prescription. The plan should not be allowed to use the price concessions to artificially lower the cost of mail order prescriptions.

Section 423.153(b)) – Quality Assurance Programs

The preamble of the proposed rule contains extensive discussion of quality assurance programs the plans should incorporate. CVS fully supports the incorporation of quality assurance programs. However, rather than requiring the prescription drug plans to establish their own quality assurance programs, the role of the plans should be to develop a system that ensures that the provider has established a quality assurance program and measures the value of such programs. The preamble also states that future reporting of error rates may be required to allow recipients to compare the quality of service in choosing a plan. All studies involved in accessing quality assurance plans have shown that the most effective quality assurance programs allow for an anonymous and confidential reporting structure with legal protection from discovery.

Section 423.851-.875 – Subpart Q – Guaranteeing Access to Choice of Coverage (fall back plans)

These sections contain the requirements that the government establish a fall back plan in the event there is a region where there are not two choices of either a risk bearing PDP or MA-PD. The final rule should make clear that these fall back plans must comply with all the access and quality standards that PDP and MA-PD must adhere to. Additionally, the fall back plan should also be required to adequately reimburse pharmacies with regard to a dispensing fee and an appropriate product cost reimbursement.

In conclusion, CVS appreciates this opportunity to comment with regard to the proposed regulations regarding the Medicare Part D portion of the Medicare Modernization Act. We would urge CMS to use its discretionary power to amend the proposed rule to address our concerns with regard to adequate reimbursement for pharmacies, access standards, quality assurance issues, and education of recipients and pharmacies.

Sincerely,

Carlos R. Ortiz, R.Ph
Vice President of Government Affairs

CO:bab

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CMS-4068-P-1240

Submitter : Mr. Robert McKay **Date & Time:** 10/04/2004 08:10:14

Organization : PharmaCare

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

This is PharmaCare's response to Medicare Drug Benefit; Comments to
The Proposed Rule.

CMS-4068-P-1240-Attach-1.rtf

Medicare Drug Benefit; Comments to The Proposed Rule

Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)

Contents

Background, Intent and Acknowledgement

Founded in 1994, PharmaCare is a wholly owned subsidiary of CVS Corporation, the nations largest operator of retail pharmacies with annual sales in excess of $33 billion. PharmaCare has more than 3,000 employees and is the most diversified pharmaceutical care management company in the country. PharmaCare holds leading positions in pharmacy benefit management services, mail-service pharmacy, specialty drug pharmacy and clinic pharmacy services. PharmaCare is also a Medicare approved national drug discount card sponsor. By the conclusion of 2004, over 140,000 Medicare beneficiaries will have enrolled in ***myPharmaCare***.

Through this document PharmaCare offers comment to the proposed rule (42 CFR Parts 403, 411, 417 and 423; Medicare program; Medicare Drug Benefit). The creation of Prescription Drug Plans (PDP's), Limited Risk Plans and Fallback Plans through the Act are of potential interest to PharmaCare. However, some aspects of the proposed rule, which we address herein, raise concerns that should be addressed by CMS. These concerns are not unique to PharmaCare as they are, in many respects, shared by our competitors. We are sure that should CMS publish a final rule that satisfactorily addresses these issues that all Medicare beneficiaries will be better served.

Finally, PharmaCare appreciates the opportunity to make comment to this proposed rule. Today PBM's are providing millions of Medicare beneficiaries drug benefits through employer sponsored plans and Medicare Choice contractor plans. Consultation between PBM's and CMS is the right course of action. Accordingly, PharmaCare offers our services freely to CMS now, and throughout the process ahead that will conclude with the successful implementation of Medicare Part-D in 2006.

The Proposed PDP Regions

Introduction. PharmaCare attended the open forum held in Chicago, IL (Rosemont) regarding the formation of regions for MA-PD and PDP's. The presentations made indicated that serious study and analysis had been given to each option under consideration. In the broader context the issue of fewer versus many regions clearly dominates the debate at hand.

Discussion. PharmaCare offers the following comments.

Comments About Fewer Regions. Of the two options being considered (10 regions or 11) we believe that the option for 11 regions has greater merit. It is our view that this option represents a better distribution of markets, or concentrations of beneficiaries, over the 10-region option. However, while fewer regions create larger pools of beneficiaries for PDP's to market to, they also offer unique barriers that also inhibit the scale value of such large multi-state regions. State insurance regulations are the most noteworthy barrier. State licensure and oversight would will prove burdensome for PDP's. As the proposed rule offers PDP's no safe-harbor in this regard, PDP's will not freely enjoy the scale inherent in multi-state regions, but will instead be forced to operate as multiple state based entities within a region. This will increase cost and hamper the ability of PDP's to effectively capitalize on the larger pools of beneficiaries offered through multi-state regions.

Comments About Many Regions. Of the four regions being considered (32, 34, 37 and 50) we believe that the option of 50 regions is most appealing and the option for 37 regions has merit as well. In summary the 50-region option simplifies many regulatory and operational considerations by equating region with state. Of the remaining regional considerations, we believe the option for 37 regions does the better job of joining several states to form the few multi-state regions. In these cases the 37 region option does the best job of preserving the

integrity of traditional regional markets; e.g. Northern New England, Pacific Northwest, etc. While not by any means uniform, insurance considerations should vary less among the states joined to form these few multi-state regions.

Recommendation. For the reasons discussed above, PharmaCare recommends many regions versus few, with 50 regions being recommended above all other considerations. We appreciate the goals and intent of CMS through the concept of larger multi-state regions. However, given the pace of this program, the challenges posed by such an approach would be too numerous and prove a barrier to program implementation. The issue of multi-state regions is always a consideration CMS could revisit in the future.

Issues Related to TROOP

Introduction. PharmaCare has studied the proposed rule regarding TROOP (True Out Of Pocket) and has participated in CMS special open door forums regarding TROOP as well. Of all of the topics worthy of comment, TROOP represents a topic in need of serious comment by industry and re-consideration by CMS.

Discussion. At the heart of the issue with TROOP is the requirement to coordinate benefits with the beneficiary's Other Health Insurance (OHI) on a real time basis. While there are several issues that make TROOP coordination problematic, it is the issue of real time coordination that is most serious.

Under the proposed rule PDP's would be required to assure TROOP through coordination with OHI as self-identified by the beneficiary upon their application. While the intent of TROOP can easily be appreciated, the practicality of coordinating OHI on a real time basis for pharmacy benefits is very problematic. In summary, with respect to pharmacy claims, the activity of claims adjudication corresponds to the actual time of service; a process that takes less than 5 seconds. This differs significantly from the process used for medical billing. Under medical claims management, claims adjudication is not associated real time with the performance of service, but instead occurs days, weeks even months later, and this lag time makes OHI coordination possible under a medical claims approach. The rule, as written, approaches TROOP coordination in the context of a medical claims management model, not the existing pharmacy model. And, it assumes this model is transferable to pharmacy, when it is not. The approach to TROOP in the proposed rule is inconsistent with pharmacy claims management standards and practice, and should be changed in the final rule. We offer amplification below to support this recommendation.

Are pharmacies the answer? Pharmacies are not the solution to accomplish TROOP. Pharmacies do not and cannot split claims. The point of sale (POS) systems used universally by pharmacies direct each claim to a designated single payor; not multiple payors. The transaction is processed in 2 to 3 seconds with a response as either paid or denied, but only from the one payor. With respect to the relationship between the patient and the pharmacy, the pharmacy is only a provider. It has no way of knowing what the beneficiary disclosed regarding OHI when the beneficiary made their application to the PDP. The pharmacy will only know to submit a beneficiaries claim to a PDP when beneficiary presents a prescription and their PDP program card.

Are PBM's the answer? Given that pharmacies are not the solution for TROOP, the question is rightfully directed to PBM systems for consideration. As the PBM system receives claims from pharmacy systems, is it possible that that the PBM system can coordinate TROOP on a real time basis? The answer is, no. The adjudication process is bi-directional only: e.g. between the pharmacy, where the claim is originated, and the PBM. PBM systems do not systematically redirect claims to other health insurance providers in real time before responding to the claims originator, the pharmacy. Coordination of benefits is most often accomplished by PBM systems by denying claims for plan members where the plan sponsor has indicated the existence of other health insurance through the eligibility file. Under these conditions a beneficiary would be denied until the plan sponsor indicated they were satisfied that the member's OHI had been exhausted. Such a determination would occur directly between the beneficiary and the plan sponsor, and outside of the claims adjudication process.

The PBM's role in coordinating TROOP is further complicated by other considerations. Today, PBM's contract almost entirely with group payers (e.g. self-insured employer plans, managed care plans, etc.), and not individuals. Should a group payer have just one source of OHI, it ***may*** be possible for the PBM to coordinate with that singular source in real-time under unique conditions;

(e.g. the PBM already had a contractual relationship with the other health insurance payer). However, as Part-D is not a group product, enrolling beneficiaries may have OHI from any number of sources (e.g. an employer wrap-plan; a Med-Sup plan; a drug manufacturer plan; etc.). As written, the proposed rule would require that TROOP be coordinated real-time with each and every OHI source identified by the beneficiary. This would require the PBM to establish contracts and real-time electronic claims processing procedures with an open-ended number of OHI sources. This is unrealistic. First, as discussed previously, PBM systems are not configured to redirect claims to OHI providers in real-time. Second, assuming the first problem could be overcome, it is unrealistic to assume that a PBM could successfully conclude contract terms and on-line claims transaction coordination with every source of OHI. Many of these sources would not even be capable of on-line claims transactions. In conclusion, PBM's and their systems are not the solution for assuring accurate coordination of TROOP.

Recommendation. PharmaCare recommends that CMS confer with the National Council for Prescription Drug Programs (NCPDP). NCPDP serves an important role for all industries associated with pharmacy programs. Most importantly they establish the electronic claims standards necessary to accomplish prescription drug program management. Together, NCPDP and CMS can coordinate a workable solution for TROOP.

Also, CMS should give serious consideration to allowing PDP's to simply deny acceptance for any applicant who indicates they have OHI. The approach to TROOP under the proposed rule is a source of unacceptable risk to potential PDP's in terms of investment and accountability. As PDP's are risk based providers they should be asked to only assume risk for beneficiaries where accurate risk accountability can be assured. Beneficiaries with OHI are perfectly suited for Limited Risk Plans or Fallback Plans, and we recommend that PDP's should not be required to enroll such beneficiaries.

The Proposed Data Set

Introduction. PharmaCare participated in a CMS sponsored Open Door Forum (ODF) on September 9, 2004 regarding the Bidders' Data Set for Prescription Drug Plans. The forum's intent was for the American Academy of Actuaries Working Group to identify the high-priority data needs for bidders, to summarize their discussions with CMS on developing a bidders data set, and to present a plan for making essential data available in a timely manner. A summary of the ODF went on to describe the need for a data set as follows: *A data set including detailed information on drug utilization is an essential element in facilitating bids by insurers to provide prescription drug coverage.*

Discussion. PharmaCare concurs that an accurate and comprehensive data set is an essential element to facilitate bidding. The ODF, however, pointed to significant problems with the approaches being pursued by the Academy's Working Group.

The data sources available to the Working Group are of little value as they are incomplete and dated. The Medicare Current Beneficiary Survey (MCBS) has significant limitations and shortcomings as an instrument for producing the necessary drug utilization information needed by potential PDP bidders. The 2001 FEP retirees' data does not reflect the many new drugs that have come to market since that time nor the changes in drug prices. In summary, these sources are inadequate and incomplete.

Recommendation. To gain the confidence of PDP's, CMS should endeavor to secure credible sources of data for the Academy's Working Group to analyze. Such sources are readily available. Three excellent sources are discussed below.

1. TRICARE. The TRICARE pharmacy benefit program includes a program unique to over 1.5 million retirees. CMS should coordinate the transfer of both a historical drug utilization file from the Department of Defense's TRICARE Management Activity (TMA) and update files as necessary. The TRICARE TMA subscribes to the standards established by NCPDP. The creation of file reflecting the data fields and layout standards of NCPDP is a task that can be easily accomplished by TMA or its contractor. PharmaCare recommends CMS act quickly as this approach to securing valuable and relevant data represents a low or no cost activity that can be accomplished in days.

2. Pharmacy Benefits Managers. Today PBM's administer pharmacy benefit programs for millions of Medicare beneficiaries through employer sponsored plans and Medicare Choice contractor plans. No better source of data is available than that which can be provided by PBM's. PharmaCare recommends that CMS ask PBM's to voluntarily offer the Working Group data files reflecting the utilization of Medicare age beneficiaries. The process would result in the largest, most robust data set possible and provide the Working Group the information they need to produce quality results.

3. Chain Drug Stores. The National Association of Chain Drug Stores (NACDS) is an excellent source of data. Pharmacies are stakeholders in this endeavor and desire a well-developed program. Their membership, if approached, would freely cooperate with CMS by sharing data.

Issues Related to PDP's and Risk

Introduction. It will be the PBM industry that makes administration of the Medicare Drug Benefit possible. However, their role as PDP's or in association with PDP's is questionable unless the proposed rule is modified. Since the enactment of MMA in December 2003, some in the PBM industry have made public comment to the issues of PDP's being treated as insurers and of the requirement to assume risk. These requirements are in inconsistent with commercial practices where PBM's are not insurers and do not assume risk. Consequently, we recommend that CMS appreciate that unless the final rule satisfactorily addresses these issues PBM's may not view Medicare as such an important new market opportunity, which in turn could place the implementation of the Medicare Drug Benefit in jeopardy.

Discussion. Risk posses many new considerations for PBM's. Several of these considerations are discussed below, and illustrate why some PBM's have indicated they may be required to forgo the opportunities presented by MMA unless the final rule is modified.

In the context of an insurer risk is defined as "the danger or probability of loss". Auto insurers, for example, know that not every policyholder will file a claim, making the probability of loss low among most policyholders and high only among a few at one time. It is the excess premium secured from non-claimant policyholders that pay for the excess costs of the few claimant policyholders. With respect to prescription drugs, however, the opposite is true. The probability of loss in never low because it can be assumed that most policyholders will be claimants and few will not. Even worse, in the case of the elderly it can be assumed that substantially ALL elderly beneficiaries will be claimants. And, as drug therapy is the primary form of treatment today for almost all chronic medical conditions that afflict the elderly, the possibility of radically curtailing drug use is unrealistic, especially given the overwhelming efficacy offered by most drug

therapies today. In summary the elderly are a very bad risk because there is almost certainty of loss.

The issue of adverse selection is also very problematic for PBM's. As the Medicare Drug Benefit will be voluntary, only the sickest beneficiaries can be expected migrate to the new Part-D leaving the premium payments for lower utilizing healthier beneficiaries unavailable to supplement the excess costs of the adverse membership. This is not conjecture, but reality. Medicare Choice contractors struggled under the weight of adverse selection for years resulting in withdrawal from numerous counties across the country. Adverse selection is assured for a PDP under the Medicare Drug Benefit.

And finally, PBM's are not insurers. Requiring PDP's to be insurance companies creates a significant new burden for PBM's and creates unintended business risk. In the precious little time available to prepare for this program a PBM faces many costly hurdles associated with state licensures. This is unknown territory for PBM's and States alike. One concern PBM's have that licensing actions may in fact trigger an unintended response from states whereby they attempt to bring substantially all PBM operations under state insurance authority. This would be a costly struggle to defend against. And, should the states succeed, it would prove very problematic to the PBM industry as it would add significant cost and seriously hamper the evolution of business practices, benefit design and even quality management programs.

Recommendation. PharmaCare recommends CMS publish a final rule that lowers the barriers posed by insurance and risk. The final rule should set out a safe harbor for PDP's with respect to state insurance regulations. And, in order to lower the adverse risk associated with Medicare aged beneficiaries, the government should consider adopting a final rule that limits the risk faced by PDP's. One example includes creating risk-free sources of revenue for PDP's such as separate program management fees rather than all-inclusive premiums.

In another example CMS could offer to cap the PDP's risk to a maximum loss. Changes such as these are important as they will serve to attract prospective PDP's. A final rule that does not mitigate the implications of insurance and risk may not attract PBM's to this program as PDP's.

Risk and The Issue of Any Willing Provider

Introduction. The issue of Any Willing Provider (AWP) is problematic for PDP's as risk bearing entities. Also, the proposed rule offers guidance that is impracticable to potential PDP's. PharmaCare believes the proposed rule should be modified to reposition the intended role of AWP to what we believe was intended by the authors of MMA.

Discussion. The MMA and the proposed rule make reference to both Any Willing Provider and pharmacy network access standards. In the context of commercial practices, the two are in some ways redundant. Prescription plan sponsors seeking pharmacy network services from a PBM, for example, specify access standards to ensure a PBM contracts with sufficient providers, but not all providers. In the process of assembling a network a PBM uses the leverage offered by the access standards to negotiate price knowing that more aggressive prices can be secured if there is no requirement to allow the participation of any willing provider. Under a requirement to assemble a network where any willing provider may participate, no such leverage exists and no access standard may be assured as providers participate at will.

It is the opinion of PharmaCare that the authors of the Act included access standards as a means for prospective PDP's to establish network contracting leverage while protecting the interests of beneficiaries. This is fundamentally consistent with any entity bearing risk and assures the government of the best possible basis of cost. And, the Federal Government also shares this opinion. The Federal Trade Commission has concluded that Any Willing Provider requirements are fundamentally in conflict with the ability of any network assembler to secure best price. Please refer to the FTC's web site at http://www.ftc.gov/opa/2004/04/ribills.htm for an example of a recent example of the Commission's position on AWP.

PharmaCare also believes the issue of Any Willing Provider has also been misinterpreted as presented in the proposed rule. The proposed rule infers that Any Willing Provider is a requirement of a PDP, which we believe incorrectly interprets the intent of the Act. PharmaCare believes the Act discusses Any Willing Provider in the context of a right of the beneficiary, not a requirement of a plan sponsor or PDP. It is common for States to extend the privilege of pharmacy Freedom of Choice (FOC) to the membership of health insurance carriers; the terms Freedom of Choice and Any Willing Provider are often used interchangeably in the context of a member or beneficiary. But this privilege offered by States to members does not necessarily flow by extesnion to health insurers as a requirement. In summary, such laws are intended to reinforce and support the freedom of individuals to secure service from providers of their choice, but not by extension require health insurers to contract with them.

Recommendation. PharmaCare recommends that the final rule clarify the intent of the Act by specifying that the law protects the right of each beneficiary to choose their own provider, but does not require the PDP to include any willing provider in their network. And, it is not sufficient enough for CMS to allow PDP's to designate such providers as "non-preferred" or "out of network" if it still requires they contract with them. In-network providers will not negotiate best price if they know other providers can participate through circuitous means. The rule should clearly state that while beneficiaries may use providers of their choice, benefits will not be payable unless they use a contracted in-network provider of the PDP. The final rule should also clarify that the access standards set out in the Act are the principle methodology for assuring adequate access and drop any reference to AWP with respect to the establishment of networks.

Medication Therapy Management (MTM)

Introduction. The final rule should make clarification with respect to Medication Therapy Management (MTM) and the role of PDP's and providers. The proposed rule raises concerns that PDP's may be required to fund MTM by themselves.

Discussion. Considerable attention has been paid to the topic of MTM. However, the proposed rule should make clarifications in several regards. First, the proposed rule leaves questions unanswered as to the source of funding for MTM services. One could interpret the proposed rule as inferring that MTM services will be paid for by PDP's. This raises concerns. Assume a provider (e.g. a pharmacy) performs an MTM service. If the obligation to pay for that service falls on the PDP then where will those funds come from? If the answer is, from the fixed premium's paid by the beneficiary and Medicare, then this poses significant risk to PDP's. Such services would represent an open checkbook to providers who could perform them at will and make payment demands on a PDP, who in turn must pay from a fixed pool of premium revenue. Even worse the MTM activity could actually cause increased drug use, which is in conflict with a fixed price risk-based program.

The proposed rule should also clarify the MTM is an activity that can be performed by the PDP itself and is not the exclusive domain of others like pharmacists, nurses and physicians. PDP's will be in the best position to perform MTM themselves as they will have all available utilization data available. The final rule should clarify that MTM is a service that may be performed by providers as exclusively determined by the PDP. Otherwise the PDP will lose control of where and how these services are performed.

And, finally, the final rule should make it clear that MTM is not an exercise or activity that is exclusively performed in person between a health care provider

and the beneficiary, but may also be performed remotely by phone, internet and by paper. These recommended approaches are very cost effective and can reach more beneficiaries than in-person approaches. And, many quality programs already exist that employ these approaches.

Recommendation. The final rule must clarify the issue of MTM. MTM cannot be an at will activity of any willing provider. PDP's must hold the authority to establish who may provide MTM to their program membership. The final rule must also clarify from what source of funds the services of MTM will be paid. PharmaCare recommends that CMS pay for MTM separately and not include MTM funding as part of an inclusive premium calculation. MTM payments should also not be subject to risk as the activity of MTM will, in many cases, cause increases in drug use (e.g. under-utilization, therapy initiation, etc.).

Beneficiary Late Enrollment Penalty

Introduction. The formula for imposing beneficiary late enrollment fees, as discussed in the proposed rule, is not aggressive enough to promote rapid beneficiary enrollment in PDP's.

Discussion. Underlying the intent of the MMA is the belief that the government's best interest is served when industry participates on a risk basis to share the financial management challenge posed by Medicare beneficiaries. To attract the most qualified entities to serve as PDP's CMS should make every effort to ensure fast and rapid adoption of Medicare Part-D through PDP's. To this end, the proposed late enrollment fee is insufficient. PharmaCare does not believe $0.36 per month is enough of a fee to motivate beneficiaries to rapidly adopt Medicare Part-D.

Recommendation. PharmaCare recommends that CMS consider a black-out period where enrollment is not authorized rather than a late penalty. For example, offering beneficiaries the right to enroll only in November and December of each year for proceeding calendar year, with January through October being closed to enrollment (e.g. the black-out). Such an approach would create a sense of urgency among beneficiaries. The late enrollment penalty, as proposed, will only promote a "wait and see" attitude. If CMS is to attract prospective PDP's, then the final rule should include an approach that creates a sense of urgency for beneficiaries to enroll in Medicare Part-D through a PDP.

Conclusive Comments & Contact Information

PharmaCare again extends our thanks to CMS for the opportunity to make comment to this proposed rule. The Medicare Drug Benefit can only be viewed as a sea change event. As such PharmaCare very much desires to take part in this exciting program. We recognize that CMS has precious little time to implement this program, however, if prospective PDP's are to value the opportunity created by the Act then CMS should give serious consideration to our recommended modifications of the proposed rule. The modifications recommended by PharmaCare are, in our opinion, modest yet essential to assuring a workable program. PharmaCare offers our service freely to CMS for the purpose of concluding a final rule.

Should CMS desire to contact PharmaCare regarding these topics, all inquiries may be made to the following individual:

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CMS-4068-P-1241

Submitter : James Finley **Date & Time:** 10/04/2004 08:10:09

Organization : National Association of Social Workers

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

See attached comments

CMS-4068-P-1241-Attach-2.doc

CMS-4068-P-1241-Attach-1.doc

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

The National Association of Social Workers (NASW) welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. NASW is the largest professional social work organization with more than 153,000 members nationwide. NASW promotes, develops, and protects the practice of social work and social workers, while enhancing the well being of individuals, families, and communities through its work, service, and advocacy. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

Coverage of Dual Eligibles (§ 423.34)

Of grave concern is the impact of the new Medicare drug benefit on those beneficiaries who currently have drug coverage through their state Medicaid programs, i.e. the dual eligibles. CMS must ensure that these very vulnerable beneficiaries receive coverage for the medications they need under the new drug benefit and are not harmed or made worse off when their drug coverage is switched from Medicaid to Medicare.

Based on social workers experience with this group of beneficiaries, we are gravely concerned that the proposed regulations would cause harmful disruption in care and inadequate drug coverage for dual eligibles. In particular, the proposed regulations do not address how access to needed medications by dual eligibles will be maintained when their drug coverage is switched from Medicaid to Medicare.

We urge CMS to take account of the unique circumstances and needs of this population, and delay transfer of drug coverage from Medicaid to Medicare for the dual eligibles for at least six months to allow adequate time to educate and enroll these vulnerable and often hard-to-reach individuals and to ensure they receive the drug coverage to which they are entitled.

CMS must also address the real threat of adverse health outcomes facing dual eligibles. Under the proposed rule, dual eligibles would effectively be forced to enroll in the lowest cost plans in their areas because the low-income subsidy they will receive will only cover the premium for these plans (and automatic enrollment would require placement in a low-cost plan). While it is critical that the transfer from Medicaid to Medicare drug coverage maintain continuity of care, the proposed regulations provide no such protection. To the contrary, the formularies for these low-cost drug plans will not be as comprehensive as the drug coverage these individuals currently have through Medicaid. Without access to the coverage they need, dual eligibles would have no real choice but to switch medications. Yet changing medications is for those with complex conditions is both very difficult and potentially dangerous. For example, abrupt changes in psychiatric medications bring the risk of serious adverse drug reactions and interactions and the potential for a severe loss of functioning.

With respect to beneficiaries with mental illness, these regulations must give meaningful effect to the concern Congress itself voiced, stating in the conference report on the Act that: "[i]f a plan chooses not to offer or restrict access to a particular medication to treat the mentally ill, the disabled will have the freedom to choose a plan that has appropriate access to the medicine needed. The Conferees believe this is critical as the severely mentally ill are a unique population with unique prescription drug needs as individual responses to mental health medications are different." [Report No. 108-391, pp. 769-770] Unfortunately, the proposed rule does not adequately provide the protection for people with mental illness that Congress called for. We urge that the regulations be revised to provide for "grandfathering" coverage of psychiatric medications for dual eligibles into the new Part D benefit, as a number of states have done in implementing preferred drug lists for their Medicaid programs.

Lastly, for the dual eligibles in particular, CMS must fund collaborative partnerships with organizations representing people with disabilities and other vulnerable populations. Such partnerships will be critical to an effective outreach and enrollment process. Targeted and hands-on outreach to vulnerable Medicare beneficiaries, especially those with low-incomes, is vitally important in the enrollment process. We strongly urge CMS to develop a specific plan for facilitating enrollment of beneficiaries with disabilities and complex medical conditions in each region that incorporates collaborative partnerships with the state and local agencies and advocacy organizations that serve them.

Alternative, Flexible Formularies for Beneficiaries for Vulnerable Populations (§ 423.120(b))

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing deteriorating health, unnecessary hospitalizations and even death, on the other. Often, people with disabilities and complex medical conditions need access to the newest medications, because they have fewer side effects and may represent a better treatment option than older less expensive drugs. Many individuals have multiple disabilities and health conditions making drug

interactions a common problem. Frequently, extended release versions of medications are needed to effectively manage these conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects making it more important for the doctor to be able to prescribe the best medication for the individual. Often that pharmacological process takes time since many people with significant disabilities must try multiple medications and only after much experimentation find the medication that is most effective for their circumstance. The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury or debilitating side effects, even hospitalization or other types of costly medical interventions.

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs, and the enormous potential for serious harm (including death) if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations who:

- are dually eligible for Medicare and Medicaid;
- live in nursing homes, ICF-MRs and other residential facilities;
- have life threatening conditions; or
- have pharmacologically complex condition such as mental illness, Alzheimer's disease, multiple sclerosis, HIV/AIDS, and epilepsy.

Furthermore, new limits on cost management tools must be imposed for these vulnerable populations. We urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications that are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

Involuntary Disenrollment for Disruptive Behavior (§ 423.44)

The proposed regulation raises grave concerns in allowing Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" (§ 423.44(d)(2)). These provisions create enormous

opportunities for discrimination against individuals with mental illness and cognitive impairments. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and as a result they could also be subject to a late enrollment penalty increasing their premiums for the rest of their lives. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage.

As a matter of principle, for a critical safety net program such as Medicare prescription drugs for dual eligibles, NASW cannot support automatic disenrollment of this population under any circumstances. We are therefore alarmed that CMS has proposed an expedited disenrollment process that would undermine the minimal standards and protections included in the proposed rule. This expedited process proposal must not be included in the final rule. In addition, CMS must provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and must waive the late enrollment penalty for these individuals as well. The final rule must include the following protections:

- drug plans must be prohibited from disenrolling a beneficiary because he/she exercises the option to make treatment decisions with which the plan disagrees, including the option of no treatment and/or no diagnostic testing;
- drug plans may not disenroll a beneficiary because he/she chooses not to comply with any treatment regimen developed by the plan or any health care professionals associated with the plan;
- documentation provided to CMS arguing for approval of a plan's proposal to involuntarily disenroll an individual must include:
  - documentation of the plan's effort to provide reasonable accommodations for individuals with disabilities in accordance with the Americans with Disabilities Act; and
  - documentation that the plan provided the beneficiary with appropriate written notice of the consequences of continued disruptive behavior or written notice of its intent to request involuntary disenrollment; and
- drug plans must provide beneficiaries subject to involuntary disenrollment with the following notices:
  - advance notice to inform the individual that the consequences of continued disruptive behavior will be disenrollment;
  - notice of intent to request CMS' permission to disenroll the individual; and
  - A planned action notice advising that CMS has approved the plan's request for approval of involuntary disenrollment.

Appeals Procedures (§§ 423.562-423.604)

The appeals processes outlined in the proposed regulations are overly complex, drawn-out, and inaccessible to beneficiaries. Under these proposed rules, there are too many levels of internal appeal that a beneficiary must request from the drug plan before receiving a truly independent review by an administrative law judge (ALJ) and the

timeframes for plan decisions are unreasonably long. In order to qualify for a hearing by an ALJ, beneficiaries must first request a coverage determination or exception from a tiered cost-sharing scheme or formulary which can take between 14 and 30 days, unless a plan honors a beneficiary's request that the determination or exception be expedited in which case it could still take up to 14 days. To appeal adverse determinations or exception decisions, beneficiaries must request plans to review their decision again and make a redetermination within 30 days unless the beneficiary paid out-of-pocket for the medication at issue, in which case the plan has 60 days to decide. Even if a plan honors a request to expedite a redetermination, the deadline for plans to make a decision could be as long as 14 days. Following a redetermination, beneficiaries may appeal to a so-called independent review entity for a reconsideration of their case, but these entities will not be authorized to review or question the criteria plans use to evaluate exceptions requests. The proposed rules do not even set deadlines for reconsideration decisions. After receiving a reconsideration decision, beneficiaries are only allowed to appeal to an administrative law judge if the amount in controversy meets a threshold level of $100 and it is unclear how CMS will calculate whether a beneficiary has met this threshold.

In addition to imposing unreasonable delays and burdens on beneficiaries, these appeal processes are far from transparent. Drug plans would be authorized to establish their own criteria for reviewing determination, exceptions, and redetermination requests and these criteria will vary from plan to plan. Plans would also be authorized to establish varying degrees of paperwork requirements for beneficiaries and their prescribing physicians who wish to request exceptions from tiered cost-sharing schemes or formularies. Far from ensuring that beneficiaries' rights are protected, which should be their primary function, these procedures would actually impede the right of beneficiaries to a fair hearing.

Beneficiaries with disabilities and complex health needs often have an extremely limited capacity to navigate grievance and appeals procedures. To accommodate the special needs of these beneficiaries and others who are vulnerable or with low income, CMS must establish a simpler process that puts a priority on ensuring ease of access and rapid results for beneficiaries and their doctors and includes a truly expedited exceptions process for individuals with immediate needs, including individuals facing health care crises, which should be modeled after the federal Medicaid requirement that states respond to prior authorization requests within 24 hours.

We also urge CMS to require plans to dispense a temporary supply of drugs in emergencies. The proposed system does not ensure that beneficiaries' rights are protected and does not guarantee beneficiaries have access to needed medications. For many individuals with disabilities such as epilepsy, mental illness or HIV, treatment interruptions can lead to serious short-term and long-term consequences. For this reasons the final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

Outreach and Enrollment (§ 423.34)

The proposed regulations do not adequately address the need for collaboration with state and local agencies and community-based organizations on outreach and enrollment of beneficiaries with disabilities and complex health conditions. In the conference report for the Medicare Modernization Act, Congress directed that "the Administrator of the Center for Medicare Choices [sic] shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriated [sic] access to pharmaceutical treatments for mental illness" (Report No. 108-391, pp. 769-770).

To respond to Congress's concern with ensuring enrollment and comprehensive coverage for beneficiaries, CMS must partner with community-based organizations focused on addressing the needs of vulnerable beneficiaries and the state and local agencies that coordinate benefits for them. Beneficiaries with special needs will most likely turn to organizations that they know and trust with questions and concerns regarding the new Part D drug benefit. Making information and educational materials available at these sites will help inform beneficiaries with mental illness about the new benefit, but providing community-based organizations with pamphlets and brochures alone is not adequate. To answer the many difficult, detailed, and time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be needed. Social workers and community-based organizations can provide the kind of detailed help needed, but they will need additional resources.

CMS must develop a specific plan for facilitating enrollment of beneficiaries with special needs, in each region that incorporates collaborative partnerships with and additional funding for state and local public and nonprofit agencies and organizations focused on these needs. In addition, in their bids, drug plans should include specific plans for encouraging enrollment of often hard-to-reach populations.

NASW strongly urges that the concerns discussed above be addressed in order to ensure access to psychiatric medications under the Part D drug benefit for the many Medicare beneficiaries who need them.

Thank you for your consideration of our comments.

Sincerely,

Toby Weismiller, ASCW
Director, Professional Development and Advocacy

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Beneficiaries with disabilities and complex health needs often have an extremely limited capacity to navigate grievance and appeals procedures. To accommodate the special needs of these beneficiaries and others who are vulnerable or with low income, CMS must establish a simpler process that puts a priority on ensuring ease of access and rapid results for beneficiaries and their doctors and includes a truly expedited exceptions process for individuals with immediate needs, including individuals facing health care crises, which should be modeled after the federal Medicaid requirement that states respond to prior authorization requests within 24 hours.

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CMS must develop a specific plan for facilitating enrollment of beneficiaries with special needs, in each region that incorporates collaborative partnerships with and additional funding for state and local public and nonprofit agencies and organizations focused on these needs. In addition, in their bids, drug plans should include specific plans for encouraging enrollment of often hard-to-reach populations.

NASW strongly urges that the concerns discussed above be addressed in order to ensure access to psychiatric medications under the Part D drug benefit for the many Medicare beneficiaries who need them.

Thank you for your consideration of our comments.

Sincerely,

Toby Weismiller, ASCW
Director, Professional Development and Advocacy

CMS-4068-P-1242

Submitter : Ms. Marcie Roth **Date & Time:** 10/04/2004 08:10:08

Organization : The National Spinal Cord Injury Association

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

see attached document

CMS-4068-P-1242-Attach-1.doc

National Spinal Cord Injury Association

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September 30, 2004

Department of Health and Human Services
Centers for Medicare and Medicaid Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

To Whom It May Concern:

The National Spinal Cord Injury Association is pleased to submit comments on the proposed rule "Medicare Program;
Medicare Prescription Drug Benefit," 69 FR 46632. The National Spinal Cord Injury Association (NSCIA), founded in 1948, is the nation's oldest and largest civilian organization dedicated to improving the quality of life for hundreds of thousands of Americans living with the results of spinal cord injury and disease (SCI/D) and their families. This number grows by thirty newly-injured people each day.

Tens of thousands of individuals with spinal cord injury or disease (sci/d) are Medicare beneficiaries. NSCIA has grave concerns because the proposed rule does not provide critical protections for people with sci/d and almost 13 million other Medicare beneficiaries with disabilities and chronic health conditions. We offer the following essential recommendations:

DESIGNATE SPECIAL POPULATIONS WHO WILL RECEIVE AFFORDABLE ACCESS TO AN ALTERNATIVE, FLEXIBLE FORMULARY:

Individuals who have sci/d or other with serious and complex health issues must have access to the right medications. Such medications are critical to leading healthy, functioning, productive lives in the community as opposed to being institutionalized in nursing homes. Not having access to the correct medications can cause expensive hospital stays and life threatening events. People with sci/d and other disabilities may need the latest medications because they have fewer side effects.
Denying the suitable medication for an individual with a disability or chronic health condition can cause serious side effects, create unnecessary health problems, and lead to costly medical interventions. We strongly support the suggestion in the proposed rule that people with disabilities and other chronic conditions require special treatment due to unique medical needs, and the enormous potential for serious harm or death if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program.

We recommend the following groups be among those included in these exempt populations:

- people who are dually eligible for Medicare and Medicaid
- people with sci/
- people who live in nursing homes and other residential facilities
- people who have life threatening conditions
- people who have pharmacologically complex conditions

POSTPONE THE IMPLEMENTATION OF THE PART D PROGRAM FOR DUAL ELIGIBLES:

Dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. Among these are many with sci/d. They rely extensively on prescription drug coverage to sustain their basic health. Because of low income, they are the most vulnerable beneficiaries. NSCIA believes there is not enough time allowed to address how drug coverage for these health and fiscally exposed beneficiaries will be transferred to Medicare on Jan. 1, 2006.

CMS and the private Part D plans giving drug coverage do not have enough time to implement a prescription drug benefit staring on January 1, 2006. These time constraints may well lead to plans that jeopardize the lives of people with sci/d and

other disabilities who fall into the dual eligible population. It is highly improbable that 6.4 million dual-eligibles could be identified, educated, and enrolled in six weeks (from November 15th the beginning of the enrollment period to January 1, 2006),

Therefore, **NSCIA urges that transfer of drug coverage from Medicaid to Medicare be delayed a minimum of six months even if legislative mandate is required.**
We further urge CMS to actively support such legislation in the current session of Congress.

FUND COLLABORATIVE PARTNERSHIPS WITH ORGANIZATIONS REPRESENTING PEOPLE WITH DISABILITIES THAT ARE CRITICAL TO AN EFFECTIVE OUTREACH AND ENROLLMENT PROCESS:

Organizations representing people with disabilities and other targeted populations of Medicare beneficiaries should be funded to collaborate with CMS in the outreach and enrollment process. These advocacy and service groups are one of the most effective inroads to disseminate outreach and enrollment information. **NSCIA strongly recommends that CMS develop national and regional partnerships with disability service and advocacy groups and local and state agencies.**

COST MANAGEMENT LIMITS AND CONSUMER PROTECTION:

NSCIA recommends that CMS make major enhancement to its provisions for consumer protection. One key example is not allowing any plan to require 100% cost sharing for any medication. These and other proposed cost burdens on the consumer could threaten and adversely effect people with sci/d and other disabilities. In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We oppose any regulations that allow cost containment practices that would limit a physician from prescribing the best medication for an individual. This elimination of said cost containment practices is especially critical for the lives of people with sci/d and other disabilities.

ENHANCE AND STRENGTHEN INADEQUATE EXCEPTIONS AND APPEALS PROCESSES:

NSCIA believes the appeals processes in the proposed rule are not accessible, too complex and will have a major adverse and deleterious impact on beneficiaries with disabilities. We
urge that CMS develop an understandable process that allows simplicity of access and fast results for beneficiaries and their doctors. NSCIA also urges an expedited appeals process. Along with many other disability organizations, NSCIA believes that the proposed rule **fails to meet Constitutional due process requirements and fails to satisfy the requirements of the statute**. The proposed rule has so many levels of cumbersome internal appeals to the drug plan that it makes unbiased appeal nearly impossible. The appeals process itself could preclude critical medications over a duration of time so as to be life threatening to people with disabilities.

The parts of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) that call for design and implementation of an exception process are vital consumer protections that must include regulations that are enforced. Such procedures could assure that individuals with sci/d and other disabilities would receive timely coverage determination for on and off formulary medications in a manner unique to their complex needs.

NSCIA joins other disability organizations in asking that CMS revamp the exceptions process to: establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

REQUIRE PLANS TO DISPENSE A TEMPORARY SUPPLY OF DRUGS IN EMERGENCIES:

Persons with sci/d, other disabilities, and chronic health conditions must have access to prescribed medications at all times. The proposed system does not ensure beneficiary
access to needed medications. Said drugs are vital to the continued, productive functioning of persons with sci/d and other disabilities. Interruption of medication regimes can cause serious health complications and may even be life threatening. Consequently, the final rule must ensure that an emergency supply of drugs be made available for dispensing while pending the resolution of an exception request or an appeal.

NSCIA appreciates your consideration of these public comments.

CMS-4068-P-1243

Submitter : Dr. John C. Lewin **Date & Time:** 10/04/2004 08:10:29

Organization : California Medical Association

Category : Physician

Issue Areas/Comments

Issues 1-10

BACKGROUND

Comments Attached.

CMS-4068-P-1243-Attach-1.doc

CMS-4068-P-1243-Attach-2.doc

California Medical Association
Physicians dedicated to the health of Californians

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014
E-mail: http://www.cms.gov/regulations/ecomments

Re: CMS-4068-P Comments on Part D, Medicare, Proposed Outpatient Drug Program Rules

Dear Dr. McClellan:

On behalf of the California Medical Association, we wish to join the American Medical Association in seeking further clarification regarding a range of patient safeguards that should be more explicitly addressed in your proposed rules. We believe it is imperative that these regulations clearly prohibit manipulations of a physician's prescribing authority that could subsequently result in disruptions in both the quality and continuity of medical care.

We strongly agree with your comments recently in the Wall Street Journal that "the choice of drugs should reflect current medical practice." In that spirit, we respectfully urge that CMS consider the following:

Benefit Design: As noted in AMA's testimony, we are concerned by 'serious deficiencies' in the USP's proposed model classification system. We find numerous circumstances whereby entire classes of vital drugs could be excluded by an HMO, PBM or other plan administrator. While some may believe this could help produce short term savings in the drug benefit program, it is inevitable that such limitations on coverage will shift the ensuing costs resulting from therapeutic failure to other parts of the Medicare program.

P&T Committee Coverage Decisions: We join the AMA in expressing our concern that absent further clarification, P&T Committees may be allowed to meet in secret, limit clinical and public input, and be stacked to favor the plan administrator's drug class preferences. It is not clear that the scope of the P&T Committees would include other coverage restriction strategies, such as prior authorization procedures or tiered/step formularies, nor if the committee's decisions would be binding on the PDP. We feel very strongly that the rule should be modified to make it clear that P&T committees must be responsible for the development of all coverage policies, and that their decisions should be made and explained openly through a transparent process that allows for public input.

Patient Protections: We are also very concerned that the plans could change formularies with only 30 days notice. You are aware that the Medicare population in general, and the dual eligible population in particular, commonly have multiple chronic conditions that require multiple ongoing drug therapies. In a majority of these patients their conditions are medically fragile and the dosages and drug products have been carefully titrated. Other than adding drug products, we believe formularies should only be modified, with adequate notice and P&T Committee approval, between plan years/contracts.

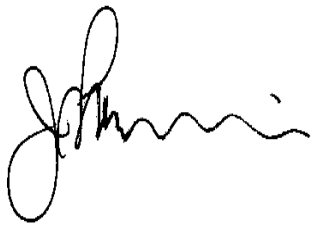
Drug Switching, Federal Preemption of State Pharmacy and Patient Protection Laws. While the preamble states that drug switching should require explicit approval by the treating physician, the rules themselves fail to expressly preserve this vital principle. Similarly, nowhere in the rule is the likely effect of the MMA on state pharmacy laws – which currently regulate the practice of therapeutic interchange – or drug switching – discussed. Switching prescriptions without the consent of the treating physician is the practice of medicine by non-physicians. Health plan or PBM employees who have virtually no history or contact with affected patients should not be permitted to override the treating physician's expert judgment. Again, Medicare is essentially a closed system—short-term savings which result in higher costs overall do not serve Medicare patients or the public well. To ensure that the final rules are not interpreted as permitting drug switching without the explicit consent of the treating physician, we urge you make it clear in the text of the regulations that state laws regulating therapeutic interchange must continue to be respected.

Office-Based Injectible Drugs for Oncology and Other Specialties: The MMA will drastically reduce the payment amount for drugs and drug administration services compared to the 2004 amounts. In addition, it appears likely that the payment methodology for drugs (106% of the manufacturer's average sales price) will result in payment amounts for many drugs that are lower than the prices at which physicians can purchase them, yet there is no mechanism in the MMA for adjustments in such circumstances. These changes have the potential to create substantial impairment of patient access to cancer and other essential treatments. Therefore, Congress should create exceptions under which CMS would be required to ensure that the payment amounts for in 2005 and later years are sufficient to cover the cost that physicians incur in purchasing the drugs. In addition, Congress should revise the MMA's transitional adjustment payment for drug administration services to an amount that will maintain the net revenue available to physicians from drugs and drug administration services in 2005 and 2006 at the same level as in 2004.

We readily acknowledge the daunting, complex nature of this new and promising program. And we applaud your efforts to implement it in a fair and responsible fashion. As you work to refine the implementing rules, we ask that the agency anticipate the consequences of arbitrarily limiting access to medically necessary drug products and work diligently to ensure that the standards and requirements that you ultimately set out for the program first and foremost do no harm.

Thank you for your consideration of these important medical principles and our mutual support of the patients we all serve.

Sincerely,



John C. Lewin, M.D.
Chief Executive Officer
California Medical Association

California Medical Association
Physicians dedicated to the health of Californians

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-4068-P
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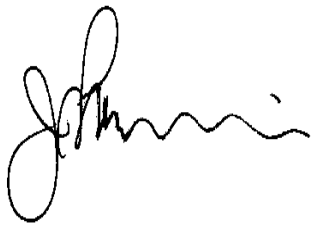


John C. Lewin, M.D.
Chief Executive Officer
California Medical Association

Submitter : Daniel Hilferty **Date & Time:** 10/04/2004 08:10:59

Organization : AmeriHealth Mercy Health Plan

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Comments from AmeriHealth Mercy Health Plan

CMS-4068-P-1244-Attach-1.doc

October 4, 2004

Mark B. McClelland, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Dr. McClellan:

AmeriHealth Mercy Health Plan is pleased to have the opportunity to submit comments in response to the notice of proposed rulemaking by the Centers for Medicare & Medicaid Services (CMS) to establish the program for the Medicare Prescription Drug Benefit under Part D. AmeriHealth Mercy Health Plan is submitting separate comments to the Medicare Advantage (MA) regulations that relate to some of the same issues discussed here.

Background

AmeriHealth Mercy Health Plan is a subsidiary jointly owned by Independence Blue Cross and Mercy Health System. AmeriHealth Mercy Health Plan is a leading provider of Medicaid managed care programs and services. Together with its affiliate Keystone Mercy Health Plan and *PerformRx*, its pharmacy benefits management division, AmeriHealth Mercy Health Plan touches the lives of more than one million Medicaid members in seven states. AmeriHealth Mercy Health Plan and its affiliates (collectively, AmeriHealth Mercy Health Plan) are very interested in the opportunities provided by the Medicare Modernization Act (MMA) to participate both in the MA program through the offering of specialized MA plans for dual eligibles and in the offering of pharmacy benefit services on behalf of specialized MA plans serving dual eligibles.

The need to effectively manage prescription drug benefits for our large mandatory enrollment Medicaid populations led AmeriHealth Mercy Health Plan to develop *Perform Rx,* a Medicaid pharmacy care management program that meets financial objectives while improving the quality of health care for members. *PerformRx* manages drug benefits and services for almost 900,000 Medicaid beneficiaries in six states.

As further background, AmeriHealth Mercy has significant experience in serving dual eligible populations. AmeriHealth Mercy Health Plan furnishes services to about 50,000 full benefit dual eligibles in the following three health plans:

- Keystone Mercy Health Plan, Southeastern Pennsylvania's largest Medicaid managed care health plan serving more than 280,000 Medical Assistance recipients, including 31,000 dual eligibles, in Bucks, Chester, Delaware, Montgomery and Philadelphia counties**.** Keystone Mercy Health Plan operates this plan under a license held by Vista Health Plan, a subsidiary of Independence Blue Cross.
- AmeriHealth Mercy Health Plan serves about 76,000 Medical Assistance recipients, including about 6, 000 dual eligibles, in fifteen counties in Central and Northeastern Pennsylvania. AmeriHealth Mercy Health Plan operates this plan under a license held by Vista Health Plan, a subsidiary of Independence Blue Cross.
- Passport Health Plan[1] is a Medicaid managed care plan that serves over 130,000 members in Louisville and 15 surrounding counties in Kentucky. Its membership includes 12,000 dual eligibles. Passport was formed in 1997 by a group of safety net Medicaid providers. AmeriHealth Mercy provides complete health plan management and administrative support services under the governance of the Passport Health Plan board. Passport Health Plan is currently in the process of completing an application to participate in the Medicare Advantage program as a specialized MA plan for dual eligibles.

Discussion

1. Introduction

As an overall comment, AmeriHealth Mercy's experience in managing comprehensive prescription drug benefits for high risk Medicaid populations is that the management of the prescription drug benefit and medical benefits (hospital, physician, ancillary, etc.) are inherently interrelated because the quality outcomes and total costs are interdependent. Good disease management programs incorporate prescription drug data and management as integral components to clinical quality improvement and utilization/cost management efforts. Successful disease and case management programs serving high risk, low income populations focus on removing barriers to services. While total medical costs can be stabilized/reduced, an individual's prescription drug utilization may actually increase with appropriate use and adherence to medication plans. Thus, from the perspective of an MA-PD plan that is managing medical and pharmaceutical services, the sponsoring MA organization has strong motivation to ensure that the Part D drug benefit is designed and administered in a manner that serves the best interests of its enrollees. Over the years, health plans have developed effective programs to appropriately manage their drug benefits. AmeriHealth Mercy Health Plan urges CMS to develop the Part D regulations in a manner that gives health plans the discretion to continue these programs.

2. Subpart B – Eligibility and Enrollment

[1] Passport Health Plan is the trade name for University Health Care, a section 501(c)(3) tax exempt organization.

In this section of our letter, we provide our rationale for requesting that CMS adopt a policy that would allow the auto-assignment of full benefit dual eligibles into an MA-PD that is offered by a health plan in which the full benefit dual eligibles are enrolled or a health plan under common ownership and control of the health plan in which the full benefit dual eligibles are enrolled. Because of the importance of these comments, AmeriHealth Mercy Health Plan has repeated these recommendations in its comments to the MA proposed rule.

The MMA establishes a mechanism for full benefit dual eligibles who will be losing their outpatient drug coverage under Medicaid to select enrollment in an MA-PD plan or a PDP. The statute allows for default enrollment into a PDP in the event that a full benefit dual eligible fails to select a PDP or an MA-PDP Plan. Based on information provided at an open door forum, our understanding is that CMS intends to have this default enrollment occur effective January 1, 2006.

In the preamble to the PDP proposed rule (page 46638), CMS explains that there are conflicting statutory provisions related to default enrollments. To address these conflicts, CMS is proposing to default full benefit dual eligibles into an MA-PD if the full benefit dual eligible was enrolled in the MA organization previously. In the preamble, CMS articulates its policy justification for this decision as follows:

> To the extent that the MA-only portion of the MA-PD plan parallels the coverage under a full benefit dual eligible individual's MA plan, enrolling the individual in the MA-PD plan would be similar to permitting the individual to remain enrolled in the MA plan while simultaneously enrolling the individual in a PDP. In other words, enrolling the individual in a MA-PD plan offered by the same MA organization is, in effect, simply adding qualified prescription drug coverage to the individual's MA benefits. For this reason, we believe the reference to ``prescription drug plans'' in section 1860D-1(b)(1)(C) of the Act should be interpreted as requiring enrollment of a full benefit dual-eligible into a plan that will provide the individual with Part D drug benefits in addition to any other benefits the individual receives under Medicare, whether through Medicare Part A and/or Part B, or through enrollment in the Medicare Advantage program under Part C. We believe this interpretation promotes the policies underlying sections 1860D-1(b)(1)(C) and 1860D-1(a)(1)(B)(ii) of the Act, giving full effect to both statutory provisions.

AmeriHealth Mercy Health Plan fully supports CMS proposed policy, but requests that CMS expand this policy to allow for default enrollments in two additional, related circumstances illustrated below. First, Passport Health Plan currently enrolls 12,000 dual eligibles and is in the process of applying for an MA-SNP to serve dual eligibles. AmeriHealth Mercy Health Plan is recommending that CMS expand its policy to allow for the current full benefit dual eligible enrollees of Passport Health Plan's Medicaid MCO who do not otherwise select an MA-PD or PDP to default into Passport Health Plan's MA-PD. Because virtually all Medicare services are covered under Medicaid, allowing such a default enrollment would permit these full benefit enrollees to continue to receive the full range of A/B services and drug benefits from the same

health plan. Moreover, AmeriHealth Mercy Health Plan believes that allowing dual eligibles to retain their prescription drug providers and the existing pharmacy management structure is fully consistent with the objectives stated above.

AmeriHealth Mercy Health Plan believes there is legal precedence to support our interpretation that would permit members of another health plan offered by the same organization to be viewed as members of the Medicare managed care organization. Section 1851(a)(3)(B) includes the provision that prohibits beneficiaries with end-stage renal disease (ESRD) to enroll in an MA plan. This paragraph includes an exception that permits the enrollment of "an individual who develops end-stage renal disease while enrolled in an MA plan may continue to be enrolled in that plan." As part of the BBA regulations, CMS was confronted with the issue of whether a Medicare beneficiary who was enrolled in a non-Medicare+Choice plan and who developed ESRD could enroll in a Medicare+Choice plan offered by the same organization. In answering this question, CMS appropriately asserted its authority to depart from the literal reading of the statute and took the following position:

> For purposes of this provision only we are considering individuals who are enrolled in a private health plan offered by the M+C organization to have been enrollees of the M+C plan when they developed ESRD. (63 FR 34976, June 26, 1998)

While this ESRD enrollment issue is in a different context from the default enrollment issue under the MMA, it illustrates the clear willingness of CMS to depart from the literal reading of the statute to reach an important and desirable policy result. In this case, that departure entailed treating a non-MA enrollee of an organization as an MA enrollee of that same organization for purposes of enrollment into an MA plan. Consistent with CMS' willingness to extend a reference to M+C organizations to a non-Medicare health plan offered by the same entity, we believe that CMS has the corresponding legal authority to make an analogous legal interpretation. AmeriHealth Mercy Health Plan believes that strong policy reasons also support this result because this interpretation would allow a single organization to coordinate the services and be responsible for the full range of Medicare and Medicaid benefits for the full benefit dual eligibles. In making this recommendation, we emphasize that these full benefit dual eligibles would have the right to disenroll from the MA-SNP, if they want.

We also believe our recommendation has policy support under the statutory provision in Section 1851(c)(3)(a)(II), which address seamless continuation of coverage. Under that provision, CMS has the authority to establish procedures under which an individual who is enrolled in a health plan (other than an MA plan) offered by an MA organization at the time of the initial election period and who fails to elect to receive coverage other than through the organization is deemed to have elected the MA plan offered by the organization. While this provision applies to initial election period when a person is first eligible for Medicare coverage, the provision demonstrates Congressional support for arrangements that facilitate enrollment into an MA plan of an enrollee covered by a non-MA plan sponsored by the same organization. In addition, this provision offers clear authority for CMS to provide for this default enrollment in the future when an

enrollee of a Medicaid MCO first becomes eligible for Medicare and the same entity also offers an MA plan.

Our second policy recommendation related to how CMS interprets the default enrollment provision is an extension of our initial request and relates to the two Pennsylvania Medicaid managed care plans: Keystone Mercy Health Plan in Southeastern Pennsylvania, and AmeriHealth Mercy Health Plan in Central and Northeastern Pennsylvania. As noted above, AmeriHealth Mercy Health Plan and its affiliate, Keystone Mercy Health Plan, are owned by Independence Blue Cross and Mercy Health System. Both of these Medicaid plans are operated under an HMO license held by Vista Health Plan, a wholly owned subsidiary of Independence Blue Cross.

Independence Blue Cross itself and through its subsidiaries has three separate MA contracts. One contract is a PPO sponsored by Independence Blue Cross itself. The second contract is held by a wholly owned subsidiary of Independence Blue Cross, Keystone Health Plan East, Inc., and is offered in Southeastern Pennsylvania. The third contract is held by AmeriHealth HMO, Inc. AmeriHealth Mercy Health Plan is requesting that CMS adopt a policy that would allow the full benefit dual eligible enrollees of AmeriHealth Mercy Health Plan and Keystone Mercy Health Plan and who do not otherwise select another MA-PD or PDP to default on January 1, 2006, into the MA-SNP sponsored by AmeriHealth HMO, Inc, and Keystone Health Plan East, Inc., respectively. In making this request, we want to be clear that substantial efforts will be made in advance of the default date to have these Medicaid enrollees either select a MA-PD plan or a drug plan. Keystone Health Plan East and AmeriHealth HMO, Inc. will be actively marketing the dual eligibles enrolled in their affiliated Medicaid managed care organizations in a manner consistent with CMS rules. However, as CMS is aware from its experience in the drug discount card program and the challenges associated with enrolling dual eligibles in the Medicare savings programs, many dual eligibles will take no action prior to January 1, 2006. AmeriHealth Mercy Health Plan strongly believes it is in the best interests of their enrollees and the Medicare program to default these enrollees into Keystone Health Plan East's MA-SNP.

AmeriHealth Mercy Health Plan also believes there is a legal precedent for allowing affiliates of organizations to avail themselves of statutory rights under the Medicare or Medicaid program. Prior to enactment of the BBA, Medicaid MCOs were prohibited from having more than 75 percent of their enrollment comprised of persons eligible for Medicare and Medicaid. Certain community health centers, migrant health centers, and Appalachian health centers were exempt from this requirement. When CMS implemented this statutory provision, CMS departed from the literal reading of the statute and extended this exemption to HMOs owned by these health centers. CMS discussed this issue in the following manner:

> As noted in the previous section, we are proposing to amend the regulations to recognize the statutory exemption from the composition of enrollment standard for certain Community, Migrant, and Appalachian Health Centers. It has come to our attention that some of these exempt centers have joined to form larger organization in order to operate an HMO of adequate size. Under simple arrangements, several community health centers have established an HMO that

> enrolls members who are then provided primary care services through the same community health centers. The HMO serves simply as the corporate vehicle allowing the centers to combine their efforts. In this circumstance, we believe that, consistent with Congressional intent, the HMO formed by centers that are exempt from the composition of enrollment standard should itself be exempt from the standard. (53 FR 746, January 12, 1988)

This discussion illustrates CMS willingness to extend statutory rights from an organization to an affiliate of that organization in appropriate circumstances. In the context of the issues being raised to CMS here, it is important to note that the complexity arising from these different organizational structures derives both from the limitations that Independence Blue Cross has to use the Blue Cross mark outside of its designated area and Medicaid managed care program requirements. Notwithstanding this complexity, it is clear that all of the entities that hold the MA contracts and Medicaid contracts with the Pennsylvania Department of Public Welfare are wholly owned subsidiaries of Independence Blue Cross. Therefore, for purposes of developing public policy interpreting the default enrollment provisions, we believe it is reasonable and appropriate for CMS to treat these affiliated companies as a single entity.

AmeriHealth Mercy Health Plan recognizes that CMS' consideration of AmeriHealth Mercy Health Plan's requests needs to be considered in the context of a broader policy that is consistent with the objectives of the MMA and serves the best interests of full benefit dual eligibles. To achieve this end, AmeriHealth Mercy Health Plan recommends that CMS adopt the following policy:

> That CMS approve default enrollment of a full benefit dual eligible who has not otherwise selected an MA-PD or PDP into an MA-PD that is administered by an MA organization (1) that operates the Medicaid MCO in which the dual eligible is enrolled or (2) that is affiliated by common ownership or control with an organization that operates the Medicaid MCO in which the dual eligible is enrolled. As a condition of CMS approving this policy, the MA organization would be obligated to meet the following conditions:
>
> 1. The MA organization would have to assure that the full benefit dual eligibles are given notice of the default enrollment and their opportunity to select other options in advance of the default enrollment as well as their continued ability to disenroll from the specialized MA-PD plan following their enrollment.
>
> 2. The bid for A/B benefits would not include beneficiary premiums or cost sharing that would be paid by the full benefit dual eligible enrollees. If the Part D premium is determined to be in excess of the low income premium subsidy, the MA-PD plan would reallocate rebate dollars to the amount of the low income premium subsidy (if permitted by CMS).
>
> 3. The MA organization must represent that substantially all of the Medicaid providers currently furnishing services to the full benefit dual eligibles are either

part of the MA-SNP's delivery system or would have the opportunity to participate in that delivery system provided that the MA organization's credentialing requirements could be met.

4. The same pharmacy benefits manager that will administer the Part D benefit on behalf of the MA-SNP must also have previously managed the pharmacy benefit for the dual eligible enrollees of the Medicaid MCO.

AmeriHealth Mercy Health Plan would welcome the opportunity to discuss with CMS its proposal. As implicitly reflected in the above conditions, AmeriHealth Mercy Health Plan is recommending that CMS allow default enrollments into an MA-PD even if the Part D premium exceeds the low income premium subsidy. We believe the enrollees' best interests will be met by enrolling them in the MA plan under the above conditions rather than forcing them into a PDP.

3. Subpart C – Benefits and Beneficiary Protections

a. USP Classification structure

AmeriHealth Mercy Health Plan supports the proposed USP classification structure. We believe that the skeletal structure does exactly what it was primarily intended to do -- prevent enrollee discrimination through non-inclusion of certain medication types and categories. This skeletal structure provides a good basis from which to create a workable formulary that will ultimately be reviewed by CMS for appropriateness. AmeriHealth Mercy Health Plan reiterates its earlier point that it is very important for CMS to give MA organizations the flexibility to administer their drug benefit in a manner that serves the best interest of their beneficiaries. AmeriHealth Mercy Health Plan has substantial experience developing and managing formularies under Medicaid programs in a number of states. These formularies make available to enrollees in a cost effective manner the pharmaceuticals they need. AmeriHealth Mercy Health Plan urges CMS not to develop requirements that impair the ability of health plans like AmeriHealth Mercy Health Plan to continue the effective pharmaceutical programs that they currently offer to their enrollees.

b. Formulary development

AmeriHealth Mercy Health Plan supports the formulary development requirements and believes that the statutory and proposed regulatory requirements are generally consistent with industry practices in the development of formularies. Under the proposed rule, the majority of members comprising the P&T committee would be required to be practicing physicians and/or practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician member would have to be an expert in the care of elderly and disabled individuals and free of conflict with respect to the PDP sponsor and PDP or MA organization and MA-PD. AmeriHealth Mercy Health Plan believes this standard, in general, is reasonable and consistent with standard industry practice. However, AmeriHealth Mercy Health Plan has one concern with regard to how CMS is

interpreting "independent." In the preamble discussion, it appears that CMS would preclude a pharmacist from being viewed as "independent" if the pharmacist was part of the pharmacy network of the MA-PD plan. AmeriHealth Mercy Health Plan believes that many health plans attempt to create their P & T Committees composed of the "best and brightest" physicians within their geographic area. They also have this same goal for their provider networks. As a result, we have concerns that it may not be possible to obtain a physician or pharmacist who meets the requisite qualifications but is not part of the health plan's network. The health plan would be forced to find a pharmacist or physician who is located outside their service area to participate on their P & T Committee. Consequently, the selected P & T Committee member would lack a good understanding of local health care issues and concerns.

c. Use of rebates to reduce cost sharing

Under §423.100 in the definition of "required prescription drug coverage" an MA-PD plan may offer enhanced alternative coverage if there is no supplementary beneficiary premium as a result of the use of rebate dollars from A/B savings. In the preamble, CMS notes that an MA-SNP may use rebate dollars to reduce the nominal copayments that apply to low-income subsidy individuals who have incomes below 135 percent of FPL. We are seeking CMS confirmation on an issue related to this position. These dual eligibles may have copayments of $1/$3 or $2/$5. Our understanding is that an MA organization offering an MA-SNP for dual eligibles may use rebate dollars to remove both levels of copayments. AmeriHealth Mercy Health Plan is requesting that CMS confirm this interpretation in the preamble to the final regulation.

d. Drugs covered under Part B and Part D

CMS sets forth a lengthy discussion in the preamble concerning issues arising from drugs that may be provided under Part B and Part D. Based on our experience in the Medicaid program, AmeriHealth Mercy Health Plan has found that enormous issues can arise regarding the appropriate classification of drugs when the classifications dictate different financial obligations. AmeriHealth Mercy Health Plan urges CMS to the fullest extent possible to provide clear guidance regarding which drugs fall under Part B and those that fall under Part D. This guidance should also explain the rules determining treatment of newly approved drugs. This guidance should also delineate clearly the circumstances in which a drug may fall under either Part B or Part D depending on the manner in which it is administered.

4. Subpart D – Cost Control and Quality Improvement

As proposed under §423.153(b), CMS is requiring MA-PD plans and PDPs to have a cost-effective drug utilization management program. This program must:

(1) Include incentives to reduce costs when medically appropriate; and
(2) Maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications.

AmeriHealth Mercy Health Plan believes an effective drug utilization program is integral to the success of the Part D program. To this end, AmeriHealth Mercy Health Plan urges CMS to convey in the preamble its support for current practices that are commonly used by health plans and pharmacy benefit managers to manage utilization and control costs.

While unfortunate, the reality in today's health care environment is that a significant amount of beneficiary fraud and abuse occurs. This type of activity occurs in spite of significant efforts on the part of both pharmacists and the majority of practicing physicians to prevent this type of behavior. AmeriHealth Mercy Health Plan asks CMS to consider providing options, policies and processes that would allow health care payers/providers to investigate potential beneficiary fraud and misuse, and when verifiable, to attempt to control the activity in question. A large number of States already have beneficiary fraud and misuse programs in place for their Medicaid programs, and, in our opinion, these programs can be extremely successful in reducing the unwanted behavior.

AmeriHealth Mercy Health Plan, through its working relationship with the Commonwealth of Pennsylvania, has designed, developed, and implemented a program that attempts to eliminate/reduce fraud and misuse of drug products within our specific member population. Our particular program is referred to as "Recipient Restriction."

The pharmacy services department for the health plan constantly monitors drug claim data, looking for potential fraud and misuse. There are a number of algorithms that exist or could be developed by CMS to give guidance on what would, or would not, be considered fraud and/or misuse. The focus of these programs is typically on drugs and drug products that have "street" or "abuse" potential, with the primary products being the therapeutic class – opiate/narcotic pain medications. A number of other products have been included and are monitored as research and practice dictate.

The current process requires that once the health plan identifies a member misusing either products or services, a request to "restrict" that member is submitted to the Commonwealth's Department of Public Welfare "Recipient Restriction" oversight committee for a review and final determination. If the committee feels that there is enough data/information to support the restriction, based on the restriction criteria that has been approved and is in place, the member is restricted to using a single provider or group of providers and/or a single retail pharmacy vendor for a period of five years. What is also important is that this restriction attaches to the recipient and follows that recipient as they move from health plan to health plan. This is an extremely important component of the program as it precludes the recipient from re-initiating the unwanted behavior simply by changing health plans.

There appears to be little comment given in the MMA to programs/processes geared toward beneficiary fraud and misuse, the ability of MA-PD plans PDPs to initiate these types of programs, or CMS's willingness/ability to support this type of program.

AmeriHealth Mercy Health Plan's experience with this type of restriction program has been very positive. Once identified and "restricted," our research shows a significant decrease in the detrimental practices and behavior of the restricted recipients.

AmeriHealth Mercy Health Plan would encourage CMS to address and clarify the types of programs and support for these programs that might be forthcoming. The ability of a health plan to take limited action against a recipient that is misusing the system, with only the slightest impact of that recipient's access to the health care system, is an extremely valuable tool to improve appropriate utilization of medications and reduce unnecessary financial expenditures. While it may not be possible to establish a program under Medicare that parallels exactly the Medicaid programs, AmeriHealth Mercy Health Plan urges CMS to consider these issues and convey in the preamble to the final rule or the rule itself the manner in which these programs may be administered as well as alternative practices that may be followed by PDPs and MA-PD plans to accomplish the same objectives.

AmeriHealth Mercy Health Plan is also seeking confirmation from CMS with regard to the ability of MA-PDs and PDPs to require that certain drugs receive prior approval before a prescription is filled. Prior approval is a common practice and CMS repeats a number of times in the preamble the ability of health plans to continue their existing programs to manage costs. We also note that the Federal Medicaid law expressly provides:

> A State may subject to prior authorization *any* covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5)." § 1396r- 8(d)(1)(A) (emphasis added).

Paragraph (5), entitled "Requirements of prior authorization programs," reads as follows:

> A State plan under this subchapter may require, *as a condition of coverage or payment* for a covered outpatient drug for which Federal financial participation is available in accordance with this section, ... the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval-
> (A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
> (B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

42 U.S.C. § 1396r-8(d)(5) (emphasis added)

AmeriHealth Mercy Health Plan believes the process we currently use, follows the federal Medicaid guidelines. This guideline has worked well for years in the Medicaid environment, and AmeriHealth Mercy Health Plan recommends that CMS approve a comparable policy for the Part D program.

5. Subpart F Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

In the preamble discussion, CMS is clear that it expects PDP sponsors and MA organizations to identify the additional costs that may arise as a result of supplemental benefits. CMS states that a portion of these costs will be associated with increased utilization of the Part D basic benefit. CMS expects that the costs associated with this increased utilization will be included in the component of the bid attributable to the supplemental benefits, not the basic benefits.

This position raises a number of very significant and troubling issues for AmeriHealth Mercy Health Plan. If AmeriHealth Mercy Health Plan were to offer a MA-SNP for dual eligibles, its enrollees would have substantial "supplemental" coverage through the payment by CMS of the low-income subsidies. Our actuaries estimate that the utilization associated with an MA-SNP is well above that associated with the basic plan -- potentially 20 percent higher. This increased utilization is for the same population; it does not reflect populations choosing the plan or the value of the cost sharing itself. It is in addition to any risk adjustment needed due to diagnosis or medical conditions of a given population. Of the total allowed costs due to the increased utilization, a portion is reimbursed through increased cost sharing subsidies or increased reinsurance subsidies. The remaining portion is not reimbursed through any of the Part D direct subsidy, the reinsurance subsidy, the low-income premium subsidy, or the low-income cost sharing subsidy. Most importantly, the additional costs associated with this additional utilization cannot be reallocated outside of the basic drug benefit because AmeriHealth Mercy Health Plan will not be offering supplemental benefits.

As a result, AmeriHealth Mercy Health Plan and other MA-SNPs will be placed at a significant competitive disadvantage to MA-PDs and PDPs that will not have these additional costs included in their basic bid. More importantly, this inequity increases the likelihood that the premium of an MA-SNP will be greater than the low-income premium subsidy in its region. If this should occur, full benefit dual eligibles, who might otherwise have no premium, will be forced to pay a premium to the MA-SNP. This occurrence could create an incentive for the full benefit dual eligibles of the MA-SNP to disenroll and enroll in another plan that may be less expensive, but may not offer the special services needed by the dual eligible population.

For this reason, AmeriHealth Mercy Health Plan opposes CMS' proposed decision to require the costs associated with increased Part D basic services that arise when supplemental benefits are provided to be removed from the basic bid.

6. Subpart G Payments to PDP Sponsors and MA Organizations Offering MA-PD plans for all Medicare Beneficiaries for Qualified Prescription Drug Coverage

On page 46688 of the preamble, CMS included the following discussion conveying its concerns that plans serving large portions of low-income subsidy beneficiaries may not be paid adequately under the new Part D risk adjustment system:

> Any risk adjustment methodology we adopt should adequately account for low-income subsidy (LIS) individuals (and whether such individuals incur higher or lower-than average drug costs). Our risk adjustment methodology should provide neither an incentive nor a disincentive to enrolling LIS individuals, and we request comments on this concern and suggestions on how we might address this issue.
>
> Our particular concern is that a risk adjustment methodology, coupled with the statutory limitation restricting low-income subsidy (LIS) payments for premiums to amounts at or below the average, could systematically underpay plans with many LIS enrollees (assuming LIS enrollees have higher costs than average enrollees). If the risk-adjustor fails to fully compensate for the higher costs associated with LIS recipients, an efficient plan that attracts a disproportionate share of LIS eligible individuals would experience higher costs to the extent the actual costs of the LIS beneficiaries are greater than the risk-adjustment compensation. Failing to discourage enrollment by LIS beneficiaries in 2006, the plan would experience higher than expected costs in that year and presumably be driven to reflect these higher costs (due to adverse selection, not efficiency) in its bid for 2007. In this hypothetical, plans would have a disincentive to attracting a disproportionate share of LIS beneficiaries. One possible solution would be to assure that the initial risk-adjustment system, which will be budget neutral across all Part D enrollees, does not undercompensate plans for enrolling LIS beneficiaries. In fact, to the extent that an initial risk-adjustor might at the margin tend to overcompensate for LIS beneficiaries, plans would have a strong incentive to disproportionately attract such beneficiaries. Plans could attract LIS beneficiaries both by designing features that would be attractive to such beneficiaries but also by bidding low. We would appreciate comments on this concern and suggestions on how we might address this potential problem.

AmeriHealth Mercy Health Plan shares the concern that the risk adjustment methodology could systematically underpay plans with many low-income subsidy enrollees. As noted above, of the total allowed costs due to the increased utilization, a portion is reimbursed though increased cost sharing subsidies or increased reinsurance subsidies. The remaining portion is not reimbursed through any of the Part D direct subsidy, the reinsurance subsidy, the low-income premium subsidy, or the low income cost sharing subsidy. Because these costs are not reimbursed, MA-SNPs will need to build them into member premium. As a result, MA-SNPs like AmeriHealth Mercy Health Plan will be less competitive than plans without such low-income eligibles.

To address this issue, CMS could include in the risk adjuster a component that reflects both the extra utilization the dually eligible Medicare/Medicaid population reflects due to its inherent risk (if it bought the basic Part D plan) and the extra utilization because it will effectively receive a much richer $1/$3 copay plan. AmeriHealth Mercy Health Plan believes that this incremental adjustment would be beyond that reflected in the standard (to be determined) diagnosis-based risk adjuster. We believe that this solution would protect both MA-SNPs and other PDP or MA-PD plans that happen to enroll low-income members.

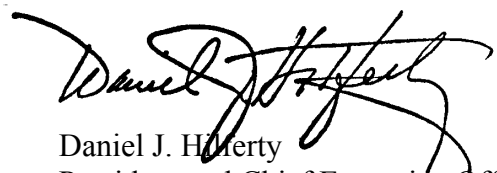
In addition to the increased costs associated with the greater utilization of services, we believe that the additional administrative expense involved in the increased utilization and the administration of the cost sharing subsidy is also unlikely to be included in:

- Standard PDP bids
- Reinsurance subsidies
- Low income premium subsidy
- Cost sharing subsidy

If so, it again would be in the member premium and put plans with LIS enrollees at a competitive disadvantage. This cost could be either a) added to a Medicaid/low income risk adjustment (as above), or b) added as a load onto the actual cost sharing reimbursement.

AmeriHealth Mercy Health Plan appreciates the opportunity to comment on these regulations. If you would like to discuss any of our comments, feel free to call me at (215) 937-8200.

Sincerely,



Daniel J. Hilferty
President and Chief Executive Officer

CMS-4068-P-1245

Submitter : Mrs. Stephanie Belling **Date & Time:** 10/04/2004 08:10:12

Organization : The Medicine Shoppe of LaCrosse, Wisconsin

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I am writing today in regards to the proposed Medicare Part D rules. As a pharmacist of the Medicine Shoppe Pharmacy located in LaCrosse, WI, I am greatly concerned about these proposed rules and the impact they will have on pharmacy services for our patients.

Please know that myself and all pharmacists want to see this Medicare Part D benefit work for all those involved. Unfortunately as past history will show, the private sector health plans have and continue to target pharmacies and pharmacy reimbursement in cost containment measures rather than teaming with pharmacy providers to enhance the quality and accessability to important health care services. We cannot continue to follow this path.

As a community pharmacist, I am concerned with three aspects of the Medicare Part D proposed rule and recommend that Centers for Medicare and Medicaid Services enable the following three policies:

1) Medicare recipients must be able to choose their own pharmacies.
It is critical that plan sponsors make every effort to include as many pharmacy providers as possible in the Part D benefit. Accessibility should be applied at a level no broader than a county to ensure all patients have ready access to the pharmacies in their community. Furthermore, plan sponsors must be required to provide pharmacy payment such that it at a minimum covers the average costs associated with dispensing prescription drugs. Private health plans often use their market force to drive down pharmacy reimbursement rates below a pharmacy's operational costs, thereby forcing pharmacy providers to shift costs to other business sectors. Medicare must now allow plan sponsors to continue this practice.

2) Implement measures to prohibit incentives designed to coerce recipients into choosing plans that exclude pharmacies.
Medicare patients should not be economically coerced into using one pharmacy over another unless the plan sponsor can justify quality reasons for a preferential pharmacy. Plan sponsors should be prohibited from providing economic incentives to recipients for using mail order pharmacies. Plan sponsors should also be prohibited from promoting pharmacies in which they have ownership interest.

3) Plan sponsors should be required to establish specified Medication Therapy Management services.
The Center for Medicare and Medicaid Services should require all plan sponsors to provide at least a specified set of medication therapy management services. Plan sponsors could provide additional MTM services, beyond the minimum required, but each must meet the CMS miminum requirements. Likewise, all plan sponsors should be directed to allow any pharmacist who receives an order for an MTM service to be able to provide that service.

All medicare eligible prescribers shoud be allowed to refer their patients in need of MTM services to a provider of such. At a minimum, each plan should be required to pay for MTM services ordered by such prescribers.

Plan sponsors should also have a plan in place to direct specifed patients, such as those with multiple chronic diseases and/or drug therapies, to MTM service providers. In turn, MTM service payment must be adequate to warrant provision of the necessary services provided by a pharmacist. As well, all pharmacists practicing within a region should be afforded the opportunity to provide MTM services.

In closing, I would like to express my appreciation for this opportunity to offer CMS my opinion of the rules being proposed for Medicare Part D benefit. I hope that my concerns and the concerns expressed by pharmacists locally and nationally are being considered.

Thank you for your time and consideration.

Sincerely,

Stephanie Belling, RPH
Wis Lic 12172
1585 Crestwood Ave
West Salem, WI 54669

CMS-4068-P-1246

Submitter : **Date & Time:** **10/04/2004 08:10:57**

Organization : **Option Care of East and Central Iowa**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

Please see comments in attached Word document.

CMS-4068-P-1246-Attach-1.doc

Option Care of East and Central Iowa is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Option Care of East and Central Iowa is a member of the national network of the Option Care home infusion companies and is located in Cedar Rapids, Iowa. We are an employee-owned company that has been specializing in this type of home care services for over 20 years. We are a member of the largest network of home infusion companies in the country. We are accredited by the Joint Commission and have earned a rather large market share in this state through clinical excellence and the resulting high patient satisfaction. We serve several hundred infusion patients on an on-going basis and have relationships with all government payers and most managed care organizations.

Option Care of East and Central Iowa appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

* Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm <http://www.nhianet.org/perdiemfinal.htm> .

* CMS should establish specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require specific standards for home infusion pharmacies under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the X12N 837 P billing format for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should mandate that prescription drug plans maintain open formularies for infusion drugs to ensure that this population of vulnerable

patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Shari Mailander, RN
Chief Operating Officer

Bryce Jackman, RPh
Director of Pharmacy

Option Care of East and Central Iowa
402 10th Street Ste 100
Cedar Rapdis, Iowa 52403

CMS-4068-P-1247

Submitter : **Date & Time:** **10/04/2004 08:10:41**

Organization : **Center on Budget and Policy Priorities**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

Please find attached our comments to the Medicare Prescription Drug Benefit proposed regulations (CMS-4068-P).

Sincerely,

Center on Budget and Policy Priorities
820 First Street, N.E., Suite 510
Washington, D.C. 20002
(202) 408-1080

CMS-4068-P-1247-Attach-1.doc

CENTER ON BUDGET AND POLICY PRIORITIES

820 First Street, NE, Suite 510, Washington, DC 20002
Tel: 202-408-1080 Fax: 202-408-1056 center@cbpp.org www.cbpp.org

October 4, 2004

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Subject: Comments on Medicare Prescription Drug Benefit Proposed Rule
(*69 Fed. Reg. 46632-46863,* August 3, 2004)

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulations that implement the new Medicare Prescription Drug Benefit enacted in last year's Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Center on Budget and Policy Priorities is a non-profit policy organization that works at the federal and state levels on fiscal policy and public programs that affect low- and moderate-income families and individuals. Our comments here focus on the new Part D benefit as it will apply to low-income Medicare beneficiaries including those who are dually eligible for both Medicare and Medicaid.

One key issue that we believe has not received appropriate attention in the proposed regulations is the historic opportunity the new drug benefit offers in improving enrollment in various public programs such as food stamps for which many low-income elderly and disabled beneficiaries are eligible. We believe that it is important that the regulation ensures that eligible beneficiaries are connected to other benefits for which they are likely to be eligible. We recognize that one agency, the Centers for Medicare & Medicaid Services (CMS) is promulgating this regulation and that the regulation relates to programs under its purview. But, in addition to Medicare, full Medicaid, and the Medicare Savings Programs for which CMS is responsible, other programs like food stamps, SSI and Social Security are the linchpins of federal support for the members of our society who are aging or experience a disability. This low-income Medicare population cannot be expected to navigate overly complicated enrollment procedures. To the extent that the government as a whole fails to coordinate these benefits, it is failing a very vulnerable population.

In addition, as noted by numerous other groups concerned with the dual eligibles and low-income Medicare beneficiaries, we find that the regulation falls short in many other areas especially in transitioning the dual eligibles from Medicaid drug coverage to the new Medicare drug benefit, ensuring that dual eligibles have access to the drugs they need, and in the processes that are envisioned for enrolling low-income beneficiaries in the low-income subsidies.

Please find below our general comments to the proposed regulations on these issues. Please note that we have also submitted more comprehensive comments along with other groups. These comments were submitted by Families USA.

Sincerely,

Robert Greenstein Executive Director	Edwin Park Senior Health Policy Analyst	Dorothy Rosenbaum Senior Policy Analyst

cc: Eric M. Bost, Under Secretary for Food, Nutrition, and Consumer Services, U.S. Department of Agriculture

Jo Anne B. Barnhart, Commissioner, Social Security Administration

I. General Comments on Improved Coordination with Other Programs Like Food Stamps

A. Background

Many Medicare beneficiaries who are eligible for a low-income subsidy under the Medicare Part D benefit will also be eligible for food stamps. The MMA and the proposed rule provide that applications for the Part D low-income subsidy may be filed with either a State's Medicaid program or with the Social Security Administration (SSA). The proposed rule has very little detail, however, about how the application process is likely to work. Because so many people who are eligible for but not participating in food stamps are likely to apply for the Part D subsidy, this application process presents an historic opportunity to connect eligible seniors and people with disabilities to the Food Stamp Program.

Many Medicare Beneficiaries Who Are Eligible for Part D Subsidies Also Are Eligible for Food Stamps

Many of the low-income Medicare beneficiaries who will be eligible for — and apply for — the new low-income drug subsidies that the prescription drug law provides are eligible for food stamps but not enrolled. A Medicare beneficiary will be eligible for some additional subsidy under Part D if his or her income, together with the income of any spouse who is present, is below 135 percent of the federal poverty level. The asset limit for the Part D low-income subsidy will be $6,000 for single beneficiaries and $9,000 for married couples. (Those with incomes below 150 percent of the poverty line with assets below $10,000 for individuals and $20,000 for couples receive a smaller low-income subsidy).

Food stamp eligibility rules are very similar — the universe of food stamp-eligible Medicare beneficiaries is a subset of the Part D-eligible population. Specifically, to be eligible for food stamps a household must have *net* income, after all available deductions are taken into account, below the federal poverty level and assets, not including a primary residence, personal items, and an automobile in most states, must be below $3,000.

Deductions play an important role in food stamp eligibility and benefit levels by taking into account certain household expenses in determining the amount of income that is available to purchase food. In practice, this means that a Medicare beneficiary could have gross income somewhat above the poverty level and still be eligible for food stamps. For the elderly and people with disabilities, the most important deductions are: a *medical expense deduction* for out-of-pocket medical expenses greater than $35 a month; a *dependent care deduction*, for expenses of up to $175 a month for adults who need care; and a *shelter deduction*, for households that have high shelter costs (including mortgage, rent, taxes, insurance, and utility expenses) in relation to their income.

The primary difference between the Part D subsidy eligibility and food stamp eligibility is the definition of who is considered in the family unit. For the Part D subsidy, only the Medicare beneficiary and his or her spouse, if present, will be considered unless there are related dependents who rely on the individual or his or her spouse for at least one-half of their financial support. For food stamps a household consists of individuals who live together and who purchase and prepare meals together. So in some instances where Medicare beneficiaries live

with others, the food stamp unit will include more people than the Part D family unit. USDA finds, however, that about half of elderly people who are eligible for food stamps but do not participate live alone, so in many cases there will be no difference.

Seniors and People With Disabilities Have Low Food Stamp Participation Rates, Despite Being Eligible for Sizable Benefits

Very low-income elderly and individuals with disabilities — those with annual incomes below about 75 percent of the poverty line (which is $6,788 for an individual and $8,554 for a couple) — are fairly well connected to the safety net; they are generally eligible for cash assistance under the Supplemental Security Income (SSI) Program and health coverage under Medicaid. The majority of these very low-income individuals do participate in food stamps.

But low-income elderly and individuals with disabilities with incomes above this level — including many such people who live below the poverty line — generally do not qualify for SSI or Medicaid, and although they are eligible for food stamps, they often are not enrolled. Overall, the program serves only about a quarter of eligible elderly people and just under half of the population of eligible adults with disabilities. In total, USDA estimates that there are over 6 million seniors and adults with disabilities who are eligible for food stamps but do not receive them.[1] Of course, Medicare beneficiaries who are not receiving SSI or Medicaid are the people who will be applying for the Part D benefit through SSA or state or local offices.

For many low-income Medicare beneficiaries, Social Security benefits bring them close to or modestly above the poverty line. For such households who do not have high expenses — for example, because they live in public housing and have no out-of-pocket medical costs — the food stamp benefit for which they qualify can be relatively low, perhaps only $10 a month. If, however, such a household has high shelter expenses, out-of-pocket medical expenses, or dependent care expenses, its monthly food stamp benefit will be significantly higher. The average Social Security recipient who has medical expenses and receives food stamps qualifies for about $50 a month in benefits. A typical household with members who are elderly or disabled and very high deductions can receive close to $90 a month or more in food stamps. Outreach messages that SSA or states use may be more useful if they explain that households with high expenses will qualify for more food stamps.

Current Responsibilities of SSA and States Make Them Appropriate to Play a Role in Enrolling Medicare Beneficiaries in Food Stamps

The states and SSA each currently have responsibilities related to the Food Stamp Program. Although food stamp benefits are 100 percent federally-funded and many of the program's eligibility and benefit rules are set by federal rules, the states have primary responsibility for virtually all aspects of the administration of the program (as they do with Medicaid), including outreach, certification and enrollment, issuance, and on-going case management. States receive a 50 percent federal match for administrative costs related to food

[1] For the Food Stamp Program an individual is considered to be elderly upon turning 60. So this figure somewhat overstates the number who would also be Medicare beneficiaries.

stamps. With only a handful of exceptions, the same local agency or local office that processes Medicaid applications also determines food stamp eligibility.

The Food Stamp Act envisions that SSA will play an important role in informing seniors and people with disabilities about food stamps. Under section 11(j)(1) of the Food Stamp Act, Social Security and SSI applicants and recipients are to be "informed of the availability of a simple application to participate in [the food stamp] program at the social security office." Section 11(j)(2) of the Food Stamp Act further requires SSA to "forward immediately" to state agencies food stamp applications from households where all members are applicants for or receive SSI. Finally, section 11(j)(2)(C) provides that the Secretary of Agriculture will reimburse the Commissioner of Social Security for any costs associated with these activities. To be clear, this means that food stamps, an entitlement with open-ended funding, can fully reimburse SSA for these food stamp-related activities without Congress needing to appropriate additional funds. (See 7 U.S.C. § 2020(j) — attached.)

Unfortunately, to our knowledge, SSA and USDA are largely out of compliance with Section 11(j)(2) of the Food Stamp Act. There is no uniform simple application currently available at social security offices for applicants or recipients to use to apply for food stamps. Not many social security offices make much effort to inform Social Security or SSI applicants about the availability of food stamps. Nationwide, the total amount that SSA received from USDA for these activities was less than $10 million in fiscal year 2003.

One promising exception is the "Combined Application Projects," or CAPs, that have been implemented in four states (Mississippi, New York, South Carolina, and Washington) in the past decade. In the CAP states, for SSI applicants who live alone, SSA provides a shortened food stamp application form with just a couple of additional questions to what the SSI application gathers. Data from the SSA application and interview are transferred to the food stamp agency, and food stamp benefits are determined without the applicant having to take any further action. (See http://www.fns.usda.gov/fsp/government/caps.pdf.) SSA has agreed to allow three additional states (Florida, Massachusetts, and Pennsylvania) to adopt this model but has declined to make the option available nationwide.

B. Comments on Subpart P Section 423.774 and Subpart S Section 423.904

The Part D enrollment process offers an historic opportunity to connect Medicare beneficiaries to food stamps and other assistance programs that might help them make ends meet. We urge you in the final regulation, and through other implementation decisions, to set up an eligibility process for the Part D low-income subsidy that allows low-income Medicare beneficiaries to be enrolled as seamlessly as possible in food stamps, as well as other state- or SSA-administered benefits for which they may qualify. This will require CMS to work collaboratively with SSA, USDA, and state agencies. Below are some specific opportunities that we see.

- **Provide information about food stamps and other major benefits for which applicants may be eligible in any outreach materials that CMS, SSA, and state Medicaid programs design and distribute.** CMS and SSA are planning

large-scale information and outreach efforts in the lead-up to the Medicare drug benefit going into effect. Mailings, on-line resources, and other materials that are made available to low-income Medicare beneficiaries and to groups that work with such beneficiaries could easily include information about the availability of food stamps and how to apply. USDA has developed an on-line prescreening tool at http://209.48.219.49/fns/.

- **Design procedures that allow applications that are filed and other information that applicants provide to be shared between SSA, state agencies, and CMS so that it is available to all agencies.** Such data sharing would allow states to target follow-up outreach to applicants who appear to be eligible for other programs, such as food stamps. For example, states could use the information that applicants provide to them or SSA for the drug benefit to automatically fill out significant sections of a food stamp application. The state could then mail the application to the elderly individual asking him or her simply to fill in the remaining questions and mail the application back, without having to come to the food stamp office.

- **Collaborate with other federal agencies, primarily USDA and SSA, on ways to enroll eligible applicants in all benefit programs.** The three agencies should seek to simplify federal program rules so that low-income Medicare beneficiaries can readily access all programs for which they qualify. A model may be the SSA Combined Application Projects that now operate in a handful of states, where SSI applicants are asked only a couple of additional questions and are certified automatically for food stamps based on their SSI applications. The standardized federal rules under these projects have allowed SSI applicants who live alone to apply for food stamps with significantly less burden than would otherwise be required.

- **Develop coordinated redetermination processes that are as simple as possible for Medicare beneficiaries.** Under the regulation, CMS seems to envision that once the Part D benefit is underway, Medicare beneficiaries will have their eligibility redetermined annually. It appears that a beneficiary who receives a Part D subsidy, is a QMB, and also receives food stamps would have to reapply separately for these three benefits at different times and would potentially have to provide virtually all of the same information to three different entities. This is an unreasonable burden for a poor senior or individual with a disability who may find it difficult and confusing to navigate three separate processes. In addition, this population tends to have relatively stable income and other circumstances. One option would be for SSA and state agencies to renew Part D eligibility based on information the beneficiary has provided for other programs, such as food stamps, if it is current. Many states have successfully used this type of “passive renewal” procedure in their Medicaid and State Children’s Health Insurance Programs (SCHIP).

- **USDA can reimburse SSA for the food stamp program's share of any costs associated with efforts to inform Social Security recipients of the availability of food stamps and other programs.** This could include, for example, outreach mailings to Medicare beneficiaries or costs associated with making computerized information available to states.

II. General Comments on Other Proposed Regulations

A. Comments on Subpart B — Eligibility and Enrollment

Enrollment of Dual Eligibles in Medicare Part D Plans

The proposed regulations fail to address adequately how responsibility for providing drug coverage for the 6.4 million Medicare beneficiaries with full Medicaid coverage (i.e., the full dual eligibles) will be appropriately transferred from Medicaid to Medicare on January 1, 2006. There are issues both of timing and of the mechanics of instituting the enrollment process. The proposed regulations do not adequately address these issues in a way that would ensure that these 6.4 million dually eligible beneficiaries avoid a potential loss of drug benefits or a gap in drug coverage, either of which could have unfortunate health consequences for these individuals.

According to the preamble, automatic enrollment of dual eligibles as required under section 423.34(d) will not begin until the end of the initial enrollment period on May 15, 2006. However, the Medicaid drug benefit for dual eligibles will no longer be available on January 1, 2006. (Federal Medicaid matching funds will no longer be available for providing outpatient drug coverage to the dual eligibles after January 1, 2006.) Given the difficulty of appropriately educating this population about Part D plan choices, it is a near certainty that a substantial number of dual eligibles will face a several month gap in coverage between the end of Medicaid's drug benefit and the scheduled automatic enrollment. This likely scenario would directly contravene Members of Congress' and the Administration's commitment that dual eligibles will be better off under Medicare Part D (or at least not be made worse off). The most appropriate solution would be to delay the cut-off of federal Medicaid matching funds to allow more adequate time to ensure an effective transition of the dual eligibles from Medicaid to the new Medicare Part D benefit. However, that would likely require statutory changes to the MMA. At the very least, CMS needs to encourage large-scale education efforts targeted to the dual eligibles by states and other organizations and allow for an earlier auto-enrollment deadline prior to January 1, 2006 to avoid gaps in coverage for the dual eligibles.

In the preamble, CMS requests comments on whether CMS or the states should perform automatic enrollment of dual eligibles. State officials are familiar with the needs of their dual eligible populations and have more data readily available on the dual eligibles in their state. They also will already be involved in the enrollment process because they are required to perform low-income subsidy enrollment; therefore, we recommend that states have the option of performing automatic enrollment. (We are concerned that under section 1860D-1(b)(1)(C) of the MMA and section 423.34(d)((2) of the proposed regulations, the auto enrollment must be conducted on a random basis, which may limit the ability of states that are conducting this auto

enrollment from moving dual eligibles to the plan that provides the greatest access to drugs. This too may require further statutory changes)

We are also extremely concerned with ensuring continuity of care for dual eligibles who have substantial drug needs. As discussed below in our comments on the need for special open formularies for the dual eligible population, for example, a disproportionate number of dual eligibles struggle with mental illness and need access to a wide variety of medications.

As outlined in the proposed regulations, dual eligibles would be forced to enroll (or be automatically enrolled) in the "benchmark" or average cost plans in their areas because, under the low-income subsidy, they will receive only a premium subsidy up to the cost of the premium for these plans. They will not receive additional premium subsidies for plans with premiums higher than the premium cost of a benchmark plan. The formularies for these plans, however, may not be as comprehensive as the drug coverage that these individuals currently have through Medicaid.

Without access to the coverage they need, dual eligibles may be forced to switch medications. In the treatment of HIV/AIDS, for example, such switches can be highly problematic and potentially deadly. We believe the same is true for a number of other illnesses and categories. Not ensuring continuity of care for prescription drugs for the dual eligibles could increase the costs of their care; dual eligibles with restricted access to drugs could end up requiring expensive services like hospitalization.

The regulations do provide a special enrollment period for full dual eligibles to use "at any time" (section 423.36). However, this provision of the regulations does not adequately address the needs of dual eligibles. There may not be adequate choice of low-cost drug plans in each region, particularly in rural areas which have not had much luck attracting Medicare managed care plans in the past. In addition, the dual eligibles are unlikely to have income or resources to pay the additional premiums (in addition to the low-income subsidy) necessary to enroll in higher cost plans that may have more comprehensive drug coverage and greater access to drugs. Moreover, the special enrollment provisions under section 423.36 do not specify that dual eligibles would not be subject to a late enrollment fee if this complex process of disenrollment and reenrollment results in a gap in coverage of more than 63 days.

In addition, full benefit dual eligibles (and their personal representatives) should receive a notice explaining their right to a special enrollment period both when they enroll in a plan and each time the prescription drug plan changes its coverage in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

In the preamble to the proposed regulations, CMS points to the exceptions process as a means of securing coverage of off-formulary medications. But the process proposed is extremely complex and will likely be impossible to navigate for people having a psychiatric crisis, facing cognitive impairments, or in the midst of aggressive chemotherapy, to list just a few examples. Moreover, the timelines established are drawn out; an expedited determination could

take as long as two weeks. Drug plans are not required to provide an emergency supply of medications until at least two weeks following a request.

Congress and the Administration have promised that dual eligible beneficiaries would be better off with this new Part D drug benefit (or at least no worse off) than they were receiving drug coverage through Medicaid. To honor this commitment, coverage of medications currently available to dual eligibles and other special populations under Medicaid must be grandfathered into the new Part D benefit just as a number of states (such as Wisconsin, Oregon, Kentucky, Texas and California) have done in implementing preferred drug lists under their Medicaid programs. For dual eligibles (and for others with life-threatening diseases such as HIV/AIDS, mental illness, cancers, and other extreme conditions), Part D plans should be required to cover their existing medications. At a minimum, this protection should be given to dual eligibles, because it is likely to be impossible for dual eligibles to enroll in more generous drug plans by paying supplemental premiums or paying for off-formulary drugs on an out-of-pocket basis.

B. Comments on Subpart C —Benefits and Beneficiary Protections

Special Formulary Protections for Dual Eligibles

Section 423.120(b) outlines the requirements on Part D prescription drug plans and on Medicare Advantage plans for their drug formularies. We strongly support the suggestion in the preamble to the proposed rule that certain populations require special treatment due to their unique medical needs. Such populations include full dual eligibles as well as institutionalized populations, persons with life-threatening conditions, and persons with pharmacologically complex conditions. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and must be protected from tiered cost-sharing that could create insurmountable access barriers. We recommend that the final rule provide for alternative, flexible formularies for special populations that include coverage for all FDA-approved covered Part D drugs with a valid prescription. Furthermore, because of the clinical importance of providing access to the specific drugs prescribed, drugs prescribed to these defined populations ought to be made available at the preferred level of cost-sharing for each drug.

In enacting the MMA, Members of Congress and the Administration committed to the principle that dual eligibles (persons eligible both for Medicare and Medicaid) would be better off (or at least not be made worse off) when their coverage for prescription drugs shifted from Medicaid to the new Medicare Part D coverage. Historically, the Medicaid prescription drug benefit has been closely tailored to the poor and generally sicker population it serves, providing beneficiaries with a range of drugs that they need with little or no co-payment. Under section 1927 of the Social Security Act, states that elect to provide prescription drug coverage under their Medicaid programs must cover all FDA-approved drugs from every manufacturer that has entered into an agreement with the Secretary of Health and Human Services to pay rebates to states for the products that the states cover. All drug manufacturers currently participate in the Medicaid rebate program.

Dual eligibles are the most vulnerable Medicare beneficiaries. Dual eligibles are people with disabilities and other serious conditions who tend to need a wide variety of prescription drugs. They are more than twice as likely to be in fair or poor health as other Medicare beneficiaries; they are three times more likely to have problems with Activities of Daily Living (ADLs) as other beneficiaries; and they are ten times more likely to be in a long-term care facility than other beneficiaries. In serving dual eligibles, Medicare prescription drug plans must be able to respond to a range of disabilities and conditions, such as physical impairments and limitations like blindness and spinal cord injury, debilitating psychiatric conditions, and other serious and disabling conditions such as Parkinson's disease and HIV/AIDS. If dual eligibles are not to be worse off when Part D prescription drug coverage begins, then they must have continued access to an alternative and flexible formulary that permits treating physicians to prescribe the full range of FDA-approved medications.

This will particularly be the case for many of the dual eligibles who reside in nursing facilities and other residential facilities. Such institutionalized beneficiaries require access to flexible formularies on the basis of their complex and multiple prescription drug needs.

Moreover, although we recommend that any alternative formulary include access to all FDA-approved medications, if the final rule permits a more restrictive alternative formulary, it should ensure that all drugs included on the formulary of participating Long-Term Care (LTC) pharmacies are included in the plan's formulary, and drugs that are preferred by the LTC pharmacies' formularies should be treated by the plan as a preferred drug. Institutionalized individuals also have little or no capacity to pay cost-sharing for non-preferred drugs or to purchase drugs for which coverage has been denied. It is imperative that any alternative formulary provide strong protections that prevent such individuals from being charged cost-sharing. For dual eligibles who reside in institutions, a condition of eligibility requires them to pledge all but a nominal personal needs allowance, usually $30 per month, to the cost of the institutional care. (We note that individuals who require an institutional level of care but live in the community under home- and community-based Medicaid waivers should have the same special protections as institutionalized beneficiaries because of their similar substantial need for prescription drugs. Otherwise, providing greater access to drugs for institutionalized individuals than to those living in the community would have the adverse effect of reversing the continued progress states have made in moving people from nursing homes to the community setting.)

C. Comments on Subpart P — Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Automatic Eligibility and Enrollment of Dual Eligibles for Low-Income Subsidy

Section 423.773 of the proposed regulations states that both full benefit dual eligibles (as well as Medicare Savings Program beneficiaries, as discussed below) are *eligible* for the additional low income subsidies, but it does not explicitly state that these beneficiaries are to be automatically *enrolled* in the subsidy program. The regulations should clarify that an individual treated as a full subsidy individual (such as a dual eligible or a MSP beneficiary) does not have to take any further action with respect to the subsidy (i.e., to make application or in any other to way verify their status), except to the extent that they need to enroll in a Part D plan. This will

help smooth the transition from Medicaid drug coverage for dual eligibles and should improve participation for others.

Treatment of Resources

Under section 423.772, we support the proposed regulation's limitation of countable resources to liquid assets only. However, the definitions of liquid assets and what it means for an asset to be able to be converted into cash in 20 days need to be clarified. The final rule should enumerate the list of countable resources that constitute liquid assets to promote clarity for states and beneficiaries. The scope of countable liquid assets should be construed narrowly, as experience under the MSP programs shows that assets tests tend to discourage enrollment and raise administrative costs for states. Experience among the states with MSPs has shown that when states waive the assets test or make it more reasonable by excluding, for example, burial plots, burial funds and life insurance from the list of countable assets, enrollment in MSP increases, with the additional costs of enrollment at least partly offset by administrative savings.

Moreover, it is harsh and inappropriate to deny an applicant the low-income drug benefit because the applicant will not liquidate a life insurance policy or burial fund. We are especially troubled by an SSA draft of the application for the low-income subsidy that asks whether an applicant has life insurance with a face value of $1,500 or more. Such a policy should not be acceptable; low-income elderly people and people with disabilities should not be disqualified from the low-income drug benefit because they have a modest life insurance policy that is intended to cover their funeral and burial costs when they die. The Food Stamp Program, for example, entirely excludes the value of a life insurance policy from its asset test. At most, the only part of a life insurance policy that should be considered is the cash surrender value to the extent that the value exceeds some much more reasonable amount, such as $20,000.

In addition, retirement accounts such as a 401(k) plan or IRA should either be fully exempt for all beneficiaries, or fully exempt for disabled Medicare beneficiaries up to age 65, with an assumed annuity value, based on the account, considered as income for all beneficiaries aged 65 and over. If calculating an annuity value would be too complicated, a simplified approach could be used, under which a fixed percentage of such an account is treated as income each year, based on Census (or other official) life expectancy tables. In other words, if a person aged 65 is assumed to live 20 years based on the life expectancy tables, five percent of the amount in the individual's 401 (k) or IRA would be counted as income each year. These accounts would *not* be counted as assets.

This is a much fairer and more rational approach. To count such accounts as assets and disqualify people with modest account balances would undercut efforts to encourage low- and moderate-income people to build some savings that can ease their poverty throughout their old age. Counting these accounts as assets for disabled beneficiaries who are below retirement age also may reduce work incentives. If such accounts are counted as assets, such individuals may be forced to liquidate modest retirement accounts. It would be far better to preserve such accounts so that the prospect of enlarging them if an individual with a disability can return to work may operate as a work incentive.

Counting the amounts in such accounts as assets is inappropriate. Such accounts are supposed to help support these people throughout their old age. Counting such accounts as assets implies that the accounts should be emptied out now to help pay for prescriptions, with the individual then left deeper in poverty for the rest of his or her life.

(Finally, we would note that the draft SSA application contains a problematic and confusing treatment of "annuities," which the application says should be treated as an asset rather than as income. The term "annuity" is popularly used for a range of financial instruments, including "life-time annuities." And an individual with a life-time annuity *no longer owns the underlying assets*. Such an individual has essentially sold the assets to the annuity company in return for a stream of income in the form of a guaranteed monthly payment for the rest of the individual's life. In these cases, it is wholly inappropriate to count the value of the underlying assets against the asset test; the individual no longer owns the assets and has no legal access to them. Furthermore, in these cases, the monthly payments that such an individual receives from the annuity company clearly ought to be counted as income. The draft SSA application is likely to lead to confusion and erroneous determinations in this area.)

Treatment of MSP Beneficiaries by SSA

We strongly support the decision reflected in section 423.773(c) to deem Medicare Savings Program ("MSP") beneficiaries automatically eligible for the low-income subsidy. This would greatly ease the administrative burden on states and SSA while also ensuring that many more MSP beneficiaries enroll in the low-income subsidy.

We are concerned, however, that MSP beneficiaries are likely to be treated differently depending on whether they apply for the low-income subsidy through Medicaid or through a SSA office. Inequities and confusion among beneficiaries may result because SSA would apply its standard for assets which may be less generous than the asset eligibility rules for MSPs in place in some states. For example, Alabama, Arizona, Delaware, and Mississippi have eliminated the assets test under the MSP programs. Eligibility requirements for the low-income subsidy should be as generous at the SSA office for subsidy-eligible individuals as at a Medicaid office, regardless of where and how people apply within the same state. Under the proposed rules, in states that have adopted less restrictive asset methodologies, people whose assets are slightly above the limits set in section 423.773 would likely be enrolled in a less generous subsidy, or have their application rejected entirely, if they apply directly through SSA, because SSA will apply the national guidelines proposed in section 423.773. However, the same people would have their application accepted if they applied through their states' Medicaid offices, were screened and then enrolled in an MSP, and were then automatically eligible for the low-income subsidy.

To resolve this problem, we propose that SSA should apply state-specific asset eligibility rules in determining eligibility for the low-income subsidy when they are more generous than under the national standard, an option discussed, though rejected, in the preamble at page 46,727. This means that for applicants from states that have eliminated the asset test or have more generous disregards under section 1902(r)(2) of the Social Security Act for MSP eligibility, SSA should apply the state's more generous rules to determine eligibility if applicable. This option is

permitted under Section 1860D-14(a)(3)(E)(iv) of the statute. (We note that the statute should be amended to allow SSA to also apply state-specific income eligibility rules when they are more generous as well.)

The regulations should also provide that subsidy applicants who appear to have excess assets *or* incomes either be screened by SSA for eligibility in an MSP program or have their applications forwarded to the state Medicaid agency to be screened for MSP eligibility. States would be precluded from requiring beneficiaries to resubmit information, such as income and asset levels, that they have already provided to SSA. Applicants would be enrolled in the appropriate MSP program, be deemed automatically eligible for the low-income subsidy under section 423.773(c) and then be enrolled in the appropriate low-income subsidy. Adopting this policy, which is not precluded by the statute, will ensure that all subsidy applicants are treated equitably and in a manner most favorable to the applicants, as well as increase participation in MSPs.

As part of this policy, the low-income subsidy application should allow an applicant to opt out of screening and enrollment for an MSP, as it is possible that a few applicants may not wish to participate in an MSP. Under Section 1860D-14(a)(3)(v)(II) of the statute, beneficiaries who are determined eligible for MSPs may be enrolled in the low-income subsidy. There is no requirement that beneficiaries actually enroll in an MSP. Therefore, applicants who meet the eligibility requirements for an MSP but who decline to enroll in the program should still be made automatically eligible for the low-income subsidy.

Because enrollment in an MSP can affect the amount of assistance a beneficiary may receive through other public assistance program, such as Section 8 housing vouchers or food stamps, there will be a profound need for beneficiary counseling during the enrollment process. We recommend that CMS plan for this need by making funds available to local agencies, including state health insurance assistance programs (SHIPs) and other community-based organizations.

In addition, we suggest that states not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective but can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP. We include the same suggestion in our comments to section 423.904(c) discussed below.

D. Comments on Subpart S — Special Rules for States — Eligibility Determinations for Subsidies and General Payment Provisions

State Medicaid Screening for Medicare Savings Programs

We believe that section 423.904(c) of the proposed regulations regarding states' obligations to screen subsidy applicants and offer them enrollment in MSPs is inadequate. In particular, proposed section 423.904(c)(2) should specify what "offer enrollment" means. We believe an applicant must be offered the opportunity to enroll during the same visit or contact (in office, by phone, or by mail), without providing further documentation or completing additional

forms. Only if enrollment is easy and convenient would Congress's intent of increasing participation in MSPs be accomplished. Furthermore, because enrollment in an MSP may be the only entry into the subsidy for some low-income beneficiaries, a simple and easy application for MSP programs is essential.

As written, section 423.904(c) would permit states to say they have "offered enrollment" if they tell applicants that they might be eligible for an MSP and can return another time to complete another application form if they wish to apply. Such an outcome would defeat the purpose of the screen-and-enroll provision included in the new Section 1935(a)(3) of the Social Security Act that was established in Section 103(a) of the statute. The low-income subsidy application should include an "opt-out" provision, under which qualified applicants would be enrolled in an MSP unless they affirmatively decline to do so. This provision would make enrollment in an MSP another way to qualify for the low-income subsidy.

Moreover, it is critical that state Medicaid offices provide good quality counseling to applicants, including their potential eligibility for other benefits such as MSPs. In addition, to ensure that enrollment requirements between MSPs and the low-income subsidy are aligned, states should not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective and can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP.

In the interest of further aligning eligibility rules for MSPs and the low-income subsidy and easing administrative burdens, we suggest that CMS should direct states to apply the definitions of resources used in Subpart P, section 423.772, if they are more generous than the MSP standards used in the individual state, in making their resource determinations for MSP applicants.

In addition, should CMS adopt a policy, as has been discussed publicly, under which most subsidy applications to state Medicaid agencies would simply be forwarded to SSA for the actual eligibility determination for the low-income subsidy, the regulations should be clear that screening for MSP eligibility must take place prior to the transmittal of the applications to SSA. Potential beneficiaries should not have to wait to be screened and offered enrollment in MSPs until after SSA processes their low-income subsidy application and provides such information back to the state Medicaid offices (if SSA in fact does so). Furthermore, an individual cannot be told by either SSA or the state that she or he is ineligible for the low-income subsidy until MSP eligibility has been determined (if the individual wishes). It would be highly problematic for an individual to receive a notice from SSA that he or she is ineligible for the low-income subsidy, have her MSP eligibility determined by the state, and then receive a notice from the state that she is eligible for both MSP and the subsidy. Alternatively, the individual may be found ineligible for the low-income subsidy by SSA and subsequently enrolled in a MSP but never redetermined for eligibility for the low-income subsidy. Whatever the mechanics, the individual must be told that MSPs are a route to subsidy eligibility.

Finally, SSA should also screen subsidy applicants for eligibility in MSPs and develop a system with states to enroll eligible beneficiaries. SSA should use the income and resource

disregards used by the state for MSPs, if they are more generous than under the uniform national definition. Applicants should not miss out on the opportunity to enroll in MSPs simply because they apply through SSA rather than state Medicaid offices. The same concerns about beneficiary education and estate recovery discussed above would apply to enrollment through SSA.

State Medicaid Screening and Enrollment for Full Medicaid

We believe that the regulations should also ensure that beneficiaries are screened not only for MSPs but also for eligibility for full Medicaid and offered enrollment if they qualify, consistent with 42 C.F.R. § 435.404. Ideally, all subsidy applicants would be screened for full Medicaid and offered enrollment if they qualify (similar to current screen-and-enroll procedures under the State Children's Health Insurance Program described in 42 C.F.R. § 457.350, and in particular for states that use separate SCHIP applications as described in 42 C.F.R. § 457.350(f)(3)). Because the importance of maintaining a simple application process for the low-income subsidy is paramount, CMS may wish to consider using a simple screening process based on information obtained through the subsidy application. This screening would trigger a follow-up with applicants who appear to be eligible for full Medicaid.

ATTACHMENT
Food Stamp Act [7 U.S.C. § 2020(j)] on SSA's responsibilities

Section 11(j) of the Food Stamp Act:

(1) Any individual who is an applicant for or recipient of supplemental security income or social security benefits (under regulations prescribed by the Secretary in conjunction with the Commissioner of Social Security) shall be informed of the availability of benefits under the food stamp program and informed of the availability of a simple application to participate in such program at the social security office.
(2) The Secretary and the Commissioner of Social Security shall revise the memorandum of understanding in effect on the date of enactment of the Food Security Act of 1985, regarding services to be provided in social security offices under this subsection and subsection (i), in a manner to ensure that—
(A) applicants for and recipients of social security benefits are adequately notified in social security offices that assistance may be available to them under this Act;
(B) applications for assistance under this Act from households in which all members are applicants for or recipients of supplemental security income will be forwarded immediately to the State agency in an efficient and timely manner; and
(C) the Commissioner of Social Security receives from the Secretary reimbursement for costs incurred to provide such services.

CMS-4068-P-1248

Submitter : Mr. Steve Roling **Date & Time:** 10/04/2004 08:10:43

Organization : Missouri Department of Social Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the Medicare Part D proposed rules. The Medicare Drug Program is a very complex program with significant ramifications for a large number of vulnerable Missourians. The Missouri Department of Social Services (DSS) urges the Centers for Medicare and Medicaid Services (CMS) issue the next version of these regulations in a format that will allow one more round of comment, even if it is a shortened comment period. We are concerned that failure to provide for additional public input when the regulation is more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

CMS-4068-P-1248-Attach-1.doc

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October 4, 2004

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Attention: CMS–4068–P

Thank you for the opportunity to comment on the Medicare Part D proposed rules. The Medicare Drug Program is a very complex program with significant ramifications for a large number of vulnerable Missourians. The Missouri Department of Social Services (DSS) urges the Centers for Medicare and Medicaid Services (CMS) issue the next version of these regulations in a format that will allow one more round of comment, even if it is a shortened comment period. We are concerned that failure to provide for additional public input when the regulation is more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

Enrollment Process

General

Missouri is concerned that the under the proposed Medicare Part D rule automatic enrollment of full benefit dual eligibles might not occur until May 15, 2006. This would cause dual eligibles active on January 1, 2006 who do not voluntarily enroll in Medicare Part D to go as long as five and a half months without prescription drug coverage. Many of the individuals who have been long time Medicaid recipients may be confused by the voluntary enrollment process and fail to enroll by January 1, 2006. Medicare's experience with the drug discount card has demonstrated that vulnerable populations often will not enroll on their own initiative in a program such as the Part D benefit, despite the advantages of the benefit being offered. Leaving dual eligibles with no coverage seems in conflict with the purpose of the Medicare Modernization Act (MMA). Automatically enrolling the full benefit dual eligibles prior to January 1, 2006 would not allow much opportunity to select a plan; however, this is preferable to having no coverage. Intermittent eligibility in Medicaid programs may further

complicate the transition to Part D and disrupt access to prescription drugs. Unique Medicaid "spenddown" or "medically needy" programs operate in 39 states. These programs allow people with high medical costs, including nursing home residents, to qualify for Medicaid by spending their income and resources down to a state-defined medical assistance eligibility level. In many cases, an individual may begin a month with a pension check or other source of income that makes them ineligible for Medicaid for the first part of the month, but once that income is put toward the cost of their care (that is, spent down), they become eligible for the remainder of the month. Depending on the spenddown period designed by the state, individuals can cycle on and off of Medicaid eligibility on as often as a monthly basis. This intermittent eligibility will significantly complicate the initial education and enrollment process and must be factored into continuing administrative and policy decisions for states, the federal government, and providers of prescription drug benefits.

Accordingly, Missouri seeks amendment to both §423.34(b) and §423.42(a) in order to clarify that a state may assist an individual with completion of the individual's Private Prescription Drug Plan (PDP) application, including executing the application on the individual's behalf, or may otherwise assist an individual in the Part D enrollment process as long as the individual is provided an opportunity to decline this assistance or "opt out" of any available PDP. Another option CMS should consider is allowing full benefit dual eligibles not enrolled in Part D to continue to receive prescription drug coverage under Medicaid with Federal Financial Participation (FFP) until the automatic enrollment date.

B. Eligibility and Enrollment (Federal Register page 46637)

2. Part D Enrollment Process (§423.34) (Federal Register page 46639)

CMS: *In implementing the automatic enrollment process for full benefit dual eligible individuals, we are considering which entity is best suited to perform the automatic and random enrollment function. We invite comment on the most appropriate method of performing automatic assignment of dual eligibles and the appropriate entity to do so.*

DSS Comments: The Missouri Department of Social Services believes automatic enrollment of full benefit dual eligibles can be handled most efficiently by the states if CMS is able to provide up-to-date information on persons currently enrolled in Medicare Part D. Having the states be responsible for performing the automatic enrollment would allow for the shortest period of time between the Medicaid approval and enrollment in Part D. DSS is concerned that the administrative cost of requiring the states to do the automatic enrollment would be an unfunded mandate. The preamble mentions compensating the states through FFP for administrative expenses or through contractual or other arrangements. Since the cost to develop a

system for automatic enrollment may be extensive, DSS feels states should receive more than the current administrative match for assuming this burden to meet this "new national workload of indeterminate size."

4. Effective Dates of Coverage and Change of Coverage (§423.38)

c. Special Enrollment Period (Federal Register page 46641)

CMS: *The rule states that for special enrollment periods, the effective date of the enrollment will be determined by CMS.*

DSS Comments: CMS should make the effective date of enrollment in Part D retroactive to the date the person's Medicaid was effective and they became a full benefit dual eligible. If the enrollment in Part D is not retroactive to the date Medicaid eligibility began, full benefit dual eligibles will have no prescription drug benefit during the prior quarter coverage. Longstanding Missouri statute requires that medical assistance (Medicaid) is only paid during such times as grants-in-aid (FFP) is provided or made available to the state.

Subpart P: Premiums and Cost-Sharing Subsidies for Low-Income Individuals (Federal Register page 46725)

2. Eligibility Determinations, Redeterminations and Applications (§423.774) (Federal Register pages 46727-46728)

CMS: *We invite comments on state Medicaid agency procedures how to best implement the determination, redetermination, and appeal process.*

DSS Comments: Section 1860D-14(a)(3)(B)(i) of the Act and the proposed 423.774 both say that determinations of eligibility for the subsidies are made by the state Medicaid agency or Social Security Administration (SSA). Our initial interpretation of this was that both agencies were required to make determinations and the Medicare recipient was free to choose which to apply with. However, it has come to our attention that SSA is proposing that the states can comply by taking applications and submitting them to SSA for the eligibility determination. This appears to conflict with Section 1935 of the Act and the proposed 423.904 that require the state Medicaid agency to make determinations of eligibility for the subsidies. If CMS believes that a state Medicaid agency can meet the requirements of both Sections 1860D-14(a)(3)(B)(i) and 1935 by taking applications and submitting them to SSA, that should be clarified in the regulations. The regulation should be clear on what obligation a state choosing this option has for keeping track of what applications were submitted and what happened to them.

The regulations do not specify the time standards within which an eligibility determination must be completed. Would the state Medicaid agency be required to complete determinations within 45 days as is required for most Medicaid eligibility determinations under 42 CFR 435.911? The regulations should specify a time standard that would apply to determinations made either by the state or SSA.

Subpart S: Special Rules for States – Eligibility Determinations for Low-Income Subsidies and General Payment Provisions (Federal Register page 46861)

CMS: *Each of the 50 states and the District of Columbia is required to provide for payment to the Secretary a phased-down contribution to defray a portion of the Medicare drug expenditures for individuals whose projected Medicaid drug coverage is assumed by Medicare Part D.*

DSS Comments: The regulations in Subpart S provide an overview of the clawback (phased-down state contribution) calculation, but it lacks the specifics for the states to estimate the clawback. The comments provided are based somewhat on information provided in conference calls attended by CMS.

The clawback is based on expenditures in calendar year 2003. The base year expenditures are trended based on National Health Expenditure (NHE) trends. The NHE trends are significantly higher than the actual increase experienced by the state. Therefore, the state will be paying a higher clawback and is further impacted since the state will continue to pay this "higher rate" for the life of the Medicare Modernization Act. Based on the last couple of years, it is also highly likely that the NHE trend will be higher than the trend experienced in Missouri Medicaid. This difference will also result in a higher clawback payment from the state.

The rebate adjustment factor is based on the pharmacy expenditures and rebates collected for the same period of time through the CMS-64 reports. When reporting these quarterly, the rebates will lag six months behind the expenditures due to the rebate process. The rebate adjustment factor artificially reduces the actual percent of rebate that is collected, which, in turn, results in a higher clawback that the state will be paying monthly to eternity. A more appropriate rebate adjustment factor would be the expenditures for calendar year 2003 and rebates collected for July 2003 – June 2004.

The clawback calculation apparently does not allow for adjustments. Missouri is a "Pay and Chase" state for pharmacy claims. Since there are no provisions for these collections in the clawback calculation, the gross per capita spent is artificially high, resulting in a higher clawback payment for Missouri. The clawback calculation also does not take into account that Medicaid recipients in calendar year 2003 were the beneficiaries of a drug

formulary that contained more drugs than they may have access to under a PDP. The clawback calculation does not allow adjustment for the more restrictive drug formulary.

Involuntary Disenrollment of Beneficiary by the PDPs (§423.44) Federal Register page 46641

CMS: *The proposed rule provides that PDPs may disenroll individuals whose behavior is disruptive.*

DSS Comments: The Department of Social Services has concerns regarding provisions in the proposed regulations to allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening." These provisions create enormous opportunities for discrimination against individuals with mental illnesses, Alzheimer's, and other cognitive conditions. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and as a result, they could also be subject to a late enrollment penalty, increasing their premiums for the rest of their lives. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage.

Under the MMA, section 1860D-1(b) directs the Secretary to establish a disenrollment process for PDPs using rules similar to a specific list of rules for the MA program. This list does not include reference to section 1851(g)(3)(B) of the Social Security Act which authorizes MA plans to disenroll beneficiaries for disruptive behavior.

Therefore, this provision regarding disenrollment of individuals by the PDP for disruptive behavior should be eliminated entirely or there should be a heightened standard for involuntary disenrollment of dual eligibles with mental health issues. There should also be expansion of the "special enrollment exceptions" for individuals disenrolled by a PDP (such as, for disruptive behavior) so that the individual will have an opportunity to join another PDP and continue with necessary medications. These "special enrollment exceptions" are necessary given the high risk of discrimination presented by the provisions for involuntary disenrollment. CMS should provide a special enrollment period for beneficiaries involuntarily disenrolled. It should include a reasonable time period for plan selection and be exempt from late enrollment penalties. Dual eligible beneficiaries who are involuntary disenrolled will face significant hardship because the Missouri Medicaid program will no longer be able to cover prescription drugs if there is no FFP.

Access to Covered Part D Drugs (§423.120) (Federal Register page 46655)

b. Formulary Requirements (Federal Register page 46659)

CMS: *To the extent that a PDP sponsored or MA organization uses a formulary to provide qualified prescription drug coverage to Part D enrollees, it would be required to meet the requirements of §423.120(b)(1) and section 1860D–4(b)(3)(A) of the Act to use a pharmaceutical and therapeutic (P&T) committee to develop and review that formulary. As a note of clarification, we interpret the requirement at section 1860D–4(b)(3)(A) of the Act that a formulary be ''developed and reviewed'' by a P&T committee as requiring that a P&T committee's decisions regarding the plan's formulary be binding on the plan. However, we request comments on this interpretation. In addition, it is our expectation that P&T committees will be involved in designing formulary tiers and any clinical programs implemented to encourage the use of preferred drugs (e.g., prior authorization, step therapy, generics programs).*

DSS Comments: Continuity of pharmaceutical treatment is of great importance to effective disease management and appropriate healthcare. As the proposed regulations themselves seem to acknowledge, PDP formularies must be developed with appropriate consideration of the point that – especially for older individuals – it is often therapeutically counter-productive, or even dangerous, to abruptly change medications. Accordingly, we believe that coordination of formulary development between State Pharmaceutical Assistance Programs (SPAP) and PDPs is especially important and should be expressly encouraged by the Part D rules.

As we understand the CMS proposal, CMS expects that the model categories and classes developed by United States Pharmacopeia (USP) will be defined so that each includes at least one drug that is approved by the Food and Drug Administration (FDA) for the indication(s) in the category or class. That is, no category or class would be created for which there is no FDA approved drug and which would therefore have to include a drug based on its "off label" indication. While DSS generally approves of the process being utilized by USP we point out an inherent flaw in the decision that, in some cases, only one drug approved in a given therapeutic class will be included in the formulary. In the case of many drugs that require lengthy periods to determine "stable" doses, abruptly changing a beneficiary's medicines in order to ensure reimbursement as a covered Part D drug could have serious consequences to that individual's health and welfare. Such negative outcomes are especially likely in the case of psychotropic compounds.

Moreover, we believe that any established formulary exceptions criteria must be flexible enough to take into account the actual circumstances of a particular beneficiary. The Secretary should provide a guideline to Medicare Advantage Prescription Drug (MA-PD) plans, as well as stand-alone

prescription drug plans, that requires such flexibility. In addition, anything less than a comprehensive formulary should be considered when calculating the state's "phase down/clawback" payment since Missouri had a non-scaled down formulary Missouri does not believe it should pay clawback/phase down for a more restricted drug formulary.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections (Federal Register page 46646)

1. Overview and Definitions (§423.100) (Federal Register page 46646)

c. Long-Term Care Facility (Federal Register page 46648)

CMS: *We request comments regarding our definition of the term long-term care facility in §423.100, which we have interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act, or a nursing facility, as defined in section 1919(a) of the Act. We are particularly interested in whether intermediate care facilities for the mentally retarded (ICF/MRs) or related conditions, described in §440.150, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. It is our understanding that there may be individuals residing in these facilities who are dually eligible for Medicaid and Medicare. Given that payment for covered Part D drugs formerly covered by Medicaid will shift to Part D of Medicare, individuals at these facilities will need to be assured access to covered Part D drugs. Our proposed definition limits our definition to skilled nursing and nursing facilities because it is our understanding that only those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies. However, to the extent that ICF/MRs and other types of facilities exclusively contract with long-term care pharmacies in a manner similar to skilled nursing and nursing facilities, we would consider modifying this definition.*

DSS Comments: As a result of the Olmstead decision, states have been moving seniors and persons with SSI benefits from institutions into less restrictive placements. These placements include ICF/MR facilities for the disabled, community care, and assisted living facilities for the aged. In addition to these less restrictive institutional settings, states have implemented waiver programs for home and community based care as an alternative to placement in a nursing home. Medicare beneficiaries spend down their assets until they are forced into nursing homes. These alternatives provide Medicare eligible beneficiaries with a choice of placement. Exclusive contracts with a long term care pharmacy should not be the deciding factor on whether or not to extend the definition of long term care facility to other forms of housing other than traditional nursing homes; the beneficiaries' qualification for Medicare and their placement should be the deciding factor. States can identify Medicare eligible individuals who were

institutionalized, and can also identify those individuals that, if it were not for the Olmstead decision or an 1115 waiver, would be institutionalized. These individuals are low income Medicare beneficiaries; having a Medicare prescription benefit at no cost will allow their income to be used for daily living expenses and not on prescriptions.

Therefore, we recommend that the final rule include a definition of "long-term care facility" that explicitly includes intermediate care facilities for persons with mental retardation and related conditions and assisted living facilities. We believe that many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

3. Establishment of Prescription Drug Plan Service Areas (§423.112) (Federal Register page 46655)

CMS: *We intend to initially designate both PDP and MA regions by January 1, 2005. In accordance with section 1858(a)(2)(C)(i) of the Act, there will be between 10 and 50 PDP regions within the 50 States and the District of Columbia and at least one PDP region covering the United States territories. The PDP regions, like the MA regions, will become operational in January 2006.*

DSS Comments: The State of Missouri believes that the establishment of PDP regions consistent with MA regions (as described in proposed §422.55) is of far less importance than establishing PDP regions that are defined by individual state boundaries. It is critical to a number of operational aspects of Part D benefits administration that each state should be a separate PDP region. As the proposed rule seems to acknowledge, existing SPAPs will play a critical role in coordinating benefits with the PDPs for the most vulnerable populations to be served under the Part D program, as well as in providing "wrap-around" coverage for beneficiaries within these populations. The administrative complexities and burden of effectuating these goals will be enormously – and unnecessarily – increased to the extent that the boundaries of PDP regions are not consistent with the state boundaries defining the relevant SPAP service areas.

6. Coordination of Benefits with Other Providers of Prescription Drug Coverage (Federal Register page 46700)

a. Coordination with SPAPs (State Pharmaceutical Assistance Programs) (Federal Register page 46701)

CMS: Our goal is to make the coordination of benefits process as functional for the beneficiary, pharmacy, and states as possible.

DSS Comments: SPAPs are prohibited from encouraging enrollees to join a particular PDP, and the law and regulatory language prohibits SPAPs

from discriminating based on the PDP in which the beneficiary is enrolled. The federal law does not prohibit a state from providing consumer advice to its citizens as to which plan might work best with a SPAP, which plan offers the best value, etc. Given the intense need for consumer assistance, we urge that the regulation either be silent on the issue or that the regulation actually encourage the states to help their citizens with the many difficult choices and questions they will be facing.

The proposed regulation portrays a much broader and very different non-discrimination rule than is contained in the statute, and is inconsistent with the express statutory language establishing limitations on that rule Under the statute's express language, a qualifying SPAP would quite plainly be permitted to encourage beneficiaries to enroll in a "preferred" PDP by any otherwise legal means that does not constitute disparate treatment of individuals in respect to determinations of eligibility for, or the amount of, assistance. In other words, while a Part D qualifying SPAP would be required to provide the same amount of "wrap-around" coverage to an individual in an alternative plan as would be provided to the individual if enrolled in a "preferred" PDP designated by the SPAP, this would not prevent the SPAP from implementing a preference for a given PDP through other means. CMS, in its proposed regulations, has rewritten this statutory rule so as apparently to prohibit *any* kind of SPAP activity that might grant preference to a given PDP or steer beneficiaries to a particular PDP; the law does not permit this substitution of agency policy for clearly expressed legislative intent.

The final regulations should include a revision of Section 423.464(e)(1)(ii) so that the rule conforms to the express language and intent of Congress in prohibiting qualifying Part D SPAPs from employing determinations of beneficiaries' eligibility or amount of benefits to favor one PDP over another; but the CMS regulations may not validly expand this statutory rule to preclude any preferential treatment of a PDP by an SPAP.

Subpart J: Coordination Under Part D Plans With Other Prescription Drug Coverage (Federal Register page 46696)

6b. Coordination With Other Prescription Drug Coverage (Federal Register page 46702)

CMS: *Comments requested regarding situations that might involve coordination between states and PDPs.*

DSS Comments: Case management services for our elderly and disabled full benefit dual eligible require the identification of prescription drugs being used by the client. We cannot rely on the patient's information, as they might not be capable of recalling all drugs they are currently using. To be effective in providing the best care to these individuals, their adjudicated drug claims data would be vital. We would expect to see these claims "crossover" to the state from CMS just as fee for service Medicare

claims do presently. The state would not want to set up data exchanges with every PDP versus one with CMS.

6c. Coordination of Benefits (Federal Register pages 46702-46703)

1.a. Covered Part D Drug (Federal Register page 46646-46647)

CMS: *Comments requested concerning gaps that may exist in the combined Medicare Part B and D coverage package.*

DSS Comments: Many of Missouri's full benefit dual eligibles do not have Part B coverage. Missouri is a 209b state and has different eligibility guidelines. These individuals would obtain their Part B covered drugs from Medicaid under the current system. Under the MMA, these drugs would not be covered under the Part D program as they are covered under the Part B. However, since the client does not have Part B but does have Part D (dual eligible), these drugs could not be covered by Medicaid. Interpretation of the law in this manner will limit the access to care these individuals should have available to them.

On page 46703 of the Federal Register it states, "We interpret the definition of covered Part D drug to exclude coverage under Part D for drugs otherwise covered and available under Parts A or B for individuals who choose not to enroll in either program. We interpret the words payment is available to mean that payment would be available to any individual who could sign up for A or B, regardless of whether they are actually enrolled." Thus, for all Part D individuals, Part A drugs and Part B drugs are "available" if they choose to pay the appropriate premiums. Consequently, Part D would not be required to pay for drugs covered under Parts A and B on the basis of a Part D eligible individual's status regardless whether the beneficiary is receiving Part A or B." For Medicaid recipients who are not eligible for Part A but could be enrolled in Part B if they choose to do so through the state buy-in program but do not take advantage of this offer, can their prescription drugs be covered by Medicaid with FFP? If not, dual eligibles will be receiving a lesser pharmacy benefit than they do currently. Our full benefit dual eligible population is accustomed to accessing drugs that are necessary to their health. Medicare's criteria for coverage of Part B drugs is much more restrictive than other insurance entities and/or Medicaid. Who would be responsible for payment if a dual eligible obtains a Part B covered drug as part of a recognized treatment plan by sources other than Medicare, the drug is rejected as non-covered by Medicare Part B using Medicare criteria, and it does not become a Part D drug? Will the beneficiary have to assume liability for their drugs? Would this become a non-covered Medicare drug payable by Medicaid at the normal federal match based on Medicaid coverage criteria? How would such a determination be made and relayed to the state and the provider? Could a process in which "exceptions" are processed for these drugs be implemented? An appeals process could be dangerous to the health of an individual who has relied on these drugs for successful treatments.

Those involved in such scenarios may be very physically or mentally ill and may not have the ability or resources to pursue the appeal process.

6.d. Collection of Data on Third Party Coverage (Federal Register page 46704)

CMS: *Comments on collection of third-party data.*

DSS Comments: The status of third party payer can change many times. Pharmacies will contact health insurance companies and Medicaid agencies now if they have discrepancies with eligibility data at the point of sale. To have them contact the disputed coverage entity should be no greater demand on their resources than they have now. This data would then be fed back to the PDPs through the coordination of benefits process who would send it to CMS for updated records.

The original collection of such data should be incorporated into the application process just as it is with the Medicaid eligibility determination process. This would require mandatory release of information by the beneficiary.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections

b. Dispensing Fees (Federal Register page 46647)

CMS: *We invite comments on three different options for the term dispensing fee.*

DSS Comments: The Department of Social Services believes that option 1 is the best interpretation of dispensing fee. Any supplies and equipment needed for the administration of the medication and any cognitive services should be reimbursed separately.

Subpart M: Grievances, Coverage Determinations, Reconsiderations and Appeals (Federal Register, page 46717)

Coverage Determination (§423.566 through §423.576)

CMS: *The PDP sponsor must make its expedited determination and notify the enrollee and the prescribing physician as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.*

DSS Comments: Currently Medicaid recipients whose prescription requests are not being honored receive a 72-hour supply of medications pending the initial coverage request. They are entitled to notice, face-to-face

hearings, and aid paid pending an appeal if their request is denied and they file their appeal within a specified time frame. All state Medicaid appeals processes are completed more expeditiously than Medicare appeals. The appeals process as described in Subpart M does not accord dual eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity to a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes.

The Missouri Department of Social Services appreciates the opportunity to submit comments on the Proposed Rule for the Medicare Prescription Drug Benefit. We welcome questions you may have or comments you may wish to discuss. Please contact Christine Rackers, Director, Division of Medical Services, at 573/751-6922.

Sincerely,

Steve Roling
Director

SR:kl

CMS-4068-P-1249

Submitter : Mr. David Zentner **Date & Time:** 10/04/2004 09:10:07

Organization : North Dakota Department of Human Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
DEPARTMENT FOR REGULATIONS & DEVELOPMENT

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CMS-4068-P-1250

Submitter : Ms. Denise Feldman **Date & Time:** 10/04/2004 08:10:27

Organization : California Healthcare Consulting, Inc.

Category : Individual

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

please see attached comments

CMS-4068-P-1250-Attach-1.pdf

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
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CMS-4068-P-1251

Submitter : Barbara Edwards **Date & Time:** 10/04/2004 08:10:41

Organization : Ohio Department of Job and Family Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments from the Ohio Department of Job and Family Services Office of Ohio Health Plans regarding the proposed regulations for the Medicare Part D prescription drug benefit.

CMS-4068-P-1251-Attach-1.doc

Bob Taft
Governor

Tom Hayes
Director

OHIO Job & Family SERVICES

30 East Broad Street • Columbus, Ohio 43215

jfs.ohio.gov

October 4, 2004

Mark McClellan, PhD, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Comments on the Proposed Rule Concerning the Medicare Prescription Drug Benefit

Dear Dr. McClellan,

Thank you for the opportunity to comment on the proposed rules regarding the Medicare Prescription Drug benefit. Within the Ohio Department of Job and Family Services, the Office of Ohio Health Plans administers Ohio Medicaid, the Medicare Premium Assistance Program, and the Ohio Disability Medical Assistance Program. Collectively, these programs cover 1.7 million Ohioans, including more than 200,000 Medicare beneficiaries.

Preserving access to prescription drugs for dual Medicare-Medicaid eligible beneficiaries ("dual eligibles") should be a priority for CMS. In Ohio, as in many states, dual eligibles have access to an open formulary, including many of the "Medicaid-optional" drugs that may not be covered by Medicare Part D (over-the-counter drugs, barbiturates, benzodiazepines, and vitamins). In addition, Ohio Medicaid consumers receive their prescriptions with zero out-of-pocket cost, except when drugs require prior authorization. For our most fragile residents, the benefit proposed in the Medicare Modernization Act (MMA) will replace a comprehensive, zero out-of-pocket plan with a more limited plan which will require out-of-pocket costs that may prohibit indigent Medicare beneficiaries from getting their prescriptions.

Access to prescriptions for Medicare beneficiaries receiving long-term care (LTC) is vitally important. Both patients living in LTC facilities and those receiving services through Medicaid home and community-based waivers should be included in this category. Access to a LTC pharmacy provider through the Prescription Drug Plan (PDP) or Medicare Advantage

Prescription Drug (MA-PD) plan, and appropriate formulary drugs including infusion therapy, are critically important for this population.

MMA requires the states to pay a phased-down state contribution toward the prescription costs of dual eligibles. The calculation of this "clawback" as set out in the proposed rule does not accurately represent the actual costs to either Medicare or to the state in providing this prescription benefit. While CMS staff have indicated that the MMA limits the information used to calculate the payment, Section 1935(c)(3) of the Social Security Act as amended by the MMA states that the Secretary may use "other data" to determine the appropriate amount. Ohio believes that this language allows more information to be used that may more accurately represent the actual costs that states would have incurred for prescription drugs for dual eligibles in the absence of Medicare Part D.

Subpart B: Eligibility and Enrollment

Section II.B.2 of the preamble referring to **Section 423.34(d)** of the proposed regulations discusses the process for auto-enrollment of full-benefit dual eligibles, and solicits comment regarding whether the federal government (CMS or its contractor) or the States (or their contracted entities) should have responsibility for administering the "random" automatic enrollment process for full benefit dual-eligible individuals who do not otherwise enroll in an MA-PD or PDP. Ohio strongly opposes this additional administrative burden, which CMS accurately describes as "a new national workload of indeterminate size," on the States. The governing legislation is clear that this responsibility should fall upon the federal government. Section 1860D-1(b)(1)(C) of the Act directs that, if there is more than one prescription drug plan available to a full-benefit dual eligible individual who has failed to enroll in a PDP or MA-PD plan, "*[t]he Secretary* shall enroll such an individual on a random basis among all such plans in the PDP region" (emphasis added).

Given this express designation of responsibility, neither the Secretary nor CMS has authority to impose responsibility for the auto-enrollment function on the States. The preamble to the proposed rule suggests that administrative costs of auto-enrollment activities by the states might have to be borne, at least in some substantial part, by the States themselves. Moreover, even if administrative costs of carrying out this function were to be 100% federally reimbursed (as would be more appropriate, given that the Part D program falls within the federal Medicare program, not the joint state/federal Medicaid program), it would nevertheless constitute a substantial, additional administrative burden on the States that they are not equipped to perform.

As the preamble to the proposed regulation acknowledges, CMS' assumption of the auto-enrollment responsibility will further the goals of national uniformity in, and facilitate federal oversight over, the process. Auto-enrollment will require accurate and timely information flow between CMS and the States in any event. There is no reason to assume that transmission of accurate Medicaid eligibility data from the States to CMS would be inherently any more problematic than transmission of accurate and timely Part D data from CMS to the States.

Recommendation: CMS should facilitate the auto-enrollment process for dual eligibles, either directly or through a contractor. Ohio believes there is no legitimate rationale for transferring to the States an administrative responsibility that Congress clearly indicated should fall upon the federal government.

Section II.B.2 of the preamble referring to **Section 423.34(d)** of the proposed regulations also discusses the timing of the auto-enrollment for dual eligibles, referring to a process to begin at "the end of the individual's initial enrollment period." We have concerns about the enrollment and the auto-enrollment process as established by this section of the draft regulations in relation to providing adequate communication and assistance in enrolling dual eligibles. First, we are concerned about the timing of the automatic enrollment process for dual eligibles because they will lose Medicaid prescription drug coverage on January 1, 2006. They must enroll, preferably through their own selection, prior to losing their Medicaid prescription drug coverage. The scheduled auto-enrollment process beginning on May 16, 2006, is too late to dovetail with the loss of their Medicaid prescription drug coverage. If this date is to work, CMS must communicate with dual eligibles concerning this change in their prescription drug benefits far in advance of the proposed October 15, 2005, mailing. Second, the proposed rule lists a plethora of concerns around auto-enrolling a full benefit dual eligible in an MA-PD or a PDP, specifying that involuntarily dis-enrolling a dual eligible from one plan in order to auto-enroll them into a plan charging a lower premium is not a viable option under the statute. Though finding a plan and premium that will fit within the low-income subsidy is a concern and further illustrates the need to assist dual eligibles in understanding their options. For this population, the concern is finding a plan which will cover all their medications as previously covered under their Medicaid drug benefit, thereby making the transition to Medicare drug coverage a seamless one.

Recommendation: CMS should change the scheduled auto-enrollment date or change the date that dual eligibles lose their Medicaid coverage, and provide in-person assistance (through federally contracted independent enrollment brokers) in order to adequately educate dual eligibles on their options and minimize the need for the auto-enrollment. In order to provide dual eligibles with the information they need to make an informed choice, PDPs, MA-PDs, CMS and SHIP agencies should not deluge dual eligibles with mailed notices and expect they will understand that they will lose their Medicaid prescription drug coverage, and that they must find a PDP or MA-PD that covers their medications.

Section II.B.10 of the preamble discusses the information that CMS will make available to PDPs and MA-PDs. Divulging beneficiary-specific information to PDPs and MA-PDs could be particularly risky for dual eligible beneficiaries. MA-PD plans have an incentive to enroll dual eligibles because they will receive an additional capitation payment (Medicaid add-on) for these higher risk beneficiaries. The dual eligible population is more vulnerable (due to age, limited English proficiency, limited education, etc.) to the risk of enrolling in a plan that does not meet their needs and having to pay out-of-pocket if their medications are not covered by the plan marketed to them. Some Medicare managed care plans have a reputation for being especially aggressive with regard to enrolling dual eligibles without providing clear information on plan limitations. Dual eligibles will require greater protections and individual assistance to select the plan that most meets their needs.

Recommendation: CMS should establish special protections for the dual eligible population, including prohibitions against direct marketing to dual eligibles by PDPs and MA-PDs.

Subpart C: Voluntary Prescription Drug Benefit and Beneficiary Protections

Section II.C.1.a of the preamble solicits "comments concerning any drugs that may require specific guidance with regard to their coverage under Part D, and any gaps that may exist in the combined 'Part D & B' coverage package." As proposed in MMA, the definition of a Part D drug excludes those drugs which may be excluded under section 1927(d)(2) of the Social Security Act. By excluding these drugs, Medicare beneficiaries may not have access to drugs such as phenobarbital (a barbiturate) or clonazepam (a benzodiazepine) for seizures, or potassium (a mineral) for the heart. For many dual eligible beneficiaries, these drugs are vitally important. The low income subsidies have no provisions for extended coverage to include these drugs. While these drugs are optional for state Medicaid programs, Ohio and most other states do cover these drugs for Medicaid consumers as an important part of the benefit package. Please also see comments below under the heading "Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation" information pertaining to Section II.F of the preamble regarding alternative coverage. Ohio believes that basic alternative coverage including the Medicaid-optional drugs is actuarially equivalent to standard coverage.

Clarification of coverage of prescription drugs under Medicare Part B is essential. The rules regarding Part B coverage are confusing, and if left to the interpretation of PDPs and MA-PDs, drugs not covered under Part B may be excluded from Part D plans. If these drugs are excluded from Part D coverage, our fear is that Medicare beneficiaries would be denied coverage.

Recommendation: CMS should include coverage for "Medicaid-optional" drugs in the Part D benefit for dual eligibles, as part of the standard package or a basic alternative plan, or within an extended package available with the low income subsidies. CMS should also clarify coverage of prescription drugs under Medicare Part B to ensure that all appropriate drugs are covered under either Part B or Part D.

Section II.C.1.c of the preamble asks for "comments regarding our definition of the term long-term care facility in **section 423.100**."

Specifically, comments were solicited concerning whether Intermediate Care Facilities for the Mentally Retarded (ICFs/MR) should be considered LTC facilities. These facilities are residential facilities providing long term care to residents, so as such are LTC facilities. Since virtually all residents of ICFs/MR in Ohio are dual eligibles, and therefore eligible for the low-income subsidies, they should be afforded the same benefits as residents of nursing facilities and skilled nursing facilities, along with all other beneficiaries receiving LTC.

As a result of the U.S. Supreme Court decision *Olmstead v. L.C.*, 527 U.S. 581 (1999), Ohio and other states have been moving seniors and persons with disabilities from institutions into less

restrictive placements. Ohio has implemented waiver programs for home and community based care as an alternative to placement in a nursing home. These alternatives provide consumers with a choice of placement, but allow them to receive the same level of care as those who reside in institutions.

Exclusive contracts with a LTC pharmacy should not be the deciding factor on whether or not to extend the definition of LTC facility to forms of housing other than traditional nursing homes; the beneficiaries' qualification for Medicare and their health care needs should be the deciding factors. Rather than defining "long-term care facility," it may be more useful to define "long-term care." States can identify dual eligible individuals who are institutionalized, and can also identify those individuals that, if it were not for the *Olmstead* decision or an 1115 waiver, would be institutionalized. These individuals are low-income Medicare beneficiaries; having a Medicare prescription benefit at zero out-of-pocket cost will allow their income to be used for daily living expenses and not on prescriptions.

Dual eligible residents of LTC facilities in Ohio are required to use all income toward the cost of care, except for a personal needs allowance of $40 per month. This amount is not enough to pay for the cost of medications obtained from out-of-network pharmacies or non-covered drugs. The personal needs allowance for patients under home and community based services waivers is higher, but is still not high enough to pay the added cost of medications that have previously been covered under the Medicaid pharmacy benefit. Parity between institutionalized and waiver serviced beneficiaries must be maintained. These most needy Medicare beneficiaries must be offered a comprehensive benefit plan with zero out-of-pocket costs.

Recommendation: CMS should include ICFs/MR in its definition of LTC facilities. Furthermore, CMS should define "long-term care" to include both patients in residential facilities as well as those who receive a level of care through a home and community based waiver that would be equivalent to care in a residential LTC facility. All Medicare beneficiaries who are either institutionalized or in Medicaid home and community based waivers should be afforded the same prescription benefits including zero copayments.

Section II.C.4.a of the preamble referring to **Section 423.120** of the proposed regulations discusses access to LTC pharmacies, and whether CMS should require, or merely encourage, PDPs and MA-PDs to include LTC pharmacies in their networks. A requirement that PDPs and MA-PDs include one or more LTC pharmacy providers will ensure access to LTC pharmacy services for all Medicare Part D beneficiaries. By merely encouraging this arrangement, Medicare beneficiaries who enter LTC arrangements while enrolled in a PDP or MA-PD without a contracted LTC pharmacy will be left with only potentially expensive out-of-network options. In addition, a PDP or MA-PD could effectively discriminate against patients in LTC by declining to contract with a LTC pharmacy. The rules governing PDPs and MA-PDs must include beneficiary protections against the few PDPs and MA-PDs which may choose to provide less-than-appropriate care. By requiring each PDP and MA-PD to include at least one LTC pharmacy in its network, beneficiaries will retain a measure of protection. In addition to requiring at least one LTC provider, PDPs and MA-PDs should also be required to contract with any LTC pharmacy that agrees to the PDP's or MA-PD's standard contract.

Recommendation: CMS should require each PDP and MA-PD to include at least one LTC pharmacy in its network, and to contract with any LTC pharmacy that agrees to the PDP's or MA-PD's standard contract.

Section II.C.4.a of the preamble referring to **Section 423.120** of the proposed regulations discusses access to federally qualified health centers (FQHCs), and whether CMS should require, or merely encourage, PDPs or MA-PDs to include FQHC pharmacies in their networks. Similar to the LTC pharmacy question, a requirement that PDPs and MA-PDs include FQHC pharmacy providers will ensure access to pharmacy services for all Medicare Part D beneficiaries. Recognizing that FQHC pharmacies would need different contractual terms, PDPs and MA-PDs should be required to approach these pharmacies and attempt to reach agreement about terms.

Recommendation: CMS should require each PDP and MA-PD to approach all FQHCs in its service area to attempt to negotiate a contract.

Section II.C.4.a of the preamble referring to **Section 423.120** of the proposed regulations discusses access to home infusion pharmacies, and whether CMS should require, or merely encourage, PDPs and MA-PDs to include home infusion pharmacies in their networks. Also similar to the LTC pharmacy question, a requirement that PDPs and MA-PDs include home infusion pharmacy providers will ensure access to pharmacy services for all Medicare Part D beneficiaries. By merely encouraging this arrangement, Medicare beneficiaries who require home infusion services while enrolled in a PDP or MA-PD without a contracted home infusion pharmacy will be left with only potentially expensive out-of network options. By requiring each PDP and MA-PD to include at least one home infusion pharmacy in its network, beneficiaries will retain a measure of protection.

Recommendation: CMS should require each PDP and MA-PD to include at least one home infusion pharmacy in its network.

Section II.C.4.b of the preamble referring to **Section 423.120** of the proposed regulations "invite[s] comments regarding standards and criteria that [CMS] could use to determine that a PDP sponsor or MA organization's formulary classification system that is not based on the model classification system does not in fact discriminate against certain classes of Part D eligible beneficiaries." To be sure that an appropriate formulary system is in place, CMS should consider the United States Pharmacopeia (USP) model guidelines to be the minimum acceptable to meet the criteria. This means that the PDP's or MA-PD's proposed classification system must contain at least as many **equivalent** categories and classes of drugs as USP's model. In addition, CMS must verify that a variety of dosage forms are available. Appropriate drug therapy may involve the use of alternate dosage forms such as injectable and easier-to-swallow oral forms (e.g. liquids or rapidly dissolving tablets) for patients unable to swallow tablets or capsules. Drugs for topical, ophthalmic, nasal, otic, vaginal, and rectal administration should also be included in PDP and MA-PD formularies.

Part of the goal of CMS' approval of PDP and MA-PD formulary classifications must be protection from unintended consequences of cost containment. Particularly in an elderly

population such as the one served by Medicare, inappropriate drug therapy may lead to hospitalization, worsening morbidity, and mortality. The added costs of these consequences would be borne by Medicare Parts A and B, rather than by the Part D PDP. This misaligned financial incentive must be mitigated by requirements to provide drugs in appropriate categories.

With the continued trend toward prescription drugs being granted over-the-counter (OTC) status, it is important that PDPs and MA-PDs not be able to exclude a required category or class of drugs because OTC options are available. These required categories and classes should be included in every plan's list of covered drugs.

Recommendation: CMS should use USP's model guidelines as the baseline for what is acceptable. PDP and MA-PD formularies must include a variety of dosage forms in at least as many equivalent categories and classes of drugs as USP's guidelines. The formulary classification must protect both the beneficiary and Medicare Parts A and B from unintended consequences of cost containment.

Subpart F: Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation

Section II.F.4 of the preamble referring to **Section 423.265** of the proposed regulations discusses actuarial equivalence of plans. This section considers differences in plan cost sharing that may be considered actuarially equivalent, but gives little information about plans that may choose to provide coverage of optional drugs under basic alternative plans. Section 1860D-2(a)(2)(A)(ii) of the Social Security Act as amended by MMA provides for "[c]overage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A)" regarding Medicaid-optional drugs. By including these drugs, to be used as alternatives to other Part D drugs, PDPs and MA-PDs will provide a more comprehensive benefit without incurring higher costs than the basic plan. This option should be considered in the regulations and Part D plans should be encouraged to provide this coverage. As mentioned above, coverage of drugs such as phenobarbital (a barbiturate) and clonazepam (a benzodiazepine) are necessary for appropriate care of seizure disorders. OTC drugs such as laxatives, aspirin, and antacids provide cost-effective care for common ailments. The availability of drugs for cough and cold symptoms will reduce inappropriate and unnecessary prescribing of antibiotics which may cause antibiotic resistance and increase hospitalizations and other health care costs. While state Medicaid programs have the option to not cover classes of drugs including those listed here, most provide at least limited coverage. Ohio provides a comprehensive benefit including a selection of agents used for the symptomatic relief of cough and colds, prescription vitamins and mineral products, nonprescription drugs, barbiturates, and benzodiazepines.

Recommendation: CMS should issue regulations encouraging basic alternative coverage including optional drugs. A benefit plan providing this alternative coverage is actuarially equivalent to the standard plan, and offers Medicare beneficiaries a more comprehensive benefit package. PDPs and MA-PDs should be encouraged to provide this basic alternative coverage.

Subpart J: Coordination under Part D Plans with Other Prescription Drug Coverage

Section II.J.6.b of the preamble referring to **Section 423.464** of the proposed regulations invites comments regarding coordination of benefits between state Medicaid programs and PDPs and MA-PDs. While this section is specific to coordination after the implementation of Part D, it is also important to consider the transition into Part D. Dual eligible beneficiaries in Ohio and most other states have a comprehensive drug benefit including open formulary and zero out-of-pocket cost for most prescriptions. This benefit will be replaced by a Part D plan which will probably provide a much more limited formulary and will require copayments for each prescription. Medicare must ensure that the transition from Medicaid prescription coverage to Part D is seamless, and no beneficiary will be unable to obtain medications. The transition process needs to ensure that no dual eligible experiences a lapse in coverage for any reason.

This seamless transition will only be accomplished with an organized, easy-to-understand auto-enrollment process. Because Medicaid coverage will end on December 31, 2005, it is imperative that all dual eligibles be enrolled in a PDP or MA-PD before Part D coverage begins. Once enrolled, the PDP or MA-PD should cover the beneficiary's existing medications during a transition period during which the PDP or MA-PD, beneficiary, and beneficiary's physicians work together to change the drug regimen to conform to the plan's formulary or to receive prior authorizations for necessary medications. Appeals and redeterminations need to be done on an accelerated timeline during the transition period, and beneficiaries must be informed of their right to appeal.

During this transition period, dual eligibles should not be subject to higher out-of-pocket costs for out-of-network pharmacies. While beneficiaries may decline the PDP or MA-PD chosen for them in an auto-enrollment process, it will take some time for the beneficiary to choose a more appropriate PDP or MA-PD that includes his or her preferred pharmacy. For dual eligibles in LTC facilities, extra protections during this transition period are even more important because they are generally locked in to a single pharmacy provider which has contracted with the facility.

Recommendation: CMS should ensure a seamless transition period for dual eligible beneficiaries. This transition period should include expedited appeals, an open formulary, and no penalties for out-of-network pharmacy use. This transition period should last for at least six months, to give the beneficiary, physicians, and the PDP or MA-PD enough time to change any drugs that are nonformulary or to appeal the formulary decision.

Section II.J.6.b of the preamble referring to **Section 423.464** of the proposed regulations invites comments regarding coordination between state Medicaid programs and PDPs and MA-PDs. This coordination of benefits must allow states flexibility to either wrap around or not wrap around the Part D benefit. State assistance may take the form of a State Pharmaceutical Assistance Plan (SPAP) as defined in the regulations, a Medicaid state plan, or another state-financed arrangement. **Regardless of the form of assistance, states should have the ability to choose not to wrap around the benefit while being satisfied CMS has assured that the state's Medicare beneficiaries are receiving appropriate drug coverage.** States should also

have the flexibility, if they do choose to wrap around the benefit, to either pay the difference between the low-income premium subsidy and the premium for a basic or extended plan, or to pay on a per-claim basis. Related to states' decision not to wrap around the Part D benefit, CMS should provide a State Plan Amendment option to exclude dual eligibles, or any consumer eligible for Medicare, from any outpatient drug coverage under Medicaid.

Recommendation: CMS should write regulations protecting the states' ability to either wrap around or not wrap around the Part D benefit, and to choose the structure of any wrap around benefit. For states that choose not to wrap around, CMS should provide protection through the state plan to exclude any Medicare-eligible consumer from Medicaid pharmacy services.

Subpart S: Special Rules for States – Eligibility Determinations for Low-Income Subsidies and General Payment Provisions

Section II.S.1 of the preamble referring to **Section 423.904** of the proposed regulations discusses states' obligations for processing applications for the low-income subsidies. States should be able to meet this obligation by simply accepting applications and forwarding them to the Social Security Administration (SSA) for eligibility determinations to be made. Similarly, all redeterminations and appeals should be done by SSA. This approach will encourage consistency to a national standard and provide accountability to all Medicare beneficiaries. Any provision in the law that a state must perform any eligibility determination for a federal program is an unfunded mandate, and as such should be eligible for 100% federal reimbursement for any state resources expended. Staff time for Ohio to implement this program will include creating rules within the Ohio Administrative Code, training of front-line workers, training of supervisory staff, and time for hearings, appeals, and oversight. In order to accomplish this unfunded mandate, information system changes would need to be made in a short amount of time. If states are to be required to begin accepting applications by July 1, 2005, these system changes are not possible. Ohio also needs time to obtain state statutory authority to perform any functions related to the Medicare benefit but unrelated to state programs. In Ohio, we have the authority to administer the Medicaid program, including the Medicare premium assistance program, but not to administer Medicare. The requirement for states to perform any function regarding eligibility for Medicare is unnecessarily burdensome.

Recommendation: CMS should issue regulations which are clear that a state's only obligation in processing applications for low-income subsidies is to accept applications to be forwarded to SSA for processing. Any resources contributed by a state to the Medicare program should be eligible for 100% federal reimbursement.

Section II.S.4 of the preamble referring to **Section 423.908** of the proposed regulations discusses the calculation of the Phased-Down State Contribution. The calculation, as proposed in rule, closely follows the instructions from MMA. However, the authorizing legislation does contain a provision, in its amendment to Section 1935(c)(3) of the Social Security Act, to use "information reported by the State in the medicaid financial management reports (form CMS-64) for the 4 quarters of calendar year 2003 *and such other data as the Secretary may require*" (emphasis

added). Ohio believes that this language allows the Secretary to consider information that does not appear on the forms CMS-64 for calendar year 2003. The intent of the legislation is to approximate the amount that would have been spent by states for Part D drugs for dual eligibles in the absence of Medicare Part D, based on the experience of 2003. Congress clearly recognized that the forms CMS-64 would not contain the full picture of states' experience in 2003. For example, drug rebates are billed approximately two months after the end of the quarter during which they were earned. Thus, rebates for much of 2003 were not billed or received until well into 2004. Federal rebate liabilities have been steadily increasing. By considering only the rebates that were received in 2003, the calculation more closely reflects 2002 experience.

A second issue is that many states, including Ohio, implemented or planned cost-saving measures in 2003 which will reduce pharmacy costs into the future. For example, Ohio implemented a Preferred Drug List (PDL) program in April 2003 which has shown savings of about 5% in overall pharmacy program costs. As with the federal rebates, the supplemental rebates associated with the PDL were not billed until several months later, so most of the revenue was received in 2004 and reported on forms CMS-64 for quarters in 2004. The Ohio PDL has been introduced in phases, with the first phase in April 2003, second phase in October 2003, and the third phase to be implemented in October 2004. Savings projections for calendar year 2005 are close to 8% of overall program costs. These additional savings should be considered by the Secretary under the "other data" provision of MMA, because they would more closely reflect the costs to Ohio for the pharmacy benefit for dual eligibles in the absence of Medicare Part D. Along with the PDL, a copayment of $3 was instituted for drugs requiring prior authorization. This copayment has improved our cost savings by encouraging Medicaid consumers to use less expensive drugs that do not require a copayment. These savings should also be considered.

A third consideration for the calculation of the phased-down payment is the inflation factor used. The legislation directs the Secretary to use the "most recent National Health Expenditure projections" to determine the inflation factor. State Medicaid programs in general, and Ohio Health Plans in particular, have consistently contained growth to a factor lower than the National Health Expenditure projections. Ohio's recommendation is that CMS consider each state's performance relative to the National Health Expenditure data, and to use a factor appropriate to each state, not to exceed the national projection.

Each state should be required to submit data that explains adjustments to be made to the "clawback" calculation. Because there is no provision for the baseline amount to be recalculated in the future, it is imperative that the liability be accurately calculated. To consider only information that was submitted in standard reports will not reflect the full experience of the states in 2003. Because of the significance of the 2003 baseline number, CMS should develop an appeals process for the phased-down state contribution calculation. This process will enable states to have a process through which to resolve any disagreement with CMS' calculations.

Recommendation: CMS should use the statutorily authorized consideration of "other data" provided by the states to determine an accurate, fair representation of the state's cost for

pharmacy benefits for dual eligibles in the absence of Medicare Part D. Each state's calculation should be different based on experience. This one-time calculation to be used in perpetuity must accurately reflect state experience. As such, a process should be developed for states to appeal CMS' determination of the payment amount.

Conclusions

Ohio Health Plans look forward to working with CMS on the implementation of Medicare Part D. Preserving access to prescription drugs for dual eligibles, the most disadvantaged seniors in our state, is a priority. It is imperative that these and all Medicare beneficiaries have access to a comprehensive drug benefit that is affordable. The cost of providing this benefit should not be unfairly shifted to states through an inappropriate Phased-Down State Contribution payment. Please consider these recommendations before issuing final regulations. If you have any questions, please do not hesitate to contact me at (614) 466-4443.

Respectfully Submitted,

Barbara Coulter Edwards
Deputy Director for Ohio Health Plans
Ohio Department of Job and Family Services

Submitter : Dr. James Nawarskas **Date & Time:** 10/04/2004 08:10:36

Organization : New Mexico Society of Health-System Pharmacists

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment for important comments

CMS-4068-P-1252-Attach-1.doc

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014
www.cms.hhs.gov/regulations/ecomments

To Whom It May Concern:

The purpose of this letter is to comment on the Medication Prescription Drug Improvement and Modernization Act of 2003 (MMA), specifically the Medication Therapy Management Program (MTMP).

The New Mexico Society of Health-System Pharmacists represents pharmacists that practice in a variety of health care settings (hospitals, federal clinics and health systems, academia, managed-care organizations, etc.). The mission of our organization is to advance the provision of pharmaceutical care and achieve optimal patient outcomes.

Currently, under New Mexico law, pharmacists can have full prescriptive authority under the supervision of a physician to provide medication therapy management limited to the scope of the physician's practice. Additionally, all registered pharmacists in New Mexico can have prescriptive authority for the following: pediatric and adult immunizations, emergency contraception, and tobacco cessation products.

Representing the New Mexico Society of Health-System Pharmacists, we make the following recommendations for successful implementation of the MTMP which will in turn lead to improved patient care.

It is our position that CMS should include in the rules:

1. **That all pharmacists are included as qualified providers of MTMP**. Pharmacists in health systems currently provide MTM services in anticoagulation clinics, cardiovascular risk reduction clinics, congestive heart failure clinics, asthma clinics, etc. These services have been repeatedly associated with improvements in the quality of patient care and reductions in healthcare costs.
2. **Targeted beneficiaries should include all patients with at least one chronic disease**. Current plans to identify beneficiaries qualified to receive MTMP focus on patients having multiple chronic conditions, receiving multiple medications and who are expected to incur high prescription drug costs. Under-use of medications often is as serious a drug-related problem as is over-use and therefore MTM eligibility should ***not*** be based solely on number of medications currently prescribed.
3. **Reimbursement rates must be determined nationally by CMS using any willing provider guidelines and ensuring appropriate coverage areas**. Ensuring standardized rates of reimbursement would inhibit PDPs from contracting with groups purely based on cost at the sacrifice of MTMP quality.

Reimbursement rates should be based upon the complexity of the service provided and commensurate with reimbursement for other healthcare providers.

4. **The patient must have freedom of choice of providers**. This would encourage competition between providers based on quality, ultimately leading to improved patient outcomes.
5. **CMS must ensure that contractors have full coverage for patient and provider access in rural and underserved areas**.

Thank you for allowing us the opportunity to provide comments on the proposed rules.

Sincerely,

James J. Nawarskas, Pharm.D., Ph.C., BCPS
President
New Mexico Society of Health-Systems Pharmacists
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Joe R. Anderson, Pharm.D., Ph.C., BCPS
Legislative Chair
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Immediate Past President
New Mexico Society of Health-System Pharmacists
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CMS-4068-P-1253

Submitter : Mr. Paul Latchford **Date & Time:** 10/04/2004 08:10:09

Organization : Monumental Life Insurance Company

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4068-P-1253-Attach-1.doc

Monumental Life Insurance Company

Direct Response Division
520 Park Avenue
Baltimore, Maryland 21201-4500

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: to CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

RE: Comments on Medicare Modernization Act of Proposed Rule Part 403

To Whom It May Concern:

We are writing to comment on the proposed rules of August 3, 2004, which would amend 42 CFR 403.205. CMS proposes to amend the federal regulatory definition of a "Medicare Supplemental Policy" to include a stand-alone limited health benefit policy or plan. Additionally, CMS proposes a disclosure form to be sent by Medigap carriers regarding Medicare Part D.

Proposed Changes to Medicare Supplemental Definition

CMS should make no changes to the current definition of Medicare Supplemental Policy except to conform to the MMA changes regarding what is not a Medicare Supplement Policy.

The MMA requires that the definition of Medicare Supplemental Policy only change to add a prescription drug plan under Part D as a type of coverage not included in the definition of the Medicare Supplemental Policy and to replace the term Medicare+Choice with Medicare Advantage. Any other changes to the definition of Medicare Supplemental Policy proposed by CMS are not authorized by the MMA. The agency does not have statutory authority to advance any changes above and beyond the two provided pursuant to the MMA.

CMS proposes to amend the definition of Medicare Supplemental Policy by including a rider attached to an individual or group policy, a stand alone limited health benefit plan or policy that supplements Medicare benefits and is sold primarily to Medicare beneficiaries or that otherwise meets the definition of the Medicare supplement policy as defined in the section, and any rider attached to a supplemental policy to become an integral part of the basic policy. This is already addressed as a matter of state law.

Additionally, CMS proposes to delete section 403.205(d)(1 through 5). In the current law these subparts are specifically listed as exclusions from the definition of Medicare Supplemental Policy. CMS has no statutory authority to delete these provisions and therefore may not removed pursuant to the proposed rule.

Notice to Medigap Prescription Policyholders.

We recommend that CMS retain the version of the "notice" required by section 104 of the MMA for Medigap carriers that was adopted by the NAIC and submitted to CMS. The NAIC approved version of the notice meets all of the statutory requirements of the MMA. We should not as Medigap carriers be required to make any assessments regarding the "value" of coverage nor to promote Medicare Advantage. The notice should go no further than to meet such requirements.

We appreciate the opportunity to offer comments on these proposals and thank you for your consideration of these comments.

Sincerely
Paul Latchford
Vice President and Counsel

CMS-4068-P-1254

Submitter : **Kevin Cranston** **Date & Time:** **10/04/2004 08:10:37**

Organization : **Massachusetts Department of Public Health**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Massachusetts Department of Public Health, HIV/AIDS Bureau

CMS-4068-P-1254-Attach-1.doc

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

MITT ROMNEY
GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

RONALD PRESTON
SECRETARY

CHRISTINE C. FERGUSON
COMMISSIONER

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014

File Code: CMS-4068-P

To Whom It May Concern:

On behalf of the state of Massachusetts, I appreciate the opportunity to comment on the proposed regulations entitled, "42 CFR Parts 403, 411, 417 and 423 Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule," 69 FR 46632. I am extremely concerned that many of the proposed regulations could negatively impact drug coverage for people living with HIV in our state, as well increasing the financial burden on the already strapped Massachusetts AIDS Drug Assistance Program (ADAP).

1.) Explicitly excluding ADAPs from being able to provide wrap-around coverage in a manner that would allow beneficiaries to reach the catastrophic limit seriously undermines the federal government's priority of providing comprehensive health care to people living with HIV/AIDS. ADAPs are an integral component of the safety net for people living with HIV/AIDS in this country and have a long history of filling gaps left by other federal programs, including Medicaid and Medicare. We strongly recommend that the final rule count cost-sharing subsidies from ADAPs as incurred costs for beneficiaries.

Massuchusetts is very concerned that the regulation also disallows state-appropriated dollars spent by ADAPs to be counted as incurred costs. It is discriminatory and unacceptable to single out state dollars used to provide medications to people living with HIV/AIDS while at the same time allowing state dollars to be used for State Pharmaceutical Assistance Programs' (SPAPs) expenditures on behalf of a beneficiary. Under the proposed regulations, SPAPs are allowed to wrap-around in a way that all costs spent on the behalf of a beneficiary count as incurred costs. States should have the flexibility to provide prescription drugs to a variety of populations, including people living with HIV/AIDS, with the state dollars appropriated. It is inexcusable to

exempt people living with HIV/AIDS from receiving this type of assistance from their state, while allowing people with other medical conditions to benefit from the use of state dollars. Ironically, persons with AIDS who live in states with SPAPs and who are eligible for assistance will have SPAP costs count toward incurred costs, while those who rely on ADAP will not.

2.) While we understand that CMS is hopeful that all prescription drug plans (PDPs) will include all necessary HIV-related drugs on their formularies, it is not required. Therefore, even individuals who benefit from the low-income protections included in the benefit may find themselves turning to ADAPs to receive the remaining necessary medications.

Massachusetts strongly supports the CMS recommendation to implement "open formularies" for special populations and strongly recommends that people with HIV/AIDS be defined as a special population. We feel this is critical to ensuring that Medicare beneficiaries with HIV/AIDS have continued and unhindered access to all of the drugs that are medically necessary for treating the disease. Furthermore, an "open formulary" will prove cost effective because it will prevent the use of more intensive and costly health care resources such as inpatient hospitalization that will occur if Medicare beneficiaries with HIV/AIDS are denied access to medically necessary prescription drugs. While the private drug plans are not at risk for this potential cost shifting, the federal government will incur these costs either through higher Medicaid expenditures or higher Medicare Part A and B expenditures.

3.) Strengthening the language regarding coverage of drugs for off-label use. It is imperative that prescription drug plans be required to cover medically accepted uses of drugs for off-label use that are standard practice in the medical community. For HIV disease, as with many complex conditions, clinical practice frequently progresses ahead of label indications as physicians learn what drug combinations best target their patient's symptoms and side effects. As an example, tenofovir (Viread) has proven effective for treating hepatitis B for people with HIV, although treatment for hepatitis B is not yet an indicated use of the drug.

4.) Imposition of co-payments. People with HIV/AIDS depend on a daily regimen of multiple medications (most of which are non-generic). Even minimal co-payments will create a financial burden for individuals who will be left to choose between paying for medications and meeting other needs, like food and housing. Dual eligibles must maintain the protection that they currently have under Medicaid and not be denied a drug for failure to pay cost sharing.

Again, thank you for the opportunity to submit comment on the proposed rule to implement the Medicare Part D prescription drug benefit. Please contact me at kevin.cranston@state.ma.us if you need further information.

Sincerely,

Kevin Cranston, MDiv
Acting Director

CMS-4068-P-1255

Submitter : Mr. Kenneth Whittemore, Jr. **Date & Time:** 10/04/2004 08:10:56

Organization : SureScripts

Category : Health Care Industry

Issue Areas/Comments

Issues 1-10

BACKGROUND

RE: CMS?4068?P; Medicare Program; Medicare Prescription Drug Benefit; 42 CFR, Part 423, Section 159, Electronic Prescription Program

This letter is in response to the proposed rule that the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register, Volume 69, Number 148, beginning on page 46632 on August 3, 2004. SureScripts appreciates the opportunity to comment on the proposed rule with respect to those provisions that will support the implementation of an electronic prescription program designed to improve the overall prescribing process for millions of Medicare beneficiaries. In fact, SureScripts has already testified before, and offered additional advice and assistance to, the National Committee on Vital and Health Statistics Subcommittee on Standards and Security as it gathered input this past summer on electronic prescribing standards that might be used for the electronic prescribing program for Medicare. We look forward to continuing to work with CMS to implement said standards and these proposed rules in a manner that improves the safety, efficiency, and quality of the overall prescribing process for all essential stakeholders.

CMS-4068-P-1255-Attach-1.doc

SureScripts
The prescription for better healthcare™

October 4, 2004

Submitted Electronically

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS—4068—P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: CMS—4068—P; Medicare Program; Medicare Prescription Drug Benefit; 42 CFR, Part 423, Section 159, Electronic Prescription Program

Dear Dr. McClellan:

This letter is in response to the proposed rule that the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register, Volume 69, Number 148, beginning on page 46632 on August 3, 2004. SureScripts appreciates the opportunity to comment on the proposed rule with respect to those provisions that will support the implementation of an electronic prescription program designed to improve the overall prescribing process for millions of Medicare beneficiaries. In fact, SureScripts has already testified before, and offered additional advice and assistance to, the National Committee on Vital and Health Statistics Subcommittee on Standards and Security as it gathered input this past summer on electronic prescribing standards that might be used for the electronic prescribing program for Medicare. We look forward to continuing to work with CMS to implement said standards and these proposed rules in a manner that improves the safety, efficiency, and quality of the overall prescribing process for all essential stakeholders.

Introduction

SureScripts was founded in August of 2001 by the National Community Pharmacists Association (NCPA) and the National Association of Chain Drug Stores (NACDS), which represent the interests of 55,000 chain and independent pharmacies. The company is committed to building relationships within the healthcare community and working collaboratively with key industry stakeholders and organizations to improve the safety, efficiency and quality of healthcare by improving the overall prescribing process. At the core of this improvement effort is SureScripts Messenger™ Services, a healthcare infrastructure that establishes electronic communications between pharmacists and physicians and enables the two-way electronic exchange of prescription information. You and your staff can find more information about SureScripts at www.surescripts.com.

SureScripts Responses to CMS Requests for Comment on the Proposed Rule

(1) CMS: We are particularly interested in comments that help us identify consensus or reach consensus on e-prescribing standards ahead of the statutory timeframe, and to help us identify and evaluate industry experience based on pilot programs engaged in e-prescribing activities in 2004 and 2005.

SureScripts selected the nationally recognized NCPDP SCRIPT Standard to serve as the foundation for its transaction engine software in 2001, and has been actively and effectively using the standard in commerce with its various physician and pharmacy technology partners since June 2003. SCRIPT currently facilitates the electronic transmission of new prescriptions, prescription refill requests and authorizations, prescription fill status notifications, prescription change request and approvals and cancellation notifications between physicians, dispensing pharmacies and pharmacists. Future enhancements to SCRIPT could address other data communication possibilities that may include patient eligibility, compliance, lab values, diagnosis, disease management protocols, patient drug therapy profiles, prescription transfers, etc.

The NCPDP SCRIPT Standard was developed through a consensus process among community pharmacy organizations, PBMs, health plans, pharmacy software vendors, database providers, and other stakeholders. It adheres to EDIFACT syntax requirements, utilizes standard EDIFACT and ASC X12 data tables, and is an American National Standard (ANS). This being the case, and in light of the success that our organization has had in employing the standard for the past sixteen months, SureScripts believes that there *is* consensus in the industry that the NCPDP SCRIPT Standard is the best standard to meet the e-prescribing needs of ambulatory Medicare beneficiaries and the physicians and pharmacists who serve them. Therefore, we encourage CMS to identify the NCPDP SCRIPT Standard as one that can be adopted ahead of the statutory timeframe.

(2) CMS: Therefore, to the extend we determine, after consultation with affected standard setting organizations and industry users, that there already is adequate industry experience with certain standards, we may propose to finalize those standards through notice and comment rulemaking even if we have not completed the pilot testing of other standards so that a portion of the standards adoptions process could be expedited. We seek comments on the desirability of this strategy, including any concerns about potential unintended consequences.

In its September 2, 2004 letter to Secretary Tommy Thompson of the Department of Health and Human Services, the National Committee on Vital and Health Statistics did identify two existing industry standards as "foundation standards" that are ready for use by the industry and could, therefore, be finalized through notice and comment rulemaking prior to the completion of pilot testing of other standards. These standards were (1) the most current version of NCPDP SCRIPT for new prescriptions, prescription renewals, cancellations, and changes between physicians and dispensers and (2) the ASC X12N 270/271 Health Care Eligibility Inquiry and Response Standard Version 004010X092A1 for conducting eligibility inquiries from physicians to

payers/PBMs. We strongly agree that it would be desirable for all stakeholders if CMS were to finalize the adoption of the NCPDP SCRIPT Standard, see no potential unintended consequences of doing so, and hence encourage the agency to proceed accordingly at this time.

(3) CMS: In order to facilitate electronic prescribing by a PDP or MA-PD sponsor, we invite public comment on additional steps to spur adoption of electronic prescribing, overcome implementation challenges, and improve Medicare operations.

Inasmuch as CMS has already added regulations at § 423.159(b) that would allow an MA-PD plan to provide separate or differential payment to a participating physician who prescribes covered Part D drugs in accordance with electronic prescription standards, we also encourage CMS to allow MA-PD plans to make similar incentive payments to participating pharmacies. Both the upfront and ongoing costs of implementing electronic prescribing will be substantial for community pharmacies (and quite likely of greater magnitude than for physicians), so such payments to pharmacies would be entirely supportable and justified.

(4) CMS: We note that any payments must be in compliance with other Federal and State laws, including "the physician self-referral prohibition at section 1877 of the Act" and the Federal anti-kickback provisions at section 1128B(b) of the Act. We are soliciting the public's view of the application of these legal authorities to the differential payments described in this section. We will share any comments regarding the anti-kickback statute with the Office of Inspector General.

Some relief from the anti-kickback statute in support of electronic prescribing would aid adoption by physicians. We are aware that hospitals, health systems, and other stakeholders are reluctant to embark on aggressive electronic prescribing initiatives on the advice of counsel because of the provisions in anti-kickback statutes. We encourage broad relief from those statutory elements that are constraining investment in electronic prescribing.

We also encourage any such relief to be mindful of the operational difficulties that would require electronic prescribing systems to be able to parse functionality on the basis of that used to benefit only Medicare beneficiaries, versus all patients. We encourage as broad a relief as possible. We also encourage that specific emphasis be placed on relief that is tied to physician and staff training, physician utilization and bi-directional communication with pharmacies.

(5) CMS: The electronic prescribing process and the technology that enables it must be cost effective, the systems must be fast and easy to use, and alerts and other data passed back to the prescriber must demonstrate value. We invite comments on these challenges and on possible Federal activities that would promote the effective use of e-prescribing by providers, including publishing best practices, and making technical information on e-prescribing products available.

The history of electronic prescribing efforts over the past decade clearly shows that the way in which electronic prescribing technologies are—or are not—effectively woven into health care providers' workflows has a strong effect on whether said technologies are adopted. On the

physician side, the time it takes to create a prescription electronically must be nearly as brief as it now takes them to write prescriptions by hand, otherwise there is a barrier to the adoption of the technology. On the pharmacy side, it is apparent that the way in which pharmacy management systems are updated to accommodate electronic prescribing can also have a significant impact on adoption and utilization. Because both physician and pharmacy systems are proprietary in nature, the companies who market these technologies rarely, if ever, share successful design features with competitors. Therefore, CMS's publishing of best practices so that all electronic prescribing companies can offer systems that address the majority of providers' needs, as well as making technical information on e-prescribing products available so that providers can make informed comparisons, should support the effective adoption and use of electronic prescribing.

(6) CMS: In addition, receptivity to the use of electronic prescribing by consumers is not well understood, especially among the elderly and disadvantaged populations. We seek additional information on how those populations may view electronic prescribing and what step may be taken to get them to use this modality and, thus, take advantage of the safety and quality benefits it offers.

In August of 2002, SureScripts released the results of a survey that Harris Interactive conducted for the company to identify the attitudes and perceptions that the public held toward electronic prescribing. The study found that Americans associated electronic prescribing with a number of benefits including:

- 61 percent felt they would have less waiting time at the pharmacy when electronic prescribing is used
- 51 percent believed that electronic prescribing would yield faster prescription renewals
- 40 percent said electronic prescribing would minimize opportunities for errors associated with handwritten prescriptions
- 26 percent responded that electronic prescribing would allow more time to discuss the medicines with their pharmacists

Though this small study was not targeted toward elderly or disadvantaged populations, it did show that the public in general does have some understanding of the benefits that they can expect to experience when health care providers communicate using electronic prescribing.

(7) CMS: We also invite comments on how to promote the use of electronic prescribing by providers, health plans and pharmacies and other entities involved in the provision and payment of health care to Medicare beneficiaries. Beyond the grants authorized in § 423.159(b) of this proposed rule, we invite comments on what incentives could be used to spur more widespread adoption, especially for early implementers.

SureScripts encourages CMS to support the use of incentives for physician practices that adopt electronic prescribing. We caution, however, that incentives that are merely hardware or software license fee giveaways may fall short of creating the longer term utilization of the

technology we all want. We do encourage CMS to consider incentive programs that contain one or more of the following elements:

- Incentives for both physician and staff use
- Incentives that require some minimum utilization of the technology, for example a minimum number of prescriptions per month
- Incentives that require bi-directional communications with pharmacies to encourage real collaboration
- Incentives that support the training of physicians and physician practice staff
- Incentives that support both the communications of new prescriptions, but also those resulting from the refill authorization process (renewals)

With respect to pharmacies, currently over 75 percent of community pharmacies in the United States have software that enables them to communicate with physicians using electronic prescribing. Given this good faith effort on the part of the pharmacy profession to become ready to use electronic prescribing, it would make good sense for CMS to further stimulate the process by offering community pharmacies financial incentives to use the technology. This is especially important because community pharmacies will be supporting a disproportionate share of the overall e-prescribing infrastructure and transaction costs.

(8) CMS: We also invite your comments on what educational efforts or data analyses might be undertaken to help health practitioners understand, or empirically confirm, and ultimately realize, the benefits of electronic prescribing.

Although there are some reports in the literature that speak to the benefits of electronic prescribing to patients, physicians, pharmacists, and other stakeholders, few could be considered authoritative. In fact, most of these reports are anecdotal in nature. Because there is such a dearth of solid research on the benefits of electronic prescribing, SureScripts has undertaken two research projects to obtain much more definitive data on the benefits of electronic prescribing. The first project is our Prescription Process Validation Project, which is more qualitative in nature, and the second is our Pharmacy ROI Project, which is more quantitative in nature. We expect to have completed both of these projects no later than early spring of 2005, and it would be our pleasure to share the results of these studies with CMS. If this would be of interest to CMS, please let us know and we will contact you as soon as we have results that merit your attention.

Additional SureScripts Comments

(9) Commercial messaging at the point of care

Congress clearly stated its concern about the potential for the commercial abuse of the electronic prescribing process by including language in the MMA that electronic prescribing standards "allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems to reduce medication errors, to avoid adverse

drug interactions, and to improve medication use." Therefore, commercial messaging at the point of care during the prescribing process should not be allowed. Point of care is defined as both at the physician office as well as at the pharmacy. Commercial messaging consists of two varieties:

- Any message delivered at the point of care that is paid to be delivered by a third party during the prescribing process should be considered a commercial message. There is a potential for messages that could be paid for by manufacturers, payers, pharmacies, PBMs, or any other party interested in determining the decision made for a particular medication or a particular pharmacy where the medication would be dispensed.
- Any message to persuade a decision at the point of care after a decision or selection of pharmacy or selection of medication is made by a provider of care should be considered a commercial message. In other words, if pop-up messages occur after a physician selects a pharmacy or after a physician selects a medication, such pop-ups should be considered a commercial message.

In addition to these types of commercial messages, an inappropriate commercial bias can be also be injected into the electronic prescribing process if physicians are not shown all relevant information. For example, showing only part of a formulary could lead a physician and the patient to assume medications not listed in an electronic prescribing application are not covered when, in fact, they may just have a higher copay than the preferred medication. Hence, physicians should be presented complete formulary information at the beginning of the prescribing process.

(10) The community pharmacist's role in the prescribing process should be supported by the proposed rule

CMS should ensure that the final e-prescribing rules support the integral role that pharmacists play in the prescribing process. These rules should facilitate the collaboration of physicians and pharmacists so that physicians have all the relevant information necessary to make truly informed prescribing decisions. Community pharmacists frequently have the most complete record of a patient's medication history because they routinely monitor and coordinate multiple physician medication therapies and provide counseling to patients regarding <u>all</u> of their medication therapies. Typically, payer payment history databases exclude:

- Medications that the patient received prior to coverage by the current PBM
- Medications that are covered under worker's compensation or a spouse's plan
- Medications that cost less than the PBM copayment and are paid for with cash
- Medications paid for by PhRMA company patient assistance programs
- Non-covered and/or "sensitive" medications that patients pay for with cash
- Medications covered by a major medical plan rather than a PBM plan
- Experimental medications not covered by PBMs
- Over-the-counter medications, vitamins, minerals, and other nutritional products

Payers also do not have information that patients provide specifically to the pharmacist during patient counseling, such as potential allergies, sensitivities, and other adverse reactions.

In order to provide the safest and most effective therapies to Medicare beneficiaries, physicians must be able to effectively interact with pharmacists to conduct drug utilization review and to ensure that prescribing decisions are appropriate. To support these efforts, e-prescribing standards should ensure that pharmacists have complete access to all of a patient's medical information and medication history. This will enhance the quality of care provided to patients and help ensure that the drug utilization review process is both cost-effective and comprehensive. Therefore, we strongly urge CMS to develop and implement e-prescribing rules that support this important bi-directional exchange of information.

Conclusion

SureScripts appreciates the opportunity to continue to provide advice and assistance to CMS as it works to implement the electronic prescription program requirements of the MMA through this proposed rule. We hope CMS will continue to take advantage of the experience that SureScripts can share with respect to the real-world implementation of electronic prescribing for the purposes of improving the safety, efficiency, and quality of the overall prescribing process. Please do not hesitate to have your staff contact us should they have any questions regarding the comments we have offered above or if the are any other ways that we can assist them in this important work.

Sincerely,

Ken Whittemore, Jr.
VP, Professional and Regulatory Affairs

ken.whittemore@surescripts.com

CMS-4068-P-1256

Submitter : Mr. Scott Shields **Date & Time:** 10/04/2004 08:10:49

Organization : Aventor

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

On behalf of Dey, L.P., we are pleased to provide CMS with comments to CMS-4068-P. We have attached our full comments and an executive summary of the comments.

CMS-4068-P-1256-Attach-2.doc

CMS-4068-P-1256-Attach-1.doc

Executive Summary
Comments on "Medicare Program; Medicare Prescription Dug Benefit; Proposed Rule"
(CMS-4068-P)

Dey, L.P. appreciates the opportunity to comment on the following issues addressed in the above-referenced proposed rule and its preamble:[1]

- Subpart C – Benefits and Beneficiary Protections
  - Section 423.100 (Definition of "Covered Part D Drug")
  - Section 423.120 (Access to Covered Part D Drugs)

- Subpart D – Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans
  - Section 423.153 (Cost and Utilization Management, Quality Assurance, Medication Therapy Management Programs, and Programs to Control Fraud, Abuse, and Waste)

Key Overall Point: CMS acknowledges the statutorily-mandated distinction between Part B and Part D drugs. Our principal concern is that the agency inappropriately suggests that certain Part B drugs with characteristics such as those described in the proposed rule's preamble – i.e., drugs covered as incident to a physician's service or furnished through an item of DME – could be covered under Part D.

"Covered Part D Drug": Dey supports the principle enunciated in the rulemaking that Part D "wraps around" Part B, providing beneficiaries with drug coverage that is seamless. However, portions of the preamble extend this "wrap around" principle beyond reasonable bounds. Specifically, the preamble cites examples that could be interpreted to confer Part D coverage on infusion and injectable drugs in situations that are currently within the Part B claims administration authority of the DMERCs. Similarly, in addressing dispensing fees for Part D drugs, CMS identifies options that, if implemented with respect to infusion drugs, could be applied more broadly – and inappropriately – to other Part B services.

> *Recommendation*: CMS should make clear that DME drugs used in situations now covered under Part B are excluded from coverage under Part D.

Access to Covered Part D Drugs: The rulemaking appropriately addresses means for ensuring that beneficiaries have access to Prescription Drug Plans (PDPs) that include in their networks' long-term care pharmacies and home infusion pharmacy providers. However, because these pharmacies/providers offer drug-related services that are typically covered under Part B, CMS should take special care to ensure that Part D coverage does not substitute for coverage available under Part B. In fact, we read the preamble's language on these points almost to invite such substitution. For example, CMS seeks comments on whether PDPs should receive performance incentives for producing Medicare savings under Parts *A and B* – virtually an open invitation to replace Part B drug coverage with Part D coverage if the PDP believes it will save money.

[1] 69 Fed Reg 46632 (Aug. 3, 2004).

The Medicare Modernization Act (MMA) clearly did not contemplate this type of Part D-Part B substitution. Indeed, the MMA, in establishing a Chronic Care Improvement Program, provided a separate means for CMS (on a demonstration basis) to test methods for identifying clinical and economic synergies among Parts A, B, and D.

> *Recommendation*: CMS should make clear that PDPs may not substitute Part D drug coverage in situations in which Part B drug coverage is available.

Medication Therapy Management: CMS solicits comments on whether the terms "multiple covered Part D drugs" and "multiple chronic diseases" should be defined by the agency itself or by PDPs. Both terms implicate use of disease management tools – tools that Dey supports. However, we are concerned that inappropriately inserting these tools into Medicare Part D, but not into Part B, could exert a counterproductive, asymmetrical effect. That is, by rewarding PDPs for exacting savings on a drug used in a situation that makes it Part D-covered (when, in other situations, it is Part B-covered) could discourage PDPs from considering the clinical factors DMERCs have long taken into account in administering Part B drug claims.

> *Recommendation*: CMS, not PDPs, should define the key terms. In so doing, the agency should maintain a level playing field among Medicare contractors, preventing PDPs from inappropriately reducing utilization for a subset of the situations in which a drug is used.

Drug Utilization Management: The preamble, in addressing industry standards for drug utilization management, suggests incentives to reduce costs "when medically appropriate" – a phrase not defined.

> *Recommendation*: The phrase "medically appropriate" should be defined to include criteria for ensuring that compounding of drugs is performed in a fashion consistent with patient safety and FDA's requirements.

DATE: October 4, 2004

Centers for Medicare and Medicaid Services

Department of Health and Human Services

Attention CMS-1429-P

P.O. Box 8012

Baltimore, Maryland 21244-8012

Re: [CMS--4068-P] Medicare Program; Medicare Program; Medicare Prescription Drug Benefit

Dear Sir or Madam:

Dey, L.P. is pleased to submit the following comments regarding the above-referenced proposed rule (Proposed Rule).[1] Dey, L.P. welcomes the opportunity to work with the Centers for Medicare and Medicaid Services (CMS) as it develops policy for drugs currently covered as a Part B benefit with the potential for coverage as a Part D benefit in 2006.

Dey, L.P. develops, manufactures, and markets prescription pharmaceuticals for the treatment of respiratory illnesses, including chronic obstructive pulmonary disease (COPD), a condition that represents a significant financial burden for the Medicare program and a serious threat to patient longevity and quality of life.

We propose that CMS clarify in the final rule to specifically exclude from Part D those drugs covered under Part B because they are incident to durable medical equipment (DME).

We are providing comments on three sections of the Proposed Rule that hold implications for the availability of drugs provided as a Part B benefit that may, under some circumstances, be provided as a Part D benefit:

1. Section 423.100, regarding the definition of a covered Part D drug;
2. Section 423.120, regarding access to covered Part D drugs; and
3. Section 423.153 in Subpart D Cost Control and Quality Improvement Requirements for Prescription Drug Plans

Various examples in the proposed rule could establish a precedent for changing coverage from an existing benefit (Part B) to a new one (Part D), thereby violating the "wrap around" principle that CMS has enunciated for Part D.

We suggest that CMS specify clearly in the final rule that drugs currently covered under Part B, either incident to a physician service, or incident to the DME benefit, be excluded from Part D coverage until such time as the Secretary issues the report on this subject (required under the Medicare Modernization Act) and the Congress acts to give CMS the authority to implement any recommended changes stemming from the report.[2]

[1] Proposed Rule, 69 Fed Reg 46631 (Aug. 3, 2004).
[2] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, sec. 101(d).

1. **Subpart C. Voluntary Prescription Drug Benefit and Beneficiary Protections**

   a. ***Proposed Section 423.100 Definition***[3]

The proposed rule includes a definition of two terms that would benefit from more specificity:

- "Covered Part D Drug,"[4] and
- "Dispensing fee."[5]

Covered Part D Drug

CMS addresses the complex issue of drugs that can be covered under Part A, B or D, depending on the form of administration and site of service. While the Part D benefit is expected to be a "wrap-around" to the other benefits, the rulemaking contains descriptions of infusion or injectable drugs that have characteristics similar to a nebulized drug, and others that are administered through DME, where the drug product could be picked up at a pharmacy and be self-administered at home.

Our concern is that the examples include situations that are currently within the purview of the DMERCs and are intended to be addressed in subsequent regulations regarding the competitive acquisition programs for Part B drugs, supplies, medical equipment and related services. We recognize that some drug delivery mechanisms are not covered under Part B, and that beneficiaries could benefit from the "wrap-around" nature of the Part D benefit.

[3] 69 Fed Reg 46646.
[4] 69 Fed Reg 46646.

However, a drug administered through DME should remain a Part B covered service when it is used in a setting which is currently covered by the DMERCs; furthermore, we propose that it should be specifically excluded from Part D. Coverage for these products has evolved over many years, and the coverage criteria and decisions reflect the complex issues that need to be considered in order to structure a program that does not disrupt existing services. This consideration is beyond the scope of reform contemplated by Congress, prior to an analysis by the Secretary.

Part D Dispensing Fee

We commend CMS for clearly stating that the definition of a dispensing fee would apply specifically to Part D, and we agree with the agency's preference for the first of the three options described in the proposed rule; i.e., a single fee associated solely with dispensing of the prescription. We recognize the need for CMS to consider Options 2 and 3 (involving the necessary equipment and supplies and the necessary professional services of a nurse or pharmacist) for home infusion drugs.

However, if Options 2 and 3 are part of the final rule, PDPs should be excluded from applying such fees to reimburse for the costs of services currently subject to Part B coverage. Our concern is that permissible instances in which Options 2 and 3 may be needed (e.g., to reimburse for the costs of supplies and services associated with home infusion drugs that may not be covered currently under Part B) could be applied more broadly and inappropriately to other Part B covered services. Our concern is specifically

[5] 69 Fed Reg 46647.

grounded in the reimbursement circumstances surrounding Dey's product, DuoNeb® Inhalation Solution ("DuoNeb"), used in the treatment of COPD. We presented these concerns in our September 17, 2004 letter in response to **[**CMS-1429-P] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005. A summary of the rationale is provided in Exhibit A.

b. Proposed Section 423.120 Access to Covered Part D Drug[6]

Our concerns relate to two provisions regarding the ways in which Medicare beneficiary access to pharmacies can be assured. Specifically, we have concerns regarding CMS preamble language pertaining to availability of PDP access to 1) long term care pharmacy, and 2) home infusion pharmacy providers.

1) Long Term Care Pharmacy

While it is appropriate for CMS to consider whether the new Medicare Prescription Drug Plans (PDPs) should be required to include long-term care pharmacies in their plans and to take into account how the PDP might reimburse these pharmacies for services such as infusion therapy and 24 hour medication delivery, our concern is that such services should be excluded from Part D coverage if Part B coverage is available.

2) Home Infusion Pharmacy

The issue is the same for home infusion pharmacies, although we note with some concern that CMS is seeking comments on ways to encourage PDPs, who do not have a medical benefit and therefore cannot realize efficiencies from reduced hospital costs, to establish

contracts with home infusion pharmacies. The potential to offer performance incentives for Part D contractors for savings under Part A or Part B goes beyond the scope of what MMA contemplated. These types of savings could more appropriately be captured under the Chronic Care Improvement Program, which MMA established as a demonstration.

2. Subpart D. Cost Controls and Quality Improvement Requirements for Prescription Drug Benefit Plans

a) Proposed Section 423.153 Cost and Utilization Management, Quality Assurance, Medication Therapy Management Programs and Programs to Control Fraud, Abuse and Waste

Two provisions of this proposed section could be detrimental to Medicare beneficiaries' continued access to Part B covered drugs and related services:

- Cost Effective Drug Utilization Management[7] (relating to the use of compounded drugs); and
- Medication Therapy Management[8] (relating to providing appropriate nebulizer utilization).

Cost Effective Drug Utilization Management

CMS solicits comments on industry standards for cost effective drug utilization management, which includes the use of incentives to reduce costs, "when medically

[6] 69 Fed Reg 46655.
[7] 69 Fed Reg 46666.
[8] 69 Fed Reg 46668.

appropriate," which is not defined. We suggest that the term "medically appropriate" should specify criteria as to when using compounded drugs would be considered a medically appropriate incentive to reduce costs.

Specifically, we believe CMS should ensure that compounding is done on a patient-name prescription basis, and that pharmacies use all compounding and admixing precautions to ensure product sterility and freedom from microbe ingress contamination. Patient safety is crucial, and the quality of the compounded product should be comparable to a commercial drug product.

Another area of concern regarding compounding is that the FDA prohibits pharmacy compounding of two or more separate FDA-approved products when a combination product approved by the FDA is commercially available.[9]

Specifically, in the past six months alone, the FDA has cited and sent warning letters to several pharmacies for the following compounding violations: preparing drug products that are commercially available, and compounding drugs "without the necessary controls to ensure drug product sterility and potency."[10,11,12]

[9] Food and Drug Administration. Compliance Policy Guidance for FDA Staff and Industry. Sec. 460.200 (Pharmacy Compounding). June 7, 2002. Accessed August 10, 2004 at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html.
[10] FDA warning letter to Axium Healthcare Pharmacy, June 7, 2004, at http://www.fda.gov/cder/warn/2004/AXIUM%20%20wl.pdf.
[11] FDA warning letter to Gentere, Inc., July 13, 2004, at http://www.fda.gov/foi/warning_letters/g4863d.htm.
12 FDA warning letter to delta Pharma, Inc., September 17, 2004, at http://www.fda.gov/foi/warning_letters/g4965d.htm.

Violations of the FDA policy against compounding commercially-available drugs affect DuoNeb, since it is a currently marketed, sterile, non-allergenic, premixed combination drug; these manufacturing processes are designed to lower the risk of drug cross-contamination and to minimize waste. The premixed, unit-dose combination of the two agents within DuoNeb enhances patient safety by minimizing the chance for medication errors, and it eliminates the need for the Medicare patient to nebulize two different solutions, resulting in faster treatment times and improved compliance.

As for the second category of violation – compounding drugs "without the necessary controls to ensure drug product sterility and potency" – quite obviously patient safety is at risk, and a threat to public health is created. We also note that, in 2002, the FDA sampled 29 drugs from compounding pharmacies and found that 10 were subpotent.[12] In all, the compounded drugs sampled by the FDA registered a 34 percent failure rate – far in excess of the comparable two percent rate for commercially-available drugs.[13]

These examples highlight the complexity unique to prescription drugs covered under Part B and the need for greater clarity and precision in the Part D proposed rule.

Medication Therapy Management Program

CMS solicits comments on whether it should define the terms "multiple covered Part D drugs" and "multiple chronic diseases", or allow the PDPs to define the terms as part of their bids to CMS. While we support the use of appropriate disease management tools

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[12] Report: Limited FDA Survey of Compounded Drug Products. Food and Drug Administration. Accessed August 24, 2004 at http://www.fda.gov/cder/pharmcomp/survey.htm.
[13] *Id.*

such as the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, our concern is that CMS maintain a level playing field among its contractors and not create an advantage for PDPs who potentially could be rewarded for reducing nebulizer use among a sub-set of COPD patients, without adequately considering clinical factors such as those included in the DMERC coverage policies.

Conclusion

Dey, L.P. appreciates the opportunity to comment on these three proposed sections that – absent additional clarification – could affect Medicare beneficiaries' access to life-saving and quality-of-life enhancing medications. We base our observation on examples contained in the proposed rule that, while casually presented, belie the underlying complexity that results when coverage could be provided under different benefits, depending on the route of administration and site of service. Coupled with the concerns we raised in our response to the proposed rule on Part B payment, we are compelled to reiterate our recommendation that CMS develop a cohesive strategy for inhalation drug therapy based on clinical guidelines and correct assumptions as to the medical necessity of nebulizer-based therapy by some patients. In addition, including pharmacy compounding as an activity whose costs may be included in the dispensing fee could be troublesome, given that on certain occasions pharmacy compounding is not appropriate and should not be reimbursed by PDPs.

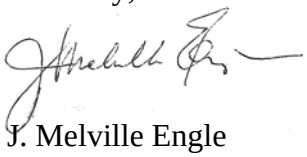
We urge CMS to revisit the proposed changes regarding a revised (or incremental) dispensing fee by conducting a study of the appropriate activities and their costs, and by considering the considerable operating and patient-support expenses borne by pharmacies.

The concept of a "service fee" may be a more appropriate description of the various pharmacy activities and expenses.

Dey, L.P. believes that CMS needs to be more specific in the final regulation about the Part D benefit for those prescription drugs that can be covered under the Part B benefit. The MMA includes several provisions related to the latter that will be implemented over the next few years and also calls for the Secretary to study these issues and report to Congress. We know the complexity of the issues related to inhalation products and support an approach that considers them in the overall context of respiratory disease costs to the Medicare program. It is important to get the right prescriptions to patients using the most appropriate delivery mechanism, be it nebulizers, MDIs, or dry powder inhalers (DPIs), all of which are found in clinical practice guidelines and will be included in Medicare's benefits as of 2006. CMS and its contractors need to strive for consistency with existing Medicare policies and FDA polices to ensure that payment policy changes do not create incentives for activities that are not consistent with the coverage of products under existing benefits and the assurances provided to the public by the FDA.

Thank you for the opportunity to present our views with respect to these selected provisions detailing how the Part D benefit will be implemented.

Sincerely,



J. Melville Engle

President and CEO

Nebulizers versus MDIs

We feel compelled to correct the record regarding the stance CMS has taken regarding the relative and comparative value of nebulizers versus MDIs. In the portion of the Proposed Rule preamble pertaining to MMA Section 305, CMS states that Medicare beneficiaries have a "strong" financial incentive to use nebulizers since the alternative inhalation drug delivery mechanism, metered dose inhalers (MDIs), currently are not covered under Part B, and beneficiaries will have to wait until January 2006 to be covered under the new Part D drug benefit. CMS also states that, based on a literature review, nebulizers are no more effective than MDIs in delivering bronchodilators, and CMS predicts a substantial shift from nebulizers to MDIs once the latter become covered under Part D beginning in 2006.[14] We fear CMS may underestimate the clinical value, patient preference and improved outcomes for nebulized respiratory medication which is based on a reduction of symptoms and improved quality of life, not financial incentives.

While it is true that some studies have shown that nebulizers and inhalers are equally effective, the performance of inhalers was augmented by spacers.[15,16,17] Spacers are designed to deliver MDI-delivered medication more easily and effectively. In common

[14] Proposed Rule, 69 Fed Reg 47546, 47548.
[15] Turner MO, Patel A, Ginsburg S, Fitzgerald JM. Bronchodilator delivery in acute airflow obstruction. A meta-analysis. *Arch Intern Med*. 1997 Aug 11-25;157(15):1736-44.
[16] Duarte AG, Momii K, Bidani A. Bronchodilator therapy with metered-dose inhaler and spacer versus nebulizer in mechanically ventilated patients: comparison of magnitude and duration of response. *Respir Care*. 2000 Jul;45(7):817-23.
[17] Schuh S, Johnson DW, Stephens D, Callahan S, Winders P, Canny GJ. Comparison of albuterol delivered by a metered dose inhaler with spacer versus a nebulizer in children with mild acute asthma. *J Pediatr*. 1999 Jul;135(1):22-7.

practice, studies have shown that patients only use spacers to be used with inhalers approximately 50 percent of the time.[18,19] **Without** accessories such as spacers, much of the medication is left in the mouth and throat, thus reducing absorption and efficacy.[20]

In addition, the literature is replete with studies showing that many patients, up to 89%, do not employ proper inhaler technique.[21,22,23] Therapeutic benefit depends on sufficient deposition of drugs in the medium and small airways; this is largely determined by a competent inhaler technique.[24,25] The most recent report of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) states that "COPD patients may have more problems in effective coordination and find it harder to use a simple Metered Dose Inhaler (MDI) than do healthy volunteers or younger asthmatics."[26]

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[18] Dow L, Phelps L, Fowler L, Waters K, Coggon D, Holgate ST. Respiratory symptoms in older people and use of domestic gas appliances. *Thorax* 1999; 54: 1104-1106. Fifty-four percent of the study population using MDIs used spacers; 45 percent of the study population using MDIs did not us a spacer.
[19] Bynum A, Hopkins D, Thomas A, Irwin C, Copeland N. The Effect of Telepharmacy Counseling on Metered-Dose Inhaler Technique Among Adolescents with Asthma in Rural Arkansas. Presentation. The University of Arkansas for Medical Sciences. 2000 American Telemedicine Association Annual Meeting. Accessed September 15, 2004 at http://www.atmeda.org/news/2000_presentations/Rural/Bynum.pps. Fifty-one percent of the study population did not use spacers with MDIs.
[20] Selroos O, Halme M. Effect of a volumatic spacer and mouth rinsing on systemic absorption of inhaled corticosteroids from a metered dose inhaler and dry powder inhaler. *Thorax*. 1991 Dec;46(12):891-4.
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[23] Johnson DH, Robart P. Inhaler technique of outpatients in the home. *Respir Care*. 2000 Oct;45(10):1182-7.
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[25] Newman SP, Moren F, Pavia D, et al. Deposition of pressurized aerosols in the human respiratory tract. *Thorax* 1981;36:52–5.
[26] Global Initiative for Chronic Obstructive Lung Disease, Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2004 Update), at 68, available at http://www.goldcopd.com.

Market research has confirmed the practical superiority of nebulizers to MDIs, as judged from the patients' perspective. One study compared the value of nebulizer systems with MDIs from the patient's perspective, based on an analysis of 1,369 questionnaires.[27] According to the study, nebulizer systems were preferred and considered by patients to be more effective at symptom control than MDIs. Key findings were as follows:

- Fifty-seven percent (57%) of patients surveyed said their symptoms were better controlled with a nebulizer system than with an MDI.
- Eighty-two percent (82%) said the nebulizer system controlled their symptoms for a longer period of time than the MDI.
- Over 80% of patients said the nebulizer system had given them a better quality of life than an MDI alone. Nearly 70% of patients surveyed said the nebulizer system had helped them avoid a trip to the emergency room.
- Fifty-six percent (56%) of these patients said use of a nebulizer system helped to avoid hospitalization.
- Fifty-eight percent (58%) of these patients had avoided unscheduled office visits by using their nebulizer systems.

In short, nebulizers are the preferred method of delivery of bronchodilators for a large proportion of COPD patients, including Medicare beneficiaries. In the preamble, CMS expresses concern that the access of beneficiaries to nebulized bronchodilators in 2005 might be restricted, due to the reduction in Part B payment rates for frequently used

[27] Safian Communications, Inc. Patient Assessment of Efficacy of Nebulizer Systems on Their Respiratory Health. April 1995 (report available on request).

bronchodilators.[28] We agree this is a serious concern, but we submit that it is not a short-term problem that will disappear in 2006. Beneficiaries' continued need for nebulized bronchodilators, even after MDIs become covered under Part D, will make it all the more essential that CMS adequately reimburse providers for these drugs under Part B on an ongoing basis.

[28] Proposed Rule, 69 Fed Reg 47549.

EXHIBIT B

Circumstances Where Compounded Combination Albuterol and Ipratropium Should Not Be Covered Under Medicare

FDA Prohibition of Certain Types of Pharmacy Compounding

Certain types of pharmacy compounding are discouraged by FDA policy, as articulated in Compliance Policy Guide (CPG), Section 460.200, issued on June 7, 2002.[29] The CPG contains factors that the agency considers in deciding whether to exercise its enforcement discretion. One factor is whether a firm **compounds drug products that are commercially available, or which are essentially copies of commercially available FDA-approved products**.[30]

If one or more of the factors identified in CPG section 460.200 are present, such compounding pharmacies may be manufacturing drugs which are subject to the new drug application (NDA) requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA), but for which the FDA has not approved an NDA, or which are misbranded or adulterated. If the FDA has not approved the manufacturing and processing procedures used by these facilities, the FDA has no assurance that the drugs produced are safe and efficacious. Safety and efficacy issues pertain to such factors as chemical stability, purity, strength,

[29] Compliance Policy Guidance for FDA Staff and Industry. Sec. 460.200 (Pharmacy Compounding). Food and Drug Administration. June 7, 2002. Accessed August 10, 2004 at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html.

[30] Emphasis supplied. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.

bioequivalency, and bioavailability. Dey, L.P. is concerned that patients may be receiving unsafe, unsterile drugs of unknown potency and composition, a needless risk when, in the case of pharmacy-compounded albuterol and ipratropium, an FDA-approved inhalation solution is available in DuoNeb® Inhalation Solution.

Based on 1) the NDA requirements of the FFDCA, and 2) CPG §460.200, pharmacy-compounded combinations of albuterol and ipratropium that contain equivalent amounts of the active ingredients in DuoNeb® Inhalation Solution are prohibited by the FDA.

Medicare Denial of Payment for Certain Types of Pharmacy Compounding

If the FDA prohibits pharmacy-compounded combinations of albuterol and ipratropium, then chapter 15, section 50.4.7 of the Medicare Benefit Policy Manual, entitled "Denial of Medicare Payment for Compounded Drugs Produced in Violation of Federal Food, Drug, and Cosmetic Act," should apply. The applicable portion of §50.4.7 reads as follows:

> Section 1862(a)(1)(A) of the Act requires that drugs must be reasonable and necessary in order to be covered under Medicare. This means, in the case of drugs, the FDA must approve them for marketing. Section 50.4.1 instructs carriers and intermediaries to deny coverage for drugs that have not received final marketing approval by the FDA, unless instructed otherwise by CMS. The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §180, instructs carriers to deny coverage of services related to the use of noncovered drugs as well. Hence, if DME or a prosthetic device is used to administer a noncovered drug, coverage is denied for both the nonapproved drug and the DME or prosthetic device.[31]

[31] Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual. Chapter 15 (Covered Medical and Other Health Services); §50.4.7 (Denial of Medicare Payment for Compounded Drugs

In order to provide consistency across all benefit categories, all Medicare contractors, including PDPs should adhere to provisions such as those in the Medicare Benefit Policy Manual. This would ensure that any claim for a drug that requires FDA approval but is not FDA-approved would be denied, regardless of the benefit category under which the claim was made. For example, payment for combination products such as albuterol and ipratropium, and the delivery system used to administer the drugs, should be limited to FDA-approved formulations.

Produced in Violation of Federal Food, Drug, and Cosmetic Act). Rev. 13. May 28, 2004. Accessed August 11, 2004 at http://www.cms.hhs.gov/manuals/102_policy/bp102c15.pdf.

Executive Summary
Comments on "Medicare Program; Medicare Prescription Dug Benefit; Proposed Rule"
(CMS-4068-P)

Dey, L.P. appreciates the opportunity to comment on the following issues addressed in the above-referenced proposed rule and its preamble:[1]

- Subpart C – Benefits and Beneficiary Protections
  - Section 423.100 (Definition of "Covered Part D Drug")
  - Section 423.120 (Access to Covered Part D Drugs)

- Subpart D – Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans
  - Section 423.153 (Cost and Utilization Management, Quality Assurance, Medication Therapy Management Programs, and Programs to Control Fraud, Abuse, and Waste)

Key Overall Point: CMS acknowledges the statutorily-mandated distinction between Part B and Part D drugs. Our principal concern is that the agency inappropriately suggests that certain Part B drugs with characteristics such as those described in the proposed rule's preamble – i.e., drugs covered as incident to a physician's service or furnished through an item of DME – could be covered under Part D.

"Covered Part D Drug": Dey supports the principle enunciated in the rulemaking that Part D "wraps around" Part B, providing beneficiaries with drug coverage that is seamless. However, portions of the preamble extend this "wrap around" principle beyond reasonable bounds. Specifically, the preamble cites examples that could be interpreted to confer Part D coverage on infusion and injectable drugs in situations that are currently within the Part B claims administration authority of the DMERCs. Similarly, in addressing dispensing fees for Part D drugs, CMS identifies options that, if implemented with respect to infusion drugs, could be applied more broadly – and inappropriately – to other Part B services.

> *Recommendation*: CMS should make clear that DME drugs used in situations now covered under Part B are excluded from coverage under Part D.

Access to Covered Part D Drugs: The rulemaking appropriately addresses means for ensuring that beneficiaries have access to Prescription Drug Plans (PDPs) that include in their networks' long-term care pharmacies and home infusion pharmacy providers. However, because these pharmacies/providers offer drug-related services that are typically covered under Part B, CMS should take special care to ensure that Part D coverage does not substitute for coverage available under Part B. In fact, we read the preamble's language on these points almost to invite such substitution. For example, CMS seeks comments on whether PDPs should receive performance incentives for producing Medicare savings under Parts *A and B* – virtually an open invitation to replace Part B drug coverage with Part D coverage if the PDP believes it will save money.

[1] 69 Fed Reg 46632 (Aug. 3, 2004).

The Medicare Modernization Act (MMA) clearly did not contemplate this type of Part D-Part B substitution. Indeed, the MMA, in establishing a Chronic Care Improvement Program, provided a separate means for CMS (on a demonstration basis) to test methods for identifying clinical and economic synergies among Parts A, B, and D.

> *Recommendation*: CMS should make clear that PDPs may not substitute Part D drug coverage in situations in which Part B drug coverage is available.

Medication Therapy Management: CMS solicits comments on whether the terms "multiple covered Part D drugs" and "multiple chronic diseases" should be defined by the agency itself or by PDPs. Both terms implicate use of disease management tools – tools that Dey supports. However, we are concerned that inappropriately inserting these tools into Medicare Part D, but not into Part B, could exert a counterproductive, asymmetrical effect. That is, by rewarding PDPs for exacting savings on a drug used in a situation that makes it Part D-covered (when, in other situations, it is Part B-covered) could discourage PDPs from considering the clinical factors DMERCs have long taken into account in administering Part B drug claims.

> *Recommendation*: CMS, not PDPs, should define the key terms. In so doing, the agency should maintain a level playing field among Medicare contractors, preventing PDPs from inappropriately reducing utilization for a subset of the situations in which a drug is used.

Drug Utilization Management: The preamble, in addressing industry standards for drug utilization management, suggests incentives to reduce costs "when medically appropriate" – a phrase not defined.

> *Recommendation*: The phrase "medically appropriate" should be defined to include criteria for ensuring that compounding of drugs is performed in a fashion consistent with patient safety and FDA's requirements.

DATE: October 4, 2004

Centers for Medicare and Medicaid Services

Department of Health and Human Services

Attention CMS-1429-P

P.O. Box 8012

Baltimore, Maryland 21244-8012

Re: [CMS--4068-P] Medicare Program; Medicare Program; Medicare Prescription Drug Benefit

Dear Sir or Madam:

Dey, L.P. is pleased to submit the following comments regarding the above-referenced proposed rule (Proposed Rule).[1] Dey, L.P. welcomes the opportunity to work with the Centers for Medicare and Medicaid Services (CMS) as it develops policy for drugs currently covered as a Part B benefit with the potential for coverage as a Part D benefit in 2006.

Dey, L.P. develops, manufactures, and markets prescription pharmaceuticals for the treatment of respiratory illnesses, including chronic obstructive pulmonary disease (COPD), a condition that represents a significant financial burden for the Medicare program and a serious threat to patient longevity and quality of life.

We propose that CMS clarify in the final rule to specifically exclude from Part D those drugs covered under Part B because they are incident to durable medical equipment (DME).

We are providing comments on three sections of the Proposed Rule that hold implications for the availability of drugs provided as a Part B benefit that may, under some circumstances, be provided as a Part D benefit:

1. Section 423.100, regarding the definition of a covered Part D drug;
2. Section 423.120, regarding access to covered Part D drugs; and
3. Section 423.153 in Subpart D Cost Control and Quality Improvement Requirements for Prescription Drug Plans

Various examples in the proposed rule could establish a precedent for changing coverage from an existing benefit (Part B) to a new one (Part D), thereby violating the "wrap around" principle that CMS has enunciated for Part D.

We suggest that CMS specify clearly in the final rule that drugs currently covered under Part B, either incident to a physician service, or incident to the DME benefit, be excluded from Part D coverage until such time as the Secretary issues the report on this subject (required under the Medicare Modernization Act) and the Congress acts to give CMS the authority to implement any recommended changes stemming from the report.[2]

[1] Proposed Rule, 69 Fed Reg 46631 (Aug. 3, 2004).
[2] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, sec. 101(d).

1. **Subpart C. Voluntary Prescription Drug Benefit and Beneficiary Protections**

   a. ***Proposed Section 423.100 Definition***[3]

The proposed rule includes a definition of two terms that would benefit from more specificity:

- "Covered Part D Drug,"[4] and
- "Dispensing fee."[5]

Covered Part D Drug

CMS addresses the complex issue of drugs that can be covered under Part A, B or D, depending on the form of administration and site of service. While the Part D benefit is expected to be a "wrap-around" to the other benefits, the rulemaking contains descriptions of infusion or injectable drugs that have characteristics similar to a nebulized drug, and others that are administered through DME, where the drug product could be picked up at a pharmacy and be self-administered at home.

Our concern is that the examples include situations that are currently within the purview of the DMERCs and are intended to be addressed in subsequent regulations regarding the competitive acquisition programs for Part B drugs, supplies, medical equipment and related services. We recognize that some drug delivery mechanisms are not covered under Part B, and that beneficiaries could benefit from the "wrap-around" nature of the Part D benefit.

[3] 69 Fed Reg 46646.
[4] 69 Fed Reg 46646.

However, a drug administered through DME should remain a Part B covered service when it is used in a setting which is currently covered by the DMERCs; furthermore, we propose that it should be specifically excluded from Part D. Coverage for these products has evolved over many years, and the coverage criteria and decisions reflect the complex issues that need to be considered in order to structure a program that does not disrupt existing services. This consideration is beyond the scope of reform contemplated by Congress, prior to an analysis by the Secretary.

Part D Dispensing Fee

We commend CMS for clearly stating that the definition of a dispensing fee would apply specifically to Part D, and we agree with the agency's preference for the first of the three options described in the proposed rule; i.e., a single fee associated solely with dispensing of the prescription. We recognize the need for CMS to consider Options 2 and 3 (involving the necessary equipment and supplies and the necessary professional services of a nurse or pharmacist) for home infusion drugs.

However, if Options 2 and 3 are part of the final rule, PDPs should be excluded from applying such fees to reimburse for the costs of services currently subject to Part B coverage. Our concern is that permissible instances in which Options 2 and 3 may be needed (e.g., to reimburse for the costs of supplies and services associated with home infusion drugs that may not be covered currently under Part B) could be applied more broadly and inappropriately to other Part B covered services. Our concern is specifically

[5] 69 Fed Reg 46647.

grounded in the reimbursement circumstances surrounding Dey's product, DuoNeb® Inhalation Solution ("DuoNeb"), used in the treatment of COPD. We presented these concerns in our September 17, 2004 letter in response to **[**CMS-1429-P] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005. A summary of the rationale is provided in Exhibit A.

b. Proposed Section 423.120 Access to Covered Part D Drug[6]

Our concerns relate to two provisions regarding the ways in which Medicare beneficiary access to pharmacies can be assured. Specifically, we have concerns regarding CMS preamble language pertaining to availability of PDP access to 1) long term care pharmacy, and 2) home infusion pharmacy providers.

1) Long Term Care Pharmacy

While it is appropriate for CMS to consider whether the new Medicare Prescription Drug Plans (PDPs) should be required to include long-term care pharmacies in their plans and to take into account how the PDP might reimburse these pharmacies for services such as infusion therapy and 24 hour medication delivery, our concern is that such services should be excluded from Part D coverage if Part B coverage is available.

2) Home Infusion Pharmacy

The issue is the same for home infusion pharmacies, although we note with some concern that CMS is seeking comments on ways to encourage PDPs, who do not have a medical benefit and therefore cannot realize efficiencies from reduced hospital costs, to establish

contracts with home infusion pharmacies. The potential to offer performance incentives for Part D contractors for savings under Part A or Part B goes beyond the scope of what MMA contemplated. These types of savings could more appropriately be captured under the Chronic Care Improvement Program, which MMA established as a demonstration.

2. Subpart D. Cost Controls and Quality Improvement Requirements for Prescription Drug Benefit Plans

a) Proposed Section 423.153 Cost and Utilization Management, Quality Assurance, Medication Therapy Management Programs and Programs to Control Fraud, Abuse and Waste

Two provisions of this proposed section could be detrimental to Medicare beneficiaries' continued access to Part B covered drugs and related services:

- Cost Effective Drug Utilization Management[7] (relating to the use of compounded drugs); and
- Medication Therapy Management[8] (relating to providing appropriate nebulizer utilization).

Cost Effective Drug Utilization Management

CMS solicits comments on industry standards for cost effective drug utilization management, which includes the use of incentives to reduce costs, "when medically

[6] 69 Fed Reg 46655.
[7] 69 Fed Reg 46666.
[8] 69 Fed Reg 46668.

appropriate," which is not defined. We suggest that the term "medically appropriate" should specify criteria as to when using compounded drugs would be considered a medically appropriate incentive to reduce costs.

Specifically, we believe CMS should ensure that compounding is done on a patient-name prescription basis, and that pharmacies use all compounding and admixing precautions to ensure product sterility and freedom from microbe ingress contamination. Patient safety is crucial, and the quality of the compounded product should be comparable to a commercial drug product.

Another area of concern regarding compounding is that the FDA prohibits pharmacy compounding of two or more separate FDA-approved products when a combination product approved by the FDA is commercially available.[9]

Specifically, in the past six months alone, the FDA has cited and sent warning letters to several pharmacies for the following compounding violations: preparing drug products that are commercially available, and compounding drugs "without the necessary controls to ensure drug product sterility and potency."[10,11,12]

[9] Food and Drug Administration. Compliance Policy Guidance for FDA Staff and Industry. Sec. 460.200 (Pharmacy Compounding). June 7, 2002. Accessed August 10, 2004 at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html.
[10] FDA warning letter to Axium Healthcare Pharmacy, June 7, 2004, at http://www.fda.gov/cder/warn/2004/AXIUM%20%20wl.pdf.
[11] FDA warning letter to Gentere, Inc., July 13, 2004, at http://www.fda.gov/foi/warning_letters/g4863d.htm.
12 FDA warning letter to delta Pharma, Inc., September 17, 2004, at http://www.fda.gov/foi/warning_letters/g4965d.htm.

Violations of the FDA policy against compounding commercially-available drugs affect DuoNeb, since it is a currently marketed, sterile, non-allergenic, premixed combination drug; these manufacturing processes are designed to lower the risk of drug cross-contamination and to minimize waste. The premixed, unit-dose combination of the two agents within DuoNeb enhances patient safety by minimizing the chance for medication errors, and it eliminates the need for the Medicare patient to nebulize two different solutions, resulting in faster treatment times and improved compliance.

As for the second category of violation – compounding drugs "without the necessary controls to ensure drug product sterility and potency" – quite obviously patient safety is at risk, and a threat to public health is created. We also note that, in 2002, the FDA sampled 29 drugs from compounding pharmacies and found that 10 were subpotent.[12] In all, the compounded drugs sampled by the FDA registered a 34 percent failure rate – far in excess of the comparable two percent rate for commercially-available drugs.[13]

These examples highlight the complexity unique to prescription drugs covered under Part B and the need for greater clarity and precision in the Part D proposed rule.

Medication Therapy Management Program

CMS solicits comments on whether it should define the terms "multiple covered Part D drugs" and "multiple chronic diseases", or allow the PDPs to define the terms as part of their bids to CMS. While we support the use of appropriate disease management tools

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[12] Report: Limited FDA Survey of Compounded Drug Products. Food and Drug Administration. Accessed August 24, 2004 at http://www.fda.gov/cder/pharmcomp/survey.htm.
[13] *Id.*

such as the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, our concern is that CMS maintain a level playing field among its contractors and not create an advantage for PDPs who potentially could be rewarded for reducing nebulizer use among a sub-set of COPD patients, without adequately considering clinical factors such as those included in the DMERC coverage policies.

Conclusion

Dey, L.P. appreciates the opportunity to comment on these three proposed sections that – absent additional clarification – could affect Medicare beneficiaries' access to life-saving and quality-of-life enhancing medications. We base our observation on examples contained in the proposed rule that, while casually presented, belie the underlying complexity that results when coverage could be provided under different benefits, depending on the route of administration and site of service. Coupled with the concerns we raised in our response to the proposed rule on Part B payment, we are compelled to reiterate our recommendation that CMS develop a cohesive strategy for inhalation drug therapy based on clinical guidelines and correct assumptions as to the medical necessity of nebulizer-based therapy by some patients. In addition, including pharmacy compounding as an activity whose costs may be included in the dispensing fee could be troublesome, given that on certain occasions pharmacy compounding is not appropriate and should not be reimbursed by PDPs.

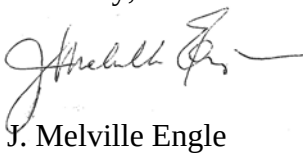
We urge CMS to revisit the proposed changes regarding a revised (or incremental) dispensing fee by conducting a study of the appropriate activities and their costs, and by considering the considerable operating and patient-support expenses borne by pharmacies.

The concept of a "service fee" may be a more appropriate description of the various pharmacy activities and expenses.

Dey, L.P. believes that CMS needs to be more specific in the final regulation about the Part D benefit for those prescription drugs that can be covered under the Part B benefit. The MMA includes several provisions related to the latter that will be implemented over the next few years and also calls for the Secretary to study these issues and report to Congress. We know the complexity of the issues related to inhalation products and support an approach that considers them in the overall context of respiratory disease costs to the Medicare program. It is important to get the right prescriptions to patients using the most appropriate delivery mechanism, be it nebulizers, MDIs, or dry powder inhalers (DPIs), all of which are found in clinical practice guidelines and will be included in Medicare's benefits as of 2006. CMS and its contractors need to strive for consistency with existing Medicare policies and FDA polices to ensure that payment policy changes do not create incentives for activities that are not consistent with the coverage of products under existing benefits and the assurances provided to the public by the FDA.

Thank you for the opportunity to present our views with respect to these selected provisions detailing how the Part D benefit will be implemented.

Sincerely,



J. Melville Engle

President and CEO

Nebulizers versus MDIs

We feel compelled to correct the record regarding the stance CMS has taken regarding the relative and comparative value of nebulizers versus MDIs. In the portion of the Proposed Rule preamble pertaining to MMA Section 305, CMS states that Medicare beneficiaries have a "strong" financial incentive to use nebulizers since the alternative inhalation drug delivery mechanism, metered dose inhalers (MDIs), currently are not covered under Part B, and beneficiaries will have to wait until January 2006 to be covered under the new Part D drug benefit. CMS also states that, based on a literature review, nebulizers are no more effective than MDIs in delivering bronchodilators, and CMS predicts a substantial shift from nebulizers to MDIs once the latter become covered under Part D beginning in 2006.[14] We fear CMS may underestimate the clinical value, patient preference and improved outcomes for nebulized respiratory medication which is based on a reduction of symptoms and improved quality of life, not financial incentives.

While it is true that some studies have shown that nebulizers and inhalers are equally effective, the performance of inhalers was augmented by spacers.[15,16,17] Spacers are designed to deliver MDI-delivered medication more easily and effectively. In common

[14] Proposed Rule, 69 Fed Reg 47546, 47548.
[15] Turner MO, Patel A, Ginsburg S, Fitzgerald JM. Bronchodilator delivery in acute airflow obstruction. A meta-analysis. *Arch Intern Med*. 1997 Aug 11-25;157(15):1736-44.
[16] Duarte AG, Momii K, Bidani A. Bronchodilator therapy with metered-dose inhaler and spacer versus nebulizer in mechanically ventilated patients: comparison of magnitude and duration of response. *Respir Care*. 2000 Jul;45(7):817-23.
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practice, studies have shown that patients only use spacers to be used with inhalers approximately 50 percent of the time.[18,19] **Without** accessories such as spacers, much of the medication is left in the mouth and throat, thus reducing absorption and efficacy.[20]

In addition, the literature is replete with studies showing that many patients, up to 89%, do not employ proper inhaler technique.[21,22,23] Therapeutic benefit depends on sufficient deposition of drugs in the medium and small airways; this is largely determined by a competent inhaler technique.[24,25] The most recent report of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) states that "COPD patients may have more problems in effective coordination and find it harder to use a simple Metered Dose Inhaler (MDI) than do healthy volunteers or younger asthmatics."[26]

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[22] ICSI Health Care Guidelines: Chronic Obstructive Pulmonary Disease, Third Edition/Dec 2003. Accessed September 2, 2004 at http://www.icsi.org/knowledge/detail.asp?catID=29&itemID=157.
[23] Johnson DH, Robart P. Inhaler technique of outpatients in the home. *Respir Care*. 2000 Oct;45(10):1182-7.
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[25] Newman SP, Moren F, Pavia D, et al. Deposition of pressurized aerosols in the human respiratory tract. *Thorax* 1981;36:52–5.
[26] Global Initiative for Chronic Obstructive Lung Disease, Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2004 Update), at 68, available at http://www.goldcopd.com.

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- Fifty-six percent (56%) of these patients said use of a nebulizer system helped to avoid hospitalization.
- Fifty-eight percent (58%) of these patients had avoided unscheduled office visits by using their nebulizer systems.

In short, nebulizers are the preferred method of delivery of bronchodilators for a large proportion of COPD patients, including Medicare beneficiaries. In the preamble, CMS expresses concern that the access of beneficiaries to nebulized bronchodilators in 2005 might be restricted, due to the reduction in Part B payment rates for frequently used

[27] Safian Communications, Inc. Patient Assessment of Efficacy of Nebulizer Systems on Their Respiratory Health. April 1995 (report available on request).

bronchodilators.[28] We agree this is a serious concern, but we submit that it is not a short-term problem that will disappear in 2006. Beneficiaries' continued need for nebulized bronchodilators, even after MDIs become covered under Part D, will make it all the more essential that CMS adequately reimburse providers for these drugs under Part B on an ongoing basis.

[28] Proposed Rule, 69 Fed Reg 47549.

EXHIBIT B

Circumstances Where Compounded Combination Albuterol and Ipratropium Should Not Be Covered Under Medicare

FDA Prohibition of Certain Types of Pharmacy Compounding

Certain types of pharmacy compounding are discouraged by FDA policy, as articulated in Compliance Policy Guide (CPG), Section 460.200, issued on June 7, 2002.[29] The CPG contains factors that the agency considers in deciding whether to exercise its enforcement discretion. One factor is whether a firm **compounds drug products that are commercially available, or which are essentially copies of commercially available FDA-approved products**.[30]

If one or more of the factors identified in CPG section 460.200 are present, such compounding pharmacies may be manufacturing drugs which are subject to the new drug application (NDA) requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA), but for which the FDA has not approved an NDA, or which are misbranded or adulterated. If the FDA has not approved the manufacturing and processing procedures used by these facilities, the FDA has no assurance that the drugs produced are safe and efficacious. Safety and efficacy issues pertain to such factors as chemical stability, purity, strength,

[29] Compliance Policy Guidance for FDA Staff and Industry. Sec. 460.200 (Pharmacy Compounding). Food and Drug Administration. June 7, 2002. Accessed August 10, 2004 at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html.

[30] Emphasis supplied. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.

bioequivalency, and bioavailability. Dey, L.P. is concerned that patients may be receiving unsafe, unsterile drugs of unknown potency and composition, a needless risk when, in the case of pharmacy-compounded albuterol and ipratropium, an FDA-approved inhalation solution is available in DuoNeb® Inhalation Solution.

Based on 1) the NDA requirements of the FFDCA, and 2) CPG §460.200, pharmacy-compounded combinations of albuterol and ipratropium that contain equivalent amounts of the active ingredients in DuoNeb® Inhalation Solution are prohibited by the FDA.

Medicare Denial of Payment for Certain Types of Pharmacy Compounding

If the FDA prohibits pharmacy-compounded combinations of albuterol and ipratropium, then chapter 15, section 50.4.7 of the Medicare Benefit Policy Manual, entitled "Denial of Medicare Payment for Compounded Drugs Produced in Violation of Federal Food, Drug, and Cosmetic Act," should apply. The applicable portion of §50.4.7 reads as follows:

> Section 1862(a)(1)(A) of the Act requires that drugs must be reasonable and necessary in order to be covered under Medicare. This means, in the case of drugs, the FDA must approve them for marketing. Section 50.4.1 instructs carriers and intermediaries to deny coverage for drugs that have not received final marketing approval by the FDA, unless instructed otherwise by CMS. The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §180, instructs carriers to deny coverage of services related to the use of noncovered drugs as well. Hence, if DME or a prosthetic device is used to administer a noncovered drug, coverage is denied for both the nonapproved drug and the DME or prosthetic device.[31]

[31] Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual. Chapter 15 (Covered Medical and Other Health Services); §50.4.7 (Denial of Medicare Payment for Compounded Drugs

In order to provide consistency across all benefit categories, all Medicare contractors, including PDPs should adhere to provisions such as those in the Medicare Benefit Policy Manual. This would ensure that any claim for a drug that requires FDA approval but is not FDA-approved would be denied, regardless of the benefit category under which the claim was made. For example, payment for combination products such as albuterol and ipratropium, and the delivery system used to administer the drugs, should be limited to FDA-approved formulations.

Produced in Violation of Federal Food, Drug, and Cosmetic Act). Rev. 13. May 28, 2004. Accessed August 11, 2004 at http://www.cms.hhs.gov/manuals/102_policy/bp102c15.pdf.

CMS-4068-P-1257

Submitter : Diane Paulson **Date & Time:** 10/04/2004 08:10:00

Organization : Medicare Advocacy Project, GBLS

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-4068-P-1257-Attach-1.doc

CMS-4068-P-1257-Attach-2.doc

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September 30, 2004

http://www.cms.hhs.gov/regulations/ecomments

Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-4068

Dear Madam or Sir:

On behalf of the clients represented by the undersigned, we wish to submit the following comments on your proposed rule for the Medicare Prescription Drug Benefit. The Medicare Advocacy Project has over 15 years of experience advocating on behalf of Medicare beneficiaries, particularly those with low incomes; the Massachusetts Law Reform Institute is a statewide advocacy organization representing low income individuals, including elders and persons with disabilities; and the Disability Law Center (DLC) is a private, nonprofit protection and advocacy agency that provides free legal assistance to individuals with disabilities throughout Massachusetts. A key mandate of DLC is ensuring that people with disabilities are able to access needed supports to live and work in the community. Because of the limited time allowed and the magnitude of the proposed rule, we are not commenting on CMS-4069, dealing with Establishment of the Medicare Advantage Program. Neither are we commenting on all the sections of the proposed prescription drug rule. Rather, we are focusing on the impact of the rule on low income beneficiaries and persons with disabilities, particularly in the Eligibility and Enrollment and Grievances, Coverage Determination, and Appeals sections. In addition, we support and agree with the more detailed and comprehensive comments submitted on one or both of the proposed rules by the Medicare Consumers Working Group and the Center for Medicare Advocacy, Inc.

We also request that time be provided for another comment period due to the many unaddressed or only vaguely addressed issues. The final regulations could include a number of errors and provisions that result in unintended consequences because so much of the final regulations will not have been seen by the public. We urge CMS to issue the next version of these regulations in a format that will allow one more round of comment, even if a shortened comment period. This is a very complex program with significant ramifications for a large number of citizens. We are concerned that failure to provide for additional public input when the regulations are more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

PART 423-VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

General comments.

1. Many pro-consumer statements in the preamble do not appear in the proposed rule. These protections bear no weight unless captured in the regulations. More should be done to reflect the Preamble's good intentions in the body of the regulations. For example:

> The Preamble discusses providing affected enrollees, prescribers, pharmacists, and pharmacies with written notice when a drug will be removed from the formulary or moved to a different tier for cost-sharing. The regulatory language does not specify that the notice should be in writing. Requirement for written notice is critical and should be specified.
>
> The Preamble gives examples of situations when a plan will be required to allow an enrollee to use a non-network pharmacy. These include situations such as when an enrollee's plan does not contract with the long-term care pharmacy which an enrollee in a nursing home must use. The regulations should include the examples CMS discusses in the preamble.

2. There are a number of areas where the law is unclear or contradictory and these areas are creating serious problems for the regulation drafters. CMS should take advantage of the law's provision calling for the submission of technical and corrective amendments. While this was supposed to have been done by June 8, 2004, it should still be done, and Congress should address these issues as soon as possible.

3. Simplicity, as well as additional support for information and counseling, is necessary to ensure that beneficiaries are reached in a comprehensible way. The sheer size and complexity of these regulations is a testament to the fact that this new law is incredibly confusing. If beneficiaries are confused, enrollment and use of the new program will be very difficult, particularly for lower income, sicker, and limited English proficiency beneficiaries. Thus whenever it is possible, CMS should seek to simplify the new program.

Addressing some of our specific concerns:

Subpart B-Eligibility and Enrollment

1. The draft regulations addressing enrollment of beneficiaries into private drug plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDPs) do not adequately address the need for hands-on outreach, particularly to low-income beneficiaries, or to beneficiaries with special needs, such as mental illness. More attention must be given to developing materials and education and enrollment campaigns focused on informing beneficiaries with disabilities, including mental illness and cognitive impairments, and those with other special needs about the new drug benefit and helping them to enroll in the best plan available.

2. Of particular concern, is enrollment of the dual eligibles. Beneficiaries covered by both Medicare and Medicaid are by definition poor and cannot afford to pay privately fo fill any gaps in medication. Congress and the Administration promised that dual eligible beneficiaries would be better off with this new Part D drug benefit than they were receiving drug coverage through Medicaid. To honor this promise, coverage of medications for dual eligibles and other special populations must be grandfathered into the new Part D benefit. In addition, CMS must require plans to establish an alternative flexible formulary for dual eligibles as suggested in the preamble to the proposed regulations. This flexible formulary would incorporate utilization management techniques that focus on improving inefficient and ineffective provider prescribing practices but

do not restrict access to medications through prior authorization, fail first, step therapy, or therapeutic substitution requirements.

3. The regulations do not adequately address how drug coverage for the dual eligibles will be transferred to Medicare on January 1, 2006. There are issues both of timing and implementing the enrollment process in a way that will ensure that these beneficiaries do not confront a loss of benefits or a gap in drug coverage, either of which could have disastrous health consequences. Specific comments on enrollment of dual eligibles and our recommendations appear in our comments on §§423.34, 423.36, 423.48 and on Subpart P.

A. We are concerned with ensuring continuity of care for dual eligibles and access to needed prescriptions. These issues and concerns apply equally to all dual eligibles, and particularly to those with special health care needs, as well as to other populations with specific needs (See our comments in Subpart C, §423.120.)

B. The proposed regulations would force dual eligibles to enroll (or be automatically enrolled) in the "benchmark" or average cost plans in their areas because the low-income subsidy they will receive will only cover the premium for these plans. The formularies for these plans will not be as comprehensive as the drug coverage these individuals currently have through Medicaid. Even though Massachusetts has restricted access to drugs in its Medicaid program with preferred drug lists and prior authorization requirements, Massachusetts has taken many steps to ensure that special populations can readily access medically necessary drugs. For example, individuals who have been stabilized on one antidepressant are not required to try another one.

C. Without access to the coverage they need, dual eligibles will be forced to switch medications, which for certain populations, such as beneficiaries with HIV/AIDS or mental illness can have serious adverse consequences. Also, failing to ensure continuity of care for dual eligibles may benefit the plans, but will undoubtedly lead to Medicare and/or state increased costs for more physician and emergency room visits, and hospitalizations. The regulations do provide a special enrollment period for dual eligibles to use "at any time" (§423.36). However, being able to enroll in a different Part D plan is inadequate to meet the special needs of dual eligibles.

D. In the preamble to the proposed regulations, CMS points to an exceptions process as a means of securing coverage of off-formulary medications (See our comments to **Subpart M-Grievances, Coverage Determination and Appeals**) But the process proposed is extremely complex and cumbersome to navigate for someone having a psychiatric crisis, facing cognitive impairments, or in the midst of aggressive chemotherapy-to list just a few examples. Moreover, the timelines established are inordinately drawn out; for example, an expedited determination could take as long as two weeks. Drug plans are not required to provide an

emergency supply of medications until at least two weeks following a request. Exception, grievance and appeal processes should not be used to substituted for open formulary access to medications.

§423.34 Enrollment Process.

§423.34 (b) Enrollment.
The final rule should provide that an authorized representative may complete the enrollment form on behalf of a Part D eligible individual.

§423.34(c), Notice Requirement.
The notice must be in writing and inform an individual who is denied enrollment of his or her appeal rights, including the right to appeal the imposition of a penalty for late enrollment.

§423.34(d) Enrollment requirement for full benefit dual eligibles.
In the Preamble, CMS requested comments on whether CMS or the states should perform automatic enrollment of dual eligibles. State officials have more readily available data identifying the dual eligibles in their state and they also will be involved in the enrollment process because they are already required to perform low-income subsidy enrollment. In addition, there is an incentive for them to enroll these individuals in Medicare drug plans because without drug coverage they will increase utilization of other Medicaid services. Thus, states should be afforded the ability to conduct auto-enrollment and receive full federal financing for this function. In addition, CMS should develop its own systems for automatic enrollment of dual eligibles in states that do not elect to do so. Also, because the proposed rule leaves unanswered key questions about who will conduct automatic enrollment of dual eligibles and how it will occur, CMS must give the public the opportunity to provide input on any proposal it develops on this issue before publishing a final regulation.

§423.34(d)(1) General Rule.
The draft regulations provide that dual eligibles will be automatically enrolled in a Part D plan if they do not enroll themselves, by the end of the initial enrollment period, which, under §423.36, is May 15, 2006. However, their Medicaid prescriptions drug coverage will end on January 1, 2006. This proposed timeline for automatic enrollment must be changed because it could expose millions of dual eligibles to a four and half month coverage gap that could have serious health consequences for this vulnerable population. Given the difficulty of reaching this population coupled with inadequate provisions for outreach and education, it is almost certain that a substantial number of dual eligibles will face a several month gap in coverage between the end of Medicaid's drug benefit and automatic enrollment. This is untenable, and directly in conflict with Congress' and the Administration's promise that dual eligibles will be better off under Medicare Part D. The transfer of drug coverage from Medicaid to Medicare Part D should be delayed. Absent a delayed transition date for dual eligible drug coverage, however, dual eligibles should be randomly assigned and enrolled in a plan that best suits their needs as early as November 15, 2005 but no later than December 1, 2005. While we would prefer to provide individuals an extended period to make informed choices, it is critical to complete auto-enrollment as early as possible to leave as much time as possible to distribute plan information

and cards to beneficiaries, allow them to switch plans, and educate them about their new drug coverage before January 1, 2006. To make this process work more smoothly, states can begin profiling individual drug histories to prepare for random auto-assignment among plans that are appropriate for the individual even before plan information is released on October 15, 2005. Additionally, CMS should fund a campaign of individualized counseling and assistance both before and after auto-enrollment to explain to individuals their choices and how to enroll in a plan; explain, if applicable, how to get benefits under the plan to which they have been auto-assigned; and explain, if applicable, that they can choose a different plan from the one to which they have been auto-assigned and assist in choosing and enrolling in such a plan.

§423.34(d)(1)(ii)
CMS must develop a solution to the issue of automatic enrollment of dual eligibles who are enrolled in MA plans that have a prescription drug benefit with a premium that is above the low-income benchmark. The solution should be the one least disruptive to medical care and should not force a dual eligible to choose among continued MA enrollment, paying added premiums, or foregoing drug coverage. For institutionalized dual eligibles, the difference between the premium and the premium subsidy should be considered an incurred medical expense and deducted from their monthly "patient paid amount" to the facility. For non-institutionalized dual eligibles, in states with pharmacy assistance programs (SPAPs) which will wrap around Part D coverage and will cover dual eligibles, the SPAPs should be authorized to pay the difference. For medically needy individuals, the cost differential would be an incurred medical expense contributing toward their spenddown, if appropriate. Otherwise, individuals should be counseled about the premium discrepancy and about their right to withdraw from the MA plan and return to original Medicare. Ideally, dual eligibles who want to remain in the MA plan should be allowed to do so and not have to pay any amount by which the MA-PD basic premium exceeds the low-income benchmark amount.

§423.34(d)(2), When there is more than one PDP in a PDP region.
Because not every PDP plan may be appropriate for each dual eligible (for example, due to formulary restrictions), CMS should limit "on a random basis" to "among such plans in the region that meet the beneficiary's particular drug needs." Also, this subsection undermines the §423.859 right of assured access to a choice of at least two qualifying plans, by acknowledging that there may be regions where there is only one PDP in a PDP region with a monthly beneficiary premium at or below the premium subsidy amount.

§423.36 Enrollment Periods.

§423.36(a)(3)(ii) Exception.
It is not clear who these beneficiaries would be.

§423.36(c) Special Enrollment Periods.
This section should be expanded to provide "special enrollment exceptions" for individuals disenrolled by a PDP (such as for disruptive behavior) so that the individual will have an opportunity to join another PDP and continue with necessary medications. These "special enrollment exceptions" are necessary given the high risk of discrimination presented by the

provisions for involuntary disenrollment. CMS should provide a special enrollment period for these beneficiaries. It should include a reasonable time period for plan selection and be exempt from late enrollment penalties. It should also be expanded to make clear that involuntary loss of creditable prescription drug coverage includes loss because the beneficiary, or beneficiary's spouse, stops working; because COBRA coverage ends or because the premiums became unaffordable.

§423.36(c)(4) Special Enrollment Periods and Dual Eligibles.
We support granting dual eligibles special enrollment periods. However, this provision does not adequately address their needs. It is unlikely that there will be much choice of low-cost drug plans in each region, particularly in rural areas which have not historically attracted many Medicare+Choice plans. For example parts of Cape Cod and Western Massachusetts have no Medicare+Choice plans. In addition, these individuals will not have the resources to pay for more comprehensive coverage. Moreover, the special enrollment provisions do not specify that dual eligibles would not be subject to a late enrollment fee if this complex process of disenrollment and reenrollment resulted in a gap in coverage of over 63 days.

In addition, full benefit dual eligibles should receive notice explaining their right to a special enrollment period when they enroll in a plan, and every time their PDP changes its plan in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

§423.36(c)(8)
The regulations should include a special enrollment period similar to the one for dual eligibles for all beneficiaries eligible for a full or partial-low income subsidy. This is necessary because if coverage for a drug is denied, these low-income beneficiaries will be unable to afford to pay for drugs during a period of appeal, or if their appeal is denied and they are locked into a plan that does not cover a drug they need.

Special enrollment periods should also be provided for all institutionalized individuals, not just institutionalized dual eligibles, since their access to needed drugs may be compromised by the design of the plans and by pharmacy access requirements, such as if their long-term care pharmacy is not required to be included in the network of all PDPs. Individuals with life-threatening situations and individuals whose situations are pharmacologically complex should have the same rights as well.

§423.38 Effective Dates.

§423.38(c) Special Enrollment Periods.
Effective date should be first day of first calendar month following special enrollment in which individual is eligible for Part D.

§423.42 Coordination of enrollment and disenrollment through PDPs

§423.42(c)(2)
Notice of disenrollment should be in writing.

§423.44 Disenrollment by the PDP.

§423.44(b)(2)(I)
CMS requested comments about the requirement to involuntarily disenroll individuals from a PDP if they no longer reside in the service area. This raises the issue of "snowbirds"-the large number of Medicare beneficiaries who move for large parts of the year. This is a problem in Massachusetts where many elders winter in warmer climates. The churning-the enrolling and disenrolling-that plans serving this population will face as they apply this section will be enormous. Because of different formularies between plans and problems of coordination, the regulations should seek to minimize plan changes and maintain continuity of care. This section, as written, could result in a significant number of plan changes, disrupting continuity of care.

Some suggested ways to address this issue better would be to require that plans as a condition of participation have a system of visitor or traveler benefits, consider exempting regional PDPs and PDPs with out-of-network services from the disenrollment requirement, require plans to provide prospective enrollees specific information on traveler benefits and "out-of-plan service policies" and clearly define the time period that a plan could consider an enrollee as "no longer resid(ing) in the PDP's service area." such that it accommodates seasonal travelers who maintain a residence in the service area.. In many cases, 90 day mail order service and arrangements with other plans will make enrolling and disenrolling unnecessary. However, beneficiaries must have a clear understanding of how a plan will serve them while temporarily out of the service area; how when they are traveling and need emergency pharmaceutical services their plan will (or will not) reimburse for those services.

§423.44(d)(2)
Provisions in the proposed regulations to allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" create enormous opportunities for discrimination against individuals with mental illnesses, Alzheimer's, and other cognitive conditions. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and accordingly be subject to a late enrollment penalty permanently increasing their premiums. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage. Moreover, CMS lacks statutory authority to authorize PDPs to involuntarily disenroll beneficiaries. Under the MMA, section 1860D-1(b) directs the Secretary to establish a disenrollment process for PDPs using rules similar to a specific list of rules for the Medicare Advantage program. This list does not include reference to section 1851(g)(3)(B) of the Social Security Act which authorizes MA plans to disenroll beneficiaries for disruptive behavior. Thus, these proposed regulations must not be included in the final rule.

Concerns with specific provisions in this section and recommendations for beneficiary protections, which, at a minimum should be provided, are as follows:

§423.44(d)(2)(vi) Reenrollment in the PDP.
In the preamble, CMS appears to be asking for comments on whether a PDP should be allowed to refuse reenrollment of an individual who has been involuntarily disenrolled if there is no other drug plan in the area. As discussed above, it is our position that there is no statutory basis for involuntarily disenrollment. If the regulations allow this for disruptive behavior, then the plans must be required to allow reenrollment. Those individuals most likely to be subject to involuntary disenrollment will not have the resources to pay for their medications out-of-pocket. These individuals are entitled to this benefit. Disruptive behavior does not disqualify you from access to prescription drug coverage and may in fact be an indication that one is in need of medical assistance. Individuals who are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period and may therefore be subject to a late penalty and increased premium as a result. This result is unfair in light of the fact that the disruptive behavior may have resulted from denial of access to needed medications. CMS should therefore provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior, must waive the late enrollment penalty for these individuals, and the regulations must include detailed articulated protections to lessen the risks inherent in authorizing sanctions for "disruptive behavior."

§423.44(d)(2)(vii) Expedited Process.
This provision should be deleted from the final rule. The proposal to establish an expedited disenrollment process in cases where an individual's disruptive or threatening behavior has caused harm to others or prevented the plan from providing services is undefined, and provides no standards, requirements or safeguards. It allows plans to employ this mechanism on the basis of behaviors described in the broadest of terms - terms which could easily be mis-applied or applied capriciously or punitively. Thus, it would undermine all the minimal protections that would otherwise apply.

§423.46 Late enrollment penalty.
CMS should delay implementation of this section for two years. The drug benefit is a new and complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. The Medicare-endorsed prescription drug discount card program has shown that, even with significant outreach, the majority of individuals eligible for the $600 low-income subsidy have not yet enrolled. We disagree that healthy beneficiaries will not apply. We believe that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness and cognitive disabilities. Implementation of the late enrollment penalty should be delayed for individuals eligible for the low-income subsidy who may not understand that they have to apply separately for the subsidy and a drug plan, thinking that application for the subsidy is sufficient.

This section should provide that when the late enrollment penalties are implemented, there will be an opportunity for enrollees to appeal late enrollment penalties; that late enrollment penalties will be coordinated with "special enrollment periods" to ensure that individuals who take advantage of the special enrollment periods do not face late penalties; that individuals who are involuntarily disenrolled are exempt from this penalty; and that if an employer or other entity

providing drug coverage to Medicare beneficiaries fails to provide adequate or correct notice of the creditable status of that coverage or a change in status of that coverage, and that coverage is not creditable, there are no late enrollment penalties.

§423.48 Information about Part D.
Medicare beneficiaries can only exercise an informed choice about their drug plan if they have adequate information about drug plan options available to them. The information should be provided annually, in writing, and include details about the plan benefit structure, cost-sharing and tiers, formulary, pharmacy network, and appeals and exception process. In order to assure that beneficiaries have the required information, the standards should be included in regulations that are binding and enforceable, and not in guidance. Minimally, the regulations should require plans to provide premium information, including whether individuals who receive the low-income subsidy will have to pay a part of the premium and, if so, the amount they will have to pay; the benefits structure and comparative value of the plans available to them; the coinsurance or copayment amounts they will need to pay for each covered Part D drug on the formulary; the specific negotiated drug prices upon which coinsurance calculations will be based and that will be available to beneficiaries if they confront the gap in coverage; formulary structure, the actual drugs on the formulary, and how the formulary can change during the plan year; participating pharmacies, mail order options, out-of-service options; and exception, appeals and grievance processes. Plans should be required to provide this information to potential enrollees in a clear manner using a standard format that will allow beneficiaries to easily compare plans. Plans should be required to provide information on negotiated prices in an easily accessible format.

The regulations should also include specific requirements for plans and states, as well as outline activities CMS will undertake, to ensure that every effort will be made to reach dual eligibles. By summer 2005 CMS and the states should launch a concerted outreach and assistance campaign for dual eligibles to alert them about the need to enroll in a Part D plan and to help them make appropriate choices. The outreach campaign would be intended to prevent default enrollment. In addition, as early as possible, and no later than October15, 2005 (assuming information is available), CMS or the states should mail standardized, easy-to-understand notices to dual eligibles that, among other things: inform them of their eligibility to receive the low income drug benefit if they enroll in a PDP or MA-PD; list choices of health plans (clearly denoting those that meet the benefit premium assistance limit) and contact information for each plan; explain that individuals will be randomly enrolled in a prescription drug plan beginning November 15 (or, if different, the appropriate date) if they fail to opt out or enroll in a plan themselves; explain how they may change their drug plans if they wish at any time; and inform them of where in their community they can go to get help with enrollment. These notices should be tested for readability by focus groups and experts. If the states are required to provide this information, CMS should reimburse 100 percent of the states' costs.

§423.50 Approval of marketing material and enrollment forms.
The marketing rules for the PDPs and MA-PDPs should be developed in the historical context of other Medicare programs. From selective marketing to outright fraud, Medicare programs historically have been afflicted with marketing abuses and scams. We urge that CMS be vigilant to identify and prohibit these problematic areas and practices as it develops final regulations.

§423.50 (e) Standards for PDP marketing.
Telemarketing should expressly be prohibited. Door-to-door solicitation is prohibited under this section and telemarketing presents many of the same dangers. The regulations should specifically prohibit prescription drug plans from initiating telephone or e-mail contact with potential enrollees, unless the potential enrollee requests contact through such means in response to a direct mail or other advertisement.

In the Preamble, CMS asked for comments on whether it would be advisable to permit prescription drug plan sponsors to market and provide additional products (such as financial services, long term care insurance, credit cards) in conjunction with Medicare prescription drug plan services. CMS should not allow plans to market other services, nor should it seek to encourage other entities, such as financial institutions, to participate as PDPs. The potential for abuse—both cherry picking of healthier beneficiaries into plans and avoidance of financial services to less healthy individuals—is enormous. CMS also asked for comments on the applicability of MA marketing requirements for PDP marketing. PDP marketing requirements should be at least as restrictive as MA marketing because of the high potential both for confusion and for individuals to be directed to—and locked-into—plans that do not best meet their needs. Beneficiaries look to providers for balanced, unbiased information, and they should be able to rely on the information that these sources provide. However, if providers or pharmacies are allowed to market plans, there is the potential for aggressive marketing of certain PDPs, regardless of whether or not that PDP is the best for the beneficiary. The adverse consequences of making a bad selection based on promotion from a trusted source are high.

§423.56 Procedures to determine and document creditable status of prescription drug coverage.

§423.56 (e) Notification.
It is essential that beneficiaries understand whether they have creditable coverage. Failure to understand the issue of creditable coverage can lead to a lifetime of higher Part D premiums. CMS must set forth specific requirements that plans provide information to Medicare beneficiaries enrolled in those plans clearly stating whether or not the coverage they have is creditable. Minimally, in 2005, information on whether coverage is creditable or not should be provided in more than one mailing, and included in such documents as quarterly retiree income statements, medical billing correspondence, etc. After 2005, CMS should develop standard notices, through its Beneficiary Notice Initiative, to be used. In years after 2006, when creditable status changes, special notification is needed to insure that beneficiaries know as soon as the decision is made to reduce coverage, so they can begin shopping for a PDP and avoid a lifetime of premium penalties. Because this is such important notification, it should be sent by registered mail, or e-mail with proof of receipt. Additionally where beneficiaries are not adequately informed by an employer or other entity that their coverage is not creditable, CMS should take action on behalf of all the individuals of that employer or other entity to provide a special enrollment period (SEP). Each individual adversely impacted by the failure of the employer or other entity to inform adequately should not have to apply or appeal for a SEP.

Subpart C-Benefits and Beneficiary Protections

§423.100 Definitions.
"Dispensing fee" should be broadly framed, in order to permit the payment of costs associated with home infusion therapy. Of the options provided in the preamble to the proposed rule, we support option 3. We do not believe that a narrowly crafted definition of dispensing fee is appropriate because the conference report at § 1860D-2(d)(1)(B) references negotiated prices in a manner that indicates that Congress intends to define negotiated prices in a way that arrives at the most accurate prices when considering a variety of both concessions and fees. Since the antibiotics, chemotherapy, pain management, parenteral nutrition and immune globulin and other drugs that are administered through home infusion are indisputably covered Part D drugs, and equipment, supplies and services are integral to the administration of home infusion therapies, costs associated with such administration should be included in the definition of dispensing fee, in order to arrive at the most accurate determination of the negotiated price. Option 1 makes an arbitrary and inappropriate distinction between costs associated with dispensing a covered Part D drug and associated costs for the delivery and administration of a covered Part D drug, and option 2 does not capture all the true costs associated with dispensing a covered Part D drug.

"Long-term care facility" should explicitly include ICF/MRs and assisted living facilities.
We recommend that the final rule include a definition of "long-term care facility" that explicitly includes intermediate care facilities for persons with mental retardation and related conditions (ICF/MRs) and assisted living facilities. This is important because many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

§423.104 Requirements related to qualified prescription drug coverage.
The final rule defines "person" so that family members can pay for covered Part D cost-sharing. The law precludes contributions from employer sponsored health plans from being counted as incurred costs and counting toward the deductible or out of pocket limit. Contributions from one employer-sponsored benefit should not receive differential treatment over contributions from another type of employer-sponsored benefit. Contributions from employer-sponsored group health coverage should be counted as an incurred cost, similar to contributions from HSAs, HRAs, and FSAs. The final rule should also count cost-sharing subsidies from AIDS Drug Assistance Programs (ADAPs) as incurred costs. The regulations also specifically state that state-appropriated dollars spent by ADAPs cannot be counted as incurred costs. It is discriminatory and unacceptable to single out state dollars used to provide medications to people living with HIV/AIDS and not allow them to count as incurred costs, while at the same time allowing state dollars paid by State Pharmaceutical Assistance Programs' (SPAPs)to count as incurred costs.

§423.104(e)(2)(ii) Establishing limits on tiered copayments.
The final rule should not allow Part D plans to apply tiered co-payments without limits. Rather, it must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs.

§423.104(h) Negotiated prices.(1) Access to negotiated prices.
No plan should be allowed to impose 100% cost-sharing for any drug. Such cost-sharing should be considered as per se discrimination against the group or groups of individuals who require that prescription.

§423.120 Access to covered Part D drugs.

§423.120(a) Assuring Pharmacy Access.
Pharmacy access standards must be met in each local service area, rather than by permitting plans to apply them across a multi-region or national service area. Permitting plans to meet the access standards across more than one local service area could cause individuals in some local service areas to not have convenient access to a local pharmacy. Also, only retail pharmacies should be counted for the purpose of meeting pharmacy access standards. It would undermine the principle that Medicare beneficiaries will have convenient access to a local pharmacy if the access standards could be met by counting pharmacies that serve only specific populations and which are not available to all parts of the general public. The final rule should require prescription drug plans to offer to contract with Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (I/T/U) pharmacies and make available a standard contract. Should the final rule not contain this requirement and in situations where an I/T/U pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy. The final rule should also require prescription drug plans to offer to contract with all LTC pharmacies and make available a standard contract. Over 80% of nursing home beds are in facilities that require the resident to use a long-term care pharmacy. Should the final rule not contain this requirement and in situations where a LTC pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy. Furthermore, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through higher cost-sharing for out-of-network access.

§1860D-11(e)(2)(D) authority to review plan designs to ensure that they do not substantially discourage enrollment by certain Part D eligible individuals.
CMS should use the authority provided under section 1860D-11(e)(2)(D) to review plan designs, as part of the bid negotiation process, to ensure that they are not likely to substantially discourage enrollment by certain Part D eligible individuals. Previous experience with Medicare+Choice plans shows that private insurers use a variety of techniques to discourage both initial and continued enrollment in a plan by enrollees with more costly health care needs. For example, Medicare+Choice plans have offset reduced cost-sharing for doctors visits with increased cost sharing for services such as skilled nursing facility care, home health care, hospital coinsurance, and cost sharing for covered chemotherapy drugs that are utilized by people with chronic and acute care needs. CMS should thus analyze formularies, cost-sharing tiers and cost-sharing levels, and how cost-sharing (including both tiers and levels) is applied to assure that people with the most costly prescriptions are not required to pay a greater percentage of the cost of those drugs. CMS also needs to assure that a variety of drugs are included in a

formulary at the preferred cost-sharing tier to treat chronic conditions and conditions that require more costly treatments. As stated above, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through higher cost-sharing for out-of-network access.

§423.120(a)(6) Level playing field between mail-order and network pharmacies.
The final rule should ensure that beneficiary out-of-pocket costs used for the purchase of covered Part D drugs count as incurred costs. A key principle of the MMA is that Medicare beneficiaries have convenient access to a local pharmacy. This principle is undermined by permitting plans to charge beneficiaries the cost differential for receiving an extended supply of a covered Part D drug through a network retail pharmacy versus a network mail-order pharmacy. However, notwithstanding this objection, the final rule should permit the cost differential charged to beneficiaries to count as an incurred cost.

§423.120(b) Formulary requirements.
We do not believe it is appropriate for the final rule to constrain prescribers' capacity to prescribe drugs for off-label uses. By not permitting a class to exist in the USP model guidelines solely because all commonly used medications are being used for off-label indications could lead plans to deny coverage for off-label uses. Off-label prescribing has become a common-and accepted-practice across the field of medicine. For example no drugs that are currently used in the treatment of lupus (a serious, life-threatening auto-immune disorder) have the treatment of lupus as an on-label indication. For the treatment of mania, certain anti-convulsants and calcium channel blockers have proven effective and certain anti-convulsants have proven effective for treatment of bipolar disorder, although these uses are not FDA-approved on-label indications. We thus oppose any provisions in the final rule that place new limits on the ability of prescribers to prescribe drugs for off-label uses-or that legitimize the denial of coverage for covered Part D drugs simply because they are used for an off-label indication.
We support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must be protected from tiered cost-sharing that could to these defined populations must be made available at the preferred level of cost-sharing for each drug. We recommend that this treatment apply to at least the following overlapping special populations: dual eligibles, institutionalized populations, persons with life-threatening conditions, and persons with pharmacologically complex conditions.

We recommend that if the final rule limits the notice requirements to persons directly affected by the change, then plans must be required to provide notice in writing, mailed directly to beneficiary, 90 days prior to the change, and the notice must inform the beneficiary of their right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary. We also recommend that the final rule place strict limits on mid-year formulary changes, requiring plans to justify a decision to remove drugs from a formulary such as the availability of new clinical evidence indicating that a particular covered Part D drug is unsafe or contraindicated for a specific use or when all manufacturers discontinue supplying a particular

covered Part D drug in the United States. Should the final rule fail to effect such a restriction, plans should be required to continue dispensing all discontinued drugs until the end of the plan year for all persons currently taking a discontinued drug as part of an ongoing treatment regimen.

§423.124 Special rules for access to covered Part D drugs at out of network pharmacies.
The final rule must establish requirements on plans to dispense a temporary supply of a drug (wherever a prescription is presented, irrespective of whether or not it is at a network pharmacy) in cases of emergency. If the emergency situation involves a coverage dispute, the plan must dispense refills until such time as the prescription expires or the coverage dispute is resolved, through either a plan decision to provide coverage for the drug or through completion of the appeal process. This requirement must also specify that a temporary supply must be dispensed even in cases where beneficiaries are unable to pay applicable cost-sharing.

The final rule should also limit out-of-network cost-sharing to no more than the difference between the maximum price charged to any in-network Part D plan in which the pharmacy participates and the in-network price. While we recommend that this limitation apply in all circumstances, at a minimum, it must be applied through the final rule, to the scenarios described in the preamble to the proposed rule.

§423.128 Dissemination of plan information.

§423.128 (d) Provision of specific information.
It is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center. The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program.

§423.128(e) Claims Information.
In addition to the required explanation of benefits elements in the proposed regulation, the explanation of benefits should also include information about relevant requirements for accessing the exceptions, grievance and appeals processes.

Subpart J-Coordination Under Part D With Other Prescription Drug Coverage

§423.464(e) Coordination with State Pharmaceutical Assistance Programs (SPAPs).

SPAPs and new SPAPs must be able to help beneficiaries 'fill in the donut,' and we appreciate CMS's efforts to coordinate this assistance. To assure that beneficiaries are receiving seamless coverage and not facing undue out of pocket expenses, an exchange of data between the PDP and the SPAP is necessary. This should include (but not be limited to) an exchange of eligibility files, exchange of claims payment and information about the drugs on the PDPs formulary and any changes to it. Also, AIDS Drug Assistance Programs (ADAPs) should be recognized as

State Pharmacy Assistance Programs and allowed to wrap around the Medicare Part D drug benefit.

Subpart M-Grievances, Coverage Determination, and Appeals

The proposed regulations fail to meet the requirements of the Due Process Clause of the Fifth Amendment to the United States Constitution. As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid recipients whose prescription requests are not being honored currently receive a 72-hour supply of medications pending the initial coverage request. They are entitled to notice, face-to-face hearings, and aid paid pending an appeal if their request is denied and they file their appeal within a specified time frame. All state Medicaid appeals processes are completed more expeditiously than Medicare appeals. The appeals process as described in Subpart M does not accord dual eligibles and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity for a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes. While we recognize that the most efficient means of protecting enrollees, amending MMA to provide for an appeals process similar to Medicaid, is beyond the authority of CMS, CMS can take steps in the final regulations to improve notice and the opportunity for speedy review.

Sections 1860D-4(f), (g), and (h) require that Part D plan sponsors establish grievance, coverage determination and reconsideration, and appeals processes in accordance with Sections 1852(f), (g) of the Social Security Act. As will be discussed in more detail below, CMS has failed to comply with the language of those provisions. Overall, the incredibly onerous exceptions process does not comply with the statutory requirements or meet the basic elements of due process. In addition, CMS, in implementing Section 1852(c) and in settlement of *Grijalva v. Shalala*, 153 F.3d 1115 (9th Cir, 1998), *vacated and remanded*, 526 U.S. 1096 (1999), adopted 42 C.F.R. §422.626, which establishes the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review for Part D. CMS needs to incorporate a similar process for Part D in order to establish a process in accordance with Section 1852(c). A similar fast-track process would also be more in keeping with due process requirements.

As a general comment, this entire subpart needs to be made much simpler. To have two tracks, depending on (1) whether one personally pays for a drug and files an appeal or (2) does not obtain the drug and files an appeal, is far too complicated. The time frames, paperwork, and processes should be simplified into one course of action that beneficiaries may hope to understand.

§423.560 Definitions.

This section defines "appeal" to exclude grievance and exceptions processes, and defines “authorized representative” as an individual authorized by an enrollee to deal with appeals. The definition of “authorized representative” needs to clarify that a doctor or representative, including a State Prescription Drug Plan (since the SPAP may be at risk in the event of PDP

actions) can be an authorized representative, and that authorized representatives can deal with exceptions and grievances as well as appeals.

§423.562 General provisions.

§423.562(b)(5)(iii)

Reconsideration by an Independent Review Entity (IRE) should be automatic, as in the Medicare+Choice plans

§423.562(c)(1)

This subsection precludes an enrollee who has no further liability to pay for prescription drugs from appealing. However, it is important to be able to appeal formulary changes. A comprehensive change in this limitation is essential to protect the health of beneficiaries. At a minimum, SPAPs should be able to appeal on behalf of an enrollee and the section should clarify that a low-income institutionalized individual can appeal a determination, even if she has no co-payment responsibilities.

§423.566 Coverage determinations.

§423.566(b) Actions that are coverage determinations.

This subsection needs to clarify further what constitutes a coverage determination. The proposed definition does not include in the list of coverage determinations from which an appeal can be taken a determination by the PDP that a drug is not a covered drug under Part D. An enrollee should be entitled to appeal to determine whether, in fact, a drug the plan claims is not covered under Part D is so covered. The definition should also clarify that denials of enrollment in a Part D plan, involuntary disenrollment from a Part D plan, and the imposition of a late enrollment penalty are coverage determinations subject to the appeals process. Finally, the regulation should state that the presentation of a prescription to the pharmacy constitutes a coverage determination. If the pharmacy does not dispense the prescription, then the request for coverage should be deemed denied, and the enrollee should be entitled to notice and to request a re-determination. Without such clarification, enrollees will not be informed of their rights, and the appeals process will become meaningless.

§423.568, Standard timeframes and notice requirements for coverage determinations.

§423.568(a) Timeframe for requests for drug benefits.

The plan should be required to provide oral notice as soon as it determines that it will extend the deadline for considering whether it will cover a drug, including notice of the right to request an expedited grievance. The oral notice should be followed-up in writing.

§423.568(b) Timeframe for requests for payment.

This section should be eliminated. There should be no distinction in time frames when an enrollee requests payment.

§423.568(c), Written notice for PDP sponsor denials.

Who gives notice? The proposed regulations place the responsibility for providing notice of a coverage determination on the plan sponsor. This presumes a situation in which the person presents a prescription, the pharmacy contacts the plan, and then the plan takes 14 days to decide whether or not to cover a drug. In reality, the pharmacy, in most instances, tells the enrollee that the plan will not cover the drug. Without notice provided by the pharmacy, most enrollees will not know to tell the pharmacy to submit the prescription anyway so they can get a notice from which to appeal. They also may not know or understand their right to seek expedited consideration of the initial coverage determination, or an exception if the drug is not on the formulary or on too high a tier. If the enrollee pays out of pocket and then seeks reimbursement from the plan, she will not be eligible for expedited consideration.

The regulations should require the plan sponsor to develop a notice explaining the right to seek a redetermination, and to ask for expedited review. The pharmacy should be required to give the notice to the enrollee. Any potential burden of such a requirement is reduced by the need to maintain electronic communications between the pharmacies and the plans in order to keep up-to-date with formularies, coinsurance, and calculations of an enrollee's out-of-pocket expenses.

The proposed regulations talk about using "approved notice language in a readable and understandable form." The regulations need to be more specific, including information about what is required to use the exceptions process. We suggest that notice should

Include information about exceptions and appeal rights immediately upon denial (including upon determination that a drug is not covered on formulary and including denials issued by the pharmacist), explain why coverage was denied and provide options in addition to the appeal procedures for obtaining necessary medications;

Include clinical or scientific basis for denial; and

Be available in multiple languages and note the availability of language services.

In addition, all notices need to be available in alternate formats to accommodate people with disabilities, and in languages other than English where a portion of the population is not English speaking. The requirements of plans and the rights of beneficiaries in this area must be spelled out in much more detail. There is also an overarching need to consider literacy problems and encourage simplicity.

§423.568(e) Effect of failure to provide timely notice.
It is nowhere spelled out how the beneficiary is apprised of this right.

§423.570 Expediting certain coverage determinations.

§423.570(a) Request for expedited determination.
CMS requests comments on who should be able to request determinations and re-determinations. An authorized representative should be able to request expedited consideration just as the authorized representative may request a coverage determination. In emergency situations, enrollees with mental health concerns and other vulnerable individuals may need someone else to act on their behalf.

§423.570(c) How the PDP sponsor must process requests.
All coverage determinations and appeals concerning drugs, including those in which the enrollee has paid for the drug, should be treated as requests for expedited review. An enrollee would suffer adverse consequences if required to wait for the longer time periods; many people will simply go without prescribed medications pending the outcome of the review. Doubling the timeframes and disallowing expedited review in cases when enrollees pay for their drugs out-of-pocket could adversely affect the health of those who forego other necessities like food and heat in order to pay for their medicine.

At a minimum, all requests for exceptions should be automatically given expedited consideration. Where someone seeks expedited review of a request to continue a drug that is no longer on the formulary, the plan should be required to process the request in 24 hours under the provision that requires an expedited review to be completed as fast as the beneficiary's condition requires. The enrollee should be given a 72-hour supply of the medicine, which is renewable if the plan decides to take longer than 72 hours. The medicine should be treated as an on-formulary drug.

If requests for an exception are not automatically treated as a request for expedited review, the rules should state that the doctor's certificate requesting expedited review and requesting an exception should be one and the same.

§423.570(d)(2)
A beneficiary should not have to wait for a written notice to learn of the right to file an expedited grievance and the right to resubmit a request with prescribing physician support.

§423.572 Timeframes and notice requirements for expedited coverage determinations.

§423.572 (b) Extensions of timeframe.
The timeframe (of 72 hours) can be extended by the plan up to 14 days on showing that an extension is in the interests of the enrollee. The regulations should be modified to read best interest of the enrollee and define interests of the enrollee to include those situations in which the drug plan seeks additional information to substantiate the enrollee's request, or when the enrollee requests additional time to gather supporting information. The regulations should also require the plan to inform the enrollee of the extension immediately, both orally and in writing, rather than "by the expiration of extension." Also, the written notice should include more than just the reasons for the delay.

There should be no extended time period for requests for payment of drugs already received. This imposes extreme hardship on low-income beneficiaries and those with multiple prescriptions who may choose to unnecessarily spend money on their medications because of the uncertainty and length of the appeals process rather than spend the money on other urgent necessities of life.
It is not clear from the proposed regulations what notice a beneficiary will receive when sometime during the year a plan changes its formulary and the drug(s) it covers. The statute says plans must make the change in information available on the internet, the Preamble discusses a

mailed notice, and the draft regulation simply says 'notice.' A change in formulary, or a change in the tiering of a drug on the formulary should be clearly explained to a beneficiary taking that drug which has been changed. That notice should be written notice and the receipt of that notice should serve as a trigger for the beneficiary's legal rights.

§423.572(d) Content of the notice of expedited determination.
See §423.568(c) comments above.

§423.572(e) Effect of failure to provide a timely notice.
How does a beneficiary know s/he can appeal the lack of timely notice?

§423.578 Exceptions process.
The proposed regulations do not explain how an enrollee will get notice about the exceptions process and/or that a drug is not included on the formulary. The only notice requirement is found in §423.120(b), which requires the plan sponsor to provide at least 30 days notice to CMS, affected enrollees, pharmacies, pharmacist and authorized prescribers before removing a drug or changing a drug's preferred or tiered status. Although the preamble talks about written, mailed notice, and the statute requires posting on the Internet, the regulatory language merely says that notice must be given.

To meet basic due process requirements concerning termination of benefits, the notice of the change must be in writing and must include an explanation of how to use the exceptions process, including the requirements for a doctor's certificate, the right to a hearing, and the reasons why a drug is not included on or removed from the formulary, or why the tier is changing, and the evidence required to establish an exception.

Proposed section §423.120(b) provides insufficient time for the notice, given the substantial burden placed on the enrollee to either get a new prescription or to gather the medical evidence. Many beneficiaries will not be able to get a doctor's appointment within 30 days, and many will not be able to change drugs without a medical evaluation. The final regulations should state that notice must be provided 90 days in advance of the change.

In addition, the exception process section should include a subsection on notice that (1) refers to §§423.120(b) and (2) requires plan sponsors to develop a notice that explains the exceptions process, the situations in which someone may seek an exception, and the information that is required to support an exception request, which the pharmacy will give to an enrollee who requests coverage for a non-formulary drug or requests to be assessed a lower cost-sharing amount.

§423.578 (a)(2).
This subsection fails to meet the statutory requirement that the Secretary establish guidelines for an exception process. The plan statutory language is not permissive; it does not say that plans may establish additional criteria if they wish. It says that the Secretary is to establish criteria and the plans are to abide by them. Plans should have no discretion whatsoever. The fact that they may establish differing tiered structures is not relevant to the statutory right to request an

exception to whatever structure they devise. In fact, the flexibility accorded to plans is why beneficiaries need strong guidelines to protect their interests.

Where the proposed regulations include guidance for criteria, the criteria listed exceed the scope of the statute. The proposed regulations list a "limited number of elements that must be included in any sponsor's exception criteria," but this list includes criteria that do not apply based on the statutory provision that states an exception applies if a physician determines that a preferred drug would not be as effective or would have adverse effects or both.

The proposed rules also fail to provide adequate guidance to physicians concerning whether the standard requiring the doctor to certify that a preferred drug would not be as effective or would cause adverse effects has been met.

The final regulation should require that the lowest co-pay that applies should apply to drugs for which an enrollee has won an exception to the tiered cost-sharing structure. That's the whole point of this process - to infuse some equity upon a showing that none of the other medications covered are as effective or may cause harm.

The final rule should also include the following omitted criteria: regulations permitting continued access to a drug at given price when there is a mid-year formulary change, and regulations requiring sponsors to give enrollees an opportunity to request exceptions to a plan's tiered cost-sharing structure other than on a case-by-case basis.

§423.578(b) Request for exceptions involving a nonformulary drug.
This subsection fails to meet the statutory requirement that the Secretary establish guidelines for an exception process. In the preamble, CMS states that "[r]equiring sponsors to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied" and will help ensure these formularies "are based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs ." However, the proposed regulations give drug plans complete discretion in determining the criteria they will use to determine exceptions requests. In addition, independent review entities "would not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." By failing to adequately define the criteria plans may use to consider exceptions requests or provide any meaningful oversight over these criteria, these proposed regulations would not ensure that formularies are based on scientific evidence and would not establish a transparent process. The regulations as written subvert CMS's stated goals.

The proposed rules set an impossibly high bar for receiving an exception by requiring prescribing physicians to produce clinical evidence and medical and scientific evidence to demonstrate that the on-formulary drug is likely to be ineffective or have adverse effects on the beneficiary. Clinical trials generally do not include older people, people with disabilities and people with co-morbidities. While some such evidence does exist, it has not been developed for all drugs and conditions. However, a physician may have extensive experience treating these kinds of patients with the condition or illness at issue and this experience should be given at least

equal weight in making such determinations. In fact, the statutory standard requires deference to the doctor's determination that all on-formulary medications would not be effective or cause adverse consequences. This required deference is not reflected in the proposed rules. It is also important that the final rules recognize the existence of individual differences in reactions to the same drug and that exceptions be available to someone who can not tolerate or who does not benefit from a drug even though that drug is beneficial to most people.

The NPRM proposes to authorize plans to require a long list of information in the written certification from the prescribing physician that an off-formulary drug is needed. This list is overly long and repetitive and may encourage drug plans to establish burdensome paperwork requirements as a hurdle to prevent physicians and consumers from following through on an exceptions request. Moreover, this proposed rule also leaves the required contents entirely up to the plan's discretion by including the catch-all phrase - "any other information reasonably necessary". The requirements for this written certification should be standardized to facilitate use of the exceptions process by providers and consumers. These standards would also help achieve CMS's stated goal of establishing a transparent process.

An important provision was left out of the requirements for receiving a dosing exception. The proposed rule states that in order to receive an exception, the physician must demonstrate that the number of doses available is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. This rule must also allow exceptions if the prescribing physician demonstrates that the number of doses available would cause an adverse reaction or harm to the enrollee - as provided in the proposed rules for other kinds of exceptions requests.

The final regulation should clarify that formulary use includes not just dose restriction, but the format of the dosage (liquid vs capsule, etc.) and packaging, such as bubble wraps for long-term care facility residents.

§423.578(c)(2) When a sponsor does not make a timely decision.
The regulation provides for a one month's supply of a drug, but only if the plan does not act timely on an exceptions determination. If the request for an exception is not given expedited treatment, the sponsor can take two weeks to issue a decision, meaning the enrollee would wait two weeks before getting the supply of medicine. Even if the exception is treated as a request for expedited review, the enrollee would still have to wait 72 hours (unless s/he could show the decision needed to be made more quickly because of her/his condition.) Most people wait to the last minute to refill a prescription, often because of drug plan and pharmacy restrictions.

It is also unclear how an enrollee knows about these rights when a sponsor does not make a timely decision.

The enrollee should be entitled to a one month's supply upon presenting the request for a refill and upon presenting a new prescription for a non-formulary drug. Plans should be required to make exception determinations and notify the enrollee in 24 hours as required under Medicaid for prior authorization determinations. 42 U.S.C. §1386r-8(d)(5)(A).

We cannot overemphasize the importance of drug coverage and ensuring no gaps in the intake of medication. In mental health and HIV/AIDS, for example, it is essential that medications be available quickly and without interruption. In the HIV/AIDS sector, for example, consistent research proves that the risk of drug resistance and resulting treatment failure significantly increases with each missed dose of therapy.

423.578(c)(3), When an exception request is approved.
The lowest coinsurance amount should apply anytime an enrollee wins an exception through this process because the drug at issues has been determined medically necessary with no on-formulary drug as a suitable alternative. The exception for the non-formulary drug thus meets the criteria for an exception to the tiered cost-sharing structure as well.

The regulation needs to clearly set forth the requirement that notice be provided when a decision is made on an exception request. The notice should explain that the decision is a coverage determination and explain the appeal rights that are available.

We commend CMS for specifying that, once an exception request is granted, a plan sponsor may not require the enrollee to keep requesting exceptions in order to continue receiving the drug. However, we are concerned that the "exception" to this protection which allows the plan to discontinue a drug if safety considerations arise, is too broad. The final regulation should be revised to permit reversal of a previously granted exception only if the FDA determines that the drug is no longer safe for treating the enrollee's disease or medical condition.

We are concerned that the timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed provisions raise similar concerns. It is extremely unfair to require longer time frames if a beneficiary has paid out of pocket for a needed medication when their alternative would be to wait two weeks to a month for a determination or an emergency one-month supply of the needed drug. Beneficiaries' health and safety may well be at risk if they are forced to forego other necessities because of the added, and most likely very significant, expense of paying out of pocket for their medicines. Although the proposed regulations include some provisions for an emergency supply of medications while a plan is considering an exceptions request, it is unreasonable and bad health policy to make beneficiaries wait two to four weeks before the drug plan must provide an emergency supply. In addition, plans should be required to demonstrate that an extension of the standard time frame for exceptions determinations is in the best interest of the enrollee and the final rule must charge independent review entities with exercising oversight over these extensions. Plans should be required to make determinations regarding exceptions requests and notify the enrollee of these determinations in 24 hours as required under Medicaid for determinations regarding prior authorization requests (42 U.S.C. 1396r-8(d)(5)(A)).

§423.580 Right to a redetermination
The proposed regulations only authorize an enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) to request a redetermination or an expedited redetermination. The enrollee's authorized representative must also be allowed to request a redetermination and an expedited redetermination. Since the proposed regulations would allow an enrollee's authorized

representative to file a request for Determinations and Exceptions, it does not make sense to not allow an enrollee's representative to pursue a claim further through the redetermination, reconsideration, and higher levels of appeal. In fact, the proposed regulations define an authorized representative as an individual authorized to act on behalf of an enrollee "in dealing with any of the levels of the appeals process".

§423.584 Expediting certain re-determinations.
The regulations need to describe in detail the notice responsibilities for both standard and expedited re-determinations, including what must be provided in the notice. This is crucial, given that the next level of review to the IRE is not automatic, as it is with Medicare Advantage plans. The notice should explain the reason for the denial, including the medical and scientific evidence relied upon, the right to request review, or expedited review, to the IRE, including timeframes and the right to submit evidence in person and orally.

§423.584(a) Who may request an expedited redetermination.
See §423.580 regarding allowing an individual's authorized representative to request an expedited re-determination.

§423.584(d)(2).
The information in the letter should also be provided orally. The enrollee should not have to wait three days for this information.

§423.586 Opportunity to submit evidence.
The regulations should establish clear criteria for informing the enrollee and the physician that they can submit evidence in person, as well as clear procedures for in-person review.

§423.590 Timeframes and responsibility for making redeterminations.
The regulation should be amended so that a plan can only extend the timeframe for a re-determination if requested to do so by the enrollee, or if the plan can demonstrate that the extension is in the best interest of the enrollee (for example, the plan needs to obtain additional information to support the enrollee's request). As previously stated, all re-determination requests, and particularly those involving exceptions, should be treated as expedited, and plans should not be given more time to resolve re-determination requests involving payment requests.

§§423.590(c) Effect of failure to meet timeframe for standard redetermination and (e) Failure to meet timeframe for expedited redetermination.
Again, how does enrollee know this and know what to do?

§423.600 Reconsideration by an independent review entity (IRE).
CMS needs to clarify in the final regulations that the role of the IRE is to provide independent, de novo review, especially in regard to the exceptions process. The preamble states that "…The IRE's review would focus on whether the PDP had properly applied its formulary exceptions criteria for the individual in question…..the IRE will not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." If the IRE does not review all the

evidence and issue a reconsideration decision based on its own analysis, then enrollees will be denied independent review, and the requirements of due process will not have been met.

Further, because, as noted above, CMS is required by the statute to set standards for the exceptions process, the IRE must have authority to determine whether the PDP's exceptions criteria comply with the statute. Otherwise, enrollees will have no mechanism for review of arbitrary and improper standards.

Since the Part D process is supposed to follow the MA process, the regulations should follow the MA regulations and require that denials automatically be sent to the IRE for reconsideration. The regulations as written create a barrier to the first level of independent review for enrollees who have difficulty following the complicated process. We dispute CMS's statement in the preamble that many of the drug appeals will involve small monetary amounts. Rather, most will involve medications for chronic conditions that enrollees take on an on-going basis; the yearly sum of the cost-sharing will be quite substantial, especially considering the income level of most people with Medicare. In addition, by requiring the enrollee to file a request for ALJ review, the first truly independent review available, CMS can satisfy the statutory requirement that the enrollee files the appeal.

If the final regulations continue to place the burden of requesting a reconsideration on the enrollee, they need to clarify that an authorized representative can act on the enrollee's behalf. Again, without such clarification, enrollees who lack the capacity to file a reconsideration request will be denied their due process rights. In addition, the prescribing doctor should also be permitted to request a reconsideration, especially since the enrollee needs the doctor's statement in order to request IRE review of an unfavorable exception request.

Finally, the enrollee should be allowed to request a reconsideration orally, especially where the request is for an expedited review.

§423.600(b).
We are pleased that CMS is requiring the IRE to solicit the view of the treating physician. We believe the IRE should also be required to solicit the view of the enrollee. However, because in our experience the MA independent contractor is often reluctant and unwilling to accept the views of and evidence from the beneficiary, the final regulation needs to be more specific. The regulation needs to specify how this will occur, including contact by telephone, email, or face-to-face meeting.

§§423.600(d).
The regulations need to establish a set timeframe by which the IRE must issue its decision in order for this process to be transparent. Enrollees will have no knowledge of the contract between CMS and the IRE and thus will not know how long they will have to wait for a reconsideration decision. Also, if contractual, the time frame can change with each new contract, putting enrollees at greater risk of adverse health consequences from being denied needed medicines. The regulation should also state that an enrollee may appeal to an ALJ if the IRE fails to act within the regulatory time frame and how the enrollee will be apprised of this right.

§423.602 Notice of reconsideration determination by the independent review entity.
The language concerning what the notice must entail is ambiguous. The notice must "inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under 423.610." Does this mean that the notice tells you that you can go to an ALJ, but only if your claim is large enough? Or does this mean the IRE only has to tell you about your right to an ALJ hearing if your claim meets the threshold amount? The latter interpretation is problematic for several reasons, including the fact that you can aggregate claims. The final regulation should state that the notice must inform the enrollee of his or her right to an ALJ hearing, and the procedure for requesting such a hearing, including the dollar amount required to request a hearing.

§423.610 Right to an ALJ Hearing.
Congress recognized the special needs of the low income, and how even small copayment amounts can cause many lower income individuals to forgo filling prescriptions. We urge CMS to provide exceptions to the ALJ threshold requirements for those receiving the Medicare subsidy. For example, the amount at controversy for a lower-income individual could be deemed to be the amount that would be at controversy if the individual were a non-subsidy eligible individual receiving the standard benefit.

It is unclear what §423.610(c) intends when it says, "Two or more appeals may be aggregated by the enrollee… if (I) the appeals have previously been reconsidered by an IRE…" Does this mean that an enrollee will have to file a new appeal each month for a prescription to treat an on-going chronic condition? Such a requirement would be unduly burdensome for enrollees, drug plans, the IRE, and the ALJs. The final regulation needs to clarify that when the plan denies coverage, in order to satisfy the jurisdictional amount an enrollee should be able to add up the cost of the medicine for a year, if the medicine treats an on-going chronic condition, or for the number of refills authorized if the underlying condition is not chronic.

Subsection (ii) says the request for the hearing must list all of the appeals to be aggregated and must be filed within 60 days after all of the IRE reconsideration determinations being appealed have been received. If you are consolidating appeals, and the first denial is in April and the last one you need to get to the jurisdictional amount is in August, will you still be timely? Or does it have to be 60 days from the first denial in April?

§423.612 Request for an ALJ Hearing.
The regulation should specify that, if an appeal is filed with the PDP, the PDP must submit the file to the IRE within 24 hours of receipt of the request, and the IRE must transmit the file to the ALJ within 24 hours. Our experience is that, without set time frames, some current reviewing entities take long periods of time, adding to the delay in the processing and resolution of ALJ appeals.

The regulations also need to require the IRE to include all of the information in the file, such as doctor's statements, statements by the enrollee, and any other evidence submitted by the enrollee, including information not relied upon in making its decision. It has been our experience that

contracting entities, including MA plans, often omit evidence submitted by the enrollee when transferring a file to the ALJ or other level of review.

§§423.634, Reopening and revising determinations and decisions and 423.638 How a PDP sponsor must effectuate expedited redeterminations or reconsidered redeterminations.
Subsection (c) in both of these draft regulations allows the PDP to take up to 60 days to implement a reversal by the IRE, an ALJ, or higher. That's totally unacceptable, since further delays may cause increased health consequences to people who have foregone medication pending appeal. Favorable decisions should be implemented in the same 72 hour time period as reversals at earlier levels of review.

Subpart P - Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§432.772 Definitions.
"Family size." We support defining family members as relatives in the household receiving at least half of their support from the applicant or applicant's spouse. In order to minimize burdens on beneficiaries, the regulations should specify that applicants will be able to self-attest to the status of dependents, without providing further documentation.

"Full subsidy eligible individuals." The definition should refer to the language of §§423.773(b) and(c), in order to avoid ambiguity.

"Income." The definition should make clear that income not actually owned by the applicant, even if his or her name is on the check, should not be counted.

"Institutionalized individual." The definition should include those individuals eligible for home and community based services under a Medicaid waiver (see, e.g., definition of "institutionalized spouse" at 42 U.S.C. § 1396r-5(h)(1)(A)), since those individuals must meet the acuity standards for Medicaid coverage in a nursing facility, and should include individuals in ICF-MRs and individuals in any institution in which they are entitled to a personal needs allowance.

The definition should not include the language "for whom payment is made by Medicaid throughout the month" since an individual could conceivably be a full benefit dual eligible recently returned from a hospital stay whose nursing facility stay would be paid for by Medicare Part A for the entire month. Even though in that month all their drugs are likely to be paid for by Medicare Part A, as a practical matter, for continuity and minimum disruption, they should not lose their status as an "institutionalized individual." The same reasoning should apply to a full benefit dual eligible individual who might be hospitalized during an entire month, during which their entire stay would also be paid for by Medicare Part A.

"Personal representative." The portion of the definition that permits an individual "acting responsibly" on behalf of an applicant needs further clarification as to who would determine that the individual is acting responsibly and what circumstances would constitute a per se conflict of interest.

"Resources." We support the limitation of countable resources to liquid assets. However the definitions of liquid assets and what it means to be able to be converted into cash in 20 days need to be clarified. The final rule should include a specific list of countable resources to promote clarity for state and beneficiaries. Resources should not include burial plots, burial funds or life insurance of any value, nor should it include any officially designated retirement account, such as an IRA, 401(k), 403(b) etc. Alternatively, the respective exclusions for the value of life insurance and burial funds should be increased to a reasonable amount, such as $10,000 per asset. Most potential low-income beneficiaries have assets below this level.

Excluding these resources will ease the application process for consumers and eligibility workers, as well as reduce administrative costs by reducing the time and effort required to verify assets. This is consistent with both Congress's and CMS's intent. Resource assessments should not include any consideration of transferred assets, as would otherwise be required under SSI rules.

We note that a current draft of the SSA application for the low-income subsidy inquires whether an applicant has life insurance with a face value of $1,500 or more. CMS must ensure that any proposed SSA application is harmonized with these rules on assets and income. As noted above, life insurance should not count towards assets, and this question should be eliminated.

§423.773 Requirements for eligibility.
We support the proposal to make dual eligibles (both full dual eligibles and those in Medicare Savings Programs (MSPs)) automatically eligible for the low-income subsidy. As we explain below, however, we believe a great deal more specificity is needed in this section. We are particularly concerned that the proposed rule leaves room for ambiguity regarding these beneficiaries' status. We believe that the proposed eligibility rules for partial dual eligibles will result in inequities and confusion. In addition, the draft regulations do not adequately explain how low-income beneficiaries are to be notified about their eligibility, nor do they explain how prescription drug plans are to determine which beneficiaries are enrolled in the low-income subsidy. The proposed rules also do not adequately protect low-income beneficiaries whose enrollment is delayed or is processed erroneously.

§423.773(a) Subsidy eligible individual.
Although the statute defines a subsidy eligible individual as one enrolled in a Part D plan, the requirement in Subpart S that states take applications for the low-income subsidy beginning July 1, 2005, before Part D plans are available to be enrolled in makes it clear that CMS believes people should be able to apply for the low-income subsidy without being enrolled in a Part D plan. This is actually imperative, as otherwise, an individual would be forced to pay a plan premium that the subsidy, in fact, pays for them. The subsidy eligibility determination would be done "conditionally" - conditioned upon the individual enrolling in a Part D plan. The regulations should reflect this reality and clearly direct both SSA and state Medicaid programs determining eligibility that the individual can both apply and be determined subsidy eligible before she or he has enrolled in a plan

§423.773(b) Full subsidy eligible individual.

The indexing of resources should indicate that rounding is always up to the next multiple of $10.

§423.773(c) Individuals treated as full subsidy eligible.
This section should conform to Subpart S § 423.904(c)(3) which requires states to notify all deemed subsidy eligible individuals of their subsidy eligibility. It should specify that the notice must be given by July 1, 2005 for those individuals eligible at that time. For those who subsequently become eligible, notice should be given at the same time the individual is notified of their eligibility for the benefit that qualifies them to be treated as a full subsidy individual. The notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. For those who will lose Medicaid coverage January 1, 2006, the notice should explain their appeal rights as well. Individuals should also be told of their right to appeal the level of subsidy to which they are entitled.

Section 209(b) states and non-1634 states must coordinate with the Social Security Administration to determine how to provide notice to SSI recipients who are not receiving Medicaid and who therefore do not appear on the state's Medicaid rolls.

§423.773 states that both full benefit dual eligibles and MSP beneficiaries are eligible for the low income subsidy, but it does not explicitly state that these beneficiaries are automatically enrolled in the subsidy program. The regulations should be absolutely clear that an individual treated as full subsidy does not have to take any further action with respect to the subsidy (i.e., make application or in any other way verify their status), but only to enroll in a Part D plan. This will help smooth the transition from Medicaid drug coverage for dual eligibles, and should improve participation for others.

§423.773(c)(3).
We support the decision reflected in this proposed subsection to deem MSP beneficiaries automatically eligible for the low-income subsidy. We are concerned, however, that inequities and confusion among beneficiaries may result because SSA will not apply the more generous income and asset MSP eligibility rules in place in some states (for example, Alabama, Arizona, Delaware, and Mississippi, which have eliminated consideration of assets for MSPs). Eligibility requirements should be the same for all subsidy-eligible individuals in a state, regardless of where and how they apply. Under the proposed regulations, in states that have adopted less restrictive income and asset methodology, people whose assets or income are slightly above the limits set in § 423.773 would be enrolled in a less generous subsidy, or have their application rejected entirely, if they apply directly through SSA, because SSA will apply the national guidelines proposed in §423.773. However, the same people would have their application accepted if they applied through their states' Medicaid offices, were screened and then enrolled in an MSP, and were then automatically eligible for the low-income subsidy.

To resolve this problem, we propose that SSA apply state-specific income and asset eligibility rules in determining eligibility for the low-income subsidy, an option discussed, though rejected, in the preamble. This means that for applicants from states that have eliminated the asset test or

increased disregards under §1902®)(2) for MSP eligibility, SSA should apply the state's rules to determine eligibility. This option is permitted under §1860D-14(a)(3)(E)(iv) of the statute.

Alternatively, the regulations should provide that subsidy applicants who appear to have excess assets or incomes would either be screened by SSA for eligibility in an MSP program, or have their applications forwarded to the state Medicaid agency to be screened for MSP eligibility. States would be precluded from requiring beneficiaries to resubmit information, such as income and asset levels, that they have already provided to SSA. Applicants would be enrolled in the appropriate MSP program, and then be enrolled in the appropriate low-income subsidy under proposed § 423.773(c). Adopting this policy, which is not precluded by statute, will ensure that all subsidy applicants are treated equitably, as well as increase participation in MSPs.

As part of this alternative policy, the low-income subsidy application should allow an applicant to opt out of screening and enrollment for an MSP, as some applicants may not wish to participate in an MSP. Under §1860D-14(a)(3)(v)(II) of the statute, beneficiaries who are determined eligible for MSPs may be enrolled in the low-income subsidy. There is no requirement that beneficiaries actually enroll in an MSP. Therefore, applicants who meet eligibility requirements for an MSP, but who decline to enroll in the program, should still be automatically eligible for the low-income subsidy.

Because enrollment in an MSP can affect the amount of assistance a beneficiary may receive through other public assistance program, such as Section 8 housing vouchers or food stamps, there will be a profound need for beneficiary counseling during the enrollment process. We recommend that CMS plan for this need by making funds available to local agencies, including state health insurance assistance programs (SHIPs), and other community-based organizations.

This draft regulation states that a state Medicaid agency must notify full benefit dual eligibles that they are eligible for the low-income subsidy and should enroll in a Part D plan. The regulations do not state, however, when this notice should be issued, or what the notice should say. Consistent with our comments above and those accompanying 423.904(c)(3), the notification should be sent to beneficiaries on or near July 1, 2005, when states will have made the automatic eligibility determinations.

We also suggest that CMS develop model notices based on input from beneficiaries, which would explain the purpose of new subsidy simply and clearly. The notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. It should also explain as simply as possible what level of subsidy the beneficiary will receive, and the beneficiary's appeal rights if she believes the subsidy level is in error.

The draft regulation fails to address eligibility issues for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) state. These beneficiaries should be informed of their likely eligibility for a low-income Medicare subsidy and given an opportunity to enroll. When they have met their spenddown, they should be informed of their entitlement to a lower co-payment, if applicable, as a deemed subsidy eligible.

Our recommendations for redeterminations of these beneficiaries are discussed below, in §423.774.

§423.773(d) Other subsidy eligible individuals.
The indexing of resources should indicate that rounding is always up to the next multiple of $10.

§423.774 Eligibility determinations, redeterminations, and applications.

§423.774(a) Determinations of whether an individual is a subsidy eligible individual.
This subsection provides that determinations of eligibility for the subsidy are to be made by state Medicaid agencies or by SSA, depending on where an individual applies. We believe that in order to ensure prompt enrollment in both the subsidy and ultimately in a plan, the regulations should specify that a determination notice must be sent to the applicant no later than 30 days after the application is filed. Because determinations for the low-income subsidy should be a simple process, very little time should be required to render a decision. Both SSA and states should be required to notify CMS with 24 hours of a individual being determined eligible for the subsidy.

§423.774(b) Effective date of initial eligibility determination.
In order to avoid delays in the ability of beneficiaries to use their subsidy benefits while their application is pending, the final rule should offer beneficiaries the option of applying through a presumptive eligibility system. Such a system would be especially helpful to beneficiaries who have enrolled in a Part D plan but are not yet receiving the low-income subsidy. Applicants can complete a short form at a provider's office or other location in which they declare their family size, income and assets. If their income and assets are below the relevant eligibility levels, they are found presumptively eligible. Applicants may still be required to complete a full application within a prescribed period of time (typically 30 to 60 days) if additional information is required. In the meantime, however, beneficiaries are given temporary cards that they can present to health care providers and receive services immediately. Experience has shown that the error rate for these enrollment systems is very low. In the rare cases where beneficiaries are later found ineligible, they and their providers are held harmless for the benefits they receive during the presumptive eligibility period.

Applicants for the low-income subsidy could be found presumptively eligible at state Medicaid offices, SSA offices, pharmacies, or other providers. If the low-income subsidy application form is simple enough, applicants could complete the form itself and self-attest to their income and assets. If they appear to be eligible, they would be enrolled in the appropriate subsidy while their application is processed. They would receive some form of temporary certification stating that they have been presumptively enrolled, which their pharmacy would accept while their application is processed. Such a system would encourage beneficiaries to apply, as they would be able to see the benefits of the system immediately.

§423.774(c) Redetermination and appeals of low-income subsidy eligibility.
There should be a provision for prompt reconsideration of a subsidy eligibility determination, for beneficiaries who believe they have either been erroneously denied eligibility or approved for the

wrong subsidy category. The provisions applying the appeal rules of state Medicaid plans or SSA do not provide for a prompt reconsideration process. Because obtaining prescription drugs is so vital, and especially because low-income beneficiaries are unable to pay the costs of their prescription drugs out of their own pockets, a quick reconsideration process is essential.

The draft regulation refers to redeterminations and appeals under the state Medicaid plan. This is inadequate, as frequent redeterminations in place in some states will cause some beneficiaries to drop out of the program. To maximize enrollment, the rule should establish that all determinations are for one year, per the Secretary's authority under the statute. We also urge CMS to adopt an annual, passive, and simple redetermination for all beneficiaries, whether they have enrolled through SSA or states. Should it be necessary, the Secretary should direct the Commissioner of SSA to create such a system. Under a passive redetermination system, beneficiaries would be sent a statement of the relevant information on file and asked to respond only if any of that information had changed over the year. If they do not respond, their coverage would continue unchanged for another year.

If states are not required to adopt passive redeterminations, we urge that redeterminations be made as they are under the state's MSP programs, or under the most passive, simplified redetermination process used for any category of coverage under the state plan.

§423.774(d), Application requirements.
This section should make clear to both states and SSA that no documents should be required of the individual as long as the applicant authorizes the agency to verify information from financial and other institutions. Documentation production should be only the absolute last resort.

Also, as we mentioned in our comments to §423.773 above, the proposed rule does not address eligibility determinations and recertification periods for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) state. Once beneficiaries become deemed subsidy eligible individuals by completing their spenddown, they should retain that status for a full year, until their next redetermination for the low-income subsidy, regardless of whether they go off Medicaid. Otherwise, individuals who go in and out of medically needy status, depending on the length of their state's budget period, will have extremely confusing changes regarding their Medicare low-income drug subsidy.

§423.800 Administration of Subsidy.

§423.800(a), Notification of eligibility for low-income subsidy.
We are concerned that there is no provision in §423.800(a) specifying a time period by which CMS must notify a plan that an enrollee is eligible for a subsidy. This is an essential step in the process, because without the subsidy, prohibitive costs will prevent low-income beneficiaries from using their Part D benefits. We propose that CMS be required to inform Part D plans of beneficiaries' enrollment in the subsidy no later than 24 hours after the application for the subsidy is approved. As this will likely be an electronic notification, it should not be burdensome. It is vital that plans know which beneficiaries are enrolled in the subsidy, so that these low-income beneficiaries do not have to pay the full cost of their prescriptions while their subsidy application is process.

§23.800(e), Reimbursement for cost sharing paid before notification of eligibility for low-income subsidy.
The draft reimbursement provisions are inadequate to protect low-income beneficiaries. The proposed regulation would require plans to reimburse low-income beneficiaries for excess copayment and premium amounts made after the effective date of the subsidy application. This is not a realistic solution to the problem facing beneficiaries who have prescription drug needs before their Part D plans are notified that the beneficiaries are subsidy-eligible and need to have their records adjusted accordingly. Low-income beneficiaries will not be able to afford to pay these costs out of their own pockets with the expectation of being reimbursed later. Instead, these beneficiaries will forego prescription drug coverage until their plan processes their subsidy, making the first month or more of their subsidy period meaningless.

Adoption of a presumptive eligibility system recommended above would alleviate this problem. As an additional alternative, the regulations should provide that beneficiaries may present their notice of approval for the subsidy to their pharmacy when they seek prescription drugs. Pharmacies should accept this notice as adequate to relieve the beneficiary from making a co-payment, and instead seek reimbursement for the beneficiary's plan.

Subpart S - Special Rules for States - Eligibility Determinations for Subsidies and General Payment Provisions

§423.904 Eligibility determinations for low-income subsidies.

§423.904(a) General Rule.
This subsection should cross reference the entire Subpart P, or, at a minimum the definitions included in §423.772.

§423.904(b) Notification to CMS.
The rule should direct states to notify CMS of eligibility determinations within 24 hours of making them, as we previously recommended with respect to SSA determinations.

§423.904(c) Screening for eligibility for Medicare cost-sharing and enrollment under the State plan.
The proposed regulation regarding states' obligations to screen subsidy applicants and offer them enrollment in Medicare Savings Programs ("MSPs") are inadequate. In particular, the regulation should specify what "offer enrollment" means. We believe an applicant must be offered the opportunity to enroll during the same visit or contact (in office, by phone, or by mail), without providing any further documentation or completing any additional forms. Only if enrollment is easy and convenient will Congress's intent of increasing participation in MSPs be accomplished. Furthermore, because under the current rules, enrollment in an MSP may be the only entry into the subsidy for some beneficiaries, a quick and easy application for MSP programs is essential. As written, the regulation would permit states to say they have "offered enrollment" simply if they tell applicants that they might be eligible for an MSP and may return another time to complete another application form if they wish to apply. Such an outcome would defeat the

purpose of the screen and enroll provision included in the new §1935(a)(3) established in §103(a) of the statute. Instead, as proposed in our comments to Subpart P, the low-income subsidy application should include an "opt-out" provision, under which qualified applicants would be enrolled in an MSP unless they affirmatively decline to do so. This provision would explain that enrollment in an MSP may be another way to qualify for the low-income subsidy.

As we explained in our comments to Subpart P, because enrollment in an MSP may affect receipt of other public benefits, there is a tremendous need for good quality counseling of beneficiaries. In addition, in order to ensure that enrollment requirements between MSPs and the low-income subsidy are aligned, states should not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective and can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP.

In the interest of further aligning eligibility rules for MSPs and the low-income subsidy and easing administrative burdens, we suggest that CMS direct states to apply the definitions of resources used in Subpart P, §423.772, in making their resource determinations for MSP applicants.

In addition, should CMS adopt a policy, as has been discussed publicly, under which most subsidy applications to state Medicaid agencies would be forwarded to SSA for the actual eligibility determination, the regulations should be clear that the screening for MSP eligibility must take place prior to the processing of the applications to SSA. Potential beneficiaries should not have to wait to be screened and offered enrollment in MSPs. Furthermore, an individual cannot be told, by either SSA or the state that she or he is ineligible for the low-income subsidy until MSP eligibility has been determined (if the individual wishes). It would be incredibly confusing for an individual to receive a notice from SSA that she is ineligible for a subsidy, have her MSP eligibility determined by the state, then receive a notice from the state that she is eligible for both MSP and the subsidy. Whatever the mechanics, the individual must be told that MSPs are a route to subsidy eligibility.

Finally, as we discussed in our comments to §423.773, SSA should also screen subsidy applicants for eligibility in MSPs as well, and develop a system with states to enroll eligible beneficiaries. Applicants should not miss out on the opportunity to enroll in MSPs because they apply through SSA rather than state Medicaid offices. The same concerns about beneficiary education and estate recovery discussed above apply to enrollment through SSA.

The regulations should also ensure that beneficiaries are screened for eligibility for full Medicaid and offered enrollment if they qualify, consistent with 42 C.F.R. §435.404. Ideally, all subsidy applicants would be screened for Medicaid, and offered enrollment if they qualify. Because the importance of maintaining a simple application process for the subsidy is paramount, CMS may wish to consider using a simple screening process based on information obtained through the subsidy application. This screening would trigger a follow-up with applicants who appear to be eligible for full Medicaid.

Many Medicare beneficiaries who are eligible for a low-income subsidy under the Part D Program will also be eligible for other important benefits. Some of these benefits, such as food stamps, are also administered by states and have eligibility rules that very closely correspond with the new eligibility rules for the Part D subsidies. Historically participation by seniors and people with disabilities in these programs has been low, despite the fact that the benefits that low-income Medicare beneficiaries would be able to receive could help them struggle less to make ends meet every month. The Part D enrollment process offers an historic opportunity to connect Medicare beneficiaries to these other programs.

Beyond saying that applications may be filed either with a State's Medicaid program or with SSA, the proposed rule has very little detail about how the application process is likely to work. We urge CMS to specify that the new eligibility process should dovetail with other programs so that low-income Medicare beneficiaries can be enrolled as seamlessly as possible in all the state- or SSA-administered benefits for which they qualify

423.904(d)(3)(ii), Cost-effectiveness of information verification.
This section should be modified to permit states to use the verification process established by the Social Security Administration to verify the income and assets of people who apply for a Part D subsidy through a state Medicaid agency.

PART 403-SPECIAL PROGRAMS AND PROJECTS

Subpart B-Medicare Supplemental Policies

Disclosure notices advising consumers of their statutory rights must be short, simple, easy to understand, and address as few issues as possible. The proposed disclosure notice concerning Medigap policies H, I, and J included in the Preamble is too long, provides unnecessary information, and includes information that may not be accurate for all beneficiaries. We suggest that the letter be modified as follows:

Delete the information about Medicare Part D at the beginning of the disclosure notice;
Delete statements about the value of Part D benefits, which are irrelevant to the issue of changes to Medigap;
Delete the second statement about the need to notify the Medigap issuer if a person later enrolls in Medicare Part D. This information is repetitive; and

Delete the information concerning enrollment issues about Medicare Part D which is unrelated to whether a Medigap policy provides creditable coverage.

In addition, we encourage CMS to develop a different notice for people who will have creditable coverage as their options will be different from those of people whose Medigap policies are not deemed to provided creditable coverage. The specific information this group of beneficiaries will need about their creditable coverage, and any required action, will vary depending on whether their coverage is employer sponsored retiree coverage, a Medigap Plan J, a pre-standard Medigap plan, or a Medigap with a rider or an innovative benefit.

The discussion in the Preamble to the Regulation beginning with Subpart T 4(c)(iii) references the difficulty of determining creditable coverage and the inability to even make that determination in advance of a final rule to implement Part D. We expect there will be confusion on this issue and that mistakes may be made by issuers in applying an actuarial test to groups of policies issued all over the country. We expect additional confusion due to the proposal to modify the definition of Medicare Supplement (Medigap) policies in §403.205 to include riders and freestanding benefits for prescription drugs. We are requesting two remedies for Medicare beneficiaries who are initially notified of creditable coverage when the coverage is no longer or never was creditable: a Special Enrollment Period in Part D and a guaranteed issue right to a Medigap policy without prescription drug benefits. We are also requesting the extension of the right to a guaranteed issue policy to Dual Eligibles who lose their eligibility to Medicaid benefits.

Thank you for the opportunity to submit comments on the proposed rule. We hope that this will not be the final opportunity to do so.

Very truly yours,

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http://www.cms.hhs.gov/regulations/ecomments

Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-4068

Dear Madam or Sir:

On behalf of the clients represented by the undersigned, we wish to submit the following comments on your proposed rule for the Medicare Prescription Drug Benefit. The Medicare Advocacy Project has over 15 years of experience advocating on behalf of Medicare beneficiaries, particularly those with low incomes; the Massachusetts Law Reform Institute is a statewide advocacy organization representing low income individuals, including elders and persons with disabilities; and the Disability Law Center (DLC) is a private, nonprofit protection and advocacy agency that provides free legal assistance to individuals with disabilities throughout Massachusetts. A key mandate of DLC is ensuring that people with disabilities are able to access needed supports to live and work in the community. Because of the limited time allowed and the magnitude of the proposed rule, we are not commenting on CMS-4069, dealing with Establishment of the Medicare Advantage Program. Neither are we commenting on all the sections of the proposed prescription drug rule. Rather, we are focusing on the impact of the rule on low income beneficiaries and persons with disabilities, particularly in the Eligibility and Enrollment and Grievances, Coverage Determination, and Appeals sections. In addition, we support and agree with the more detailed and comprehensive comments submitted on one or both of the proposed rules by the Medicare Consumers Working Group and the Center for Medicare Advocacy, Inc.

We also request that time be provided for another comment period due to the many unaddressed or only vaguely addressed issues. The final regulations could include a number of errors and provisions that result in unintended consequences because so much of the final regulations will not have been seen by the public. We urge CMS to issue the next version of these regulations in a format that will allow one more round of comment, even if a shortened comment period. This is a very complex program with significant ramifications for a large number of citizens. We are concerned that failure to provide for additional public input when the regulations are more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

PART 423-VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

General comments.

1. Many pro-consumer statements in the preamble do not appear in the proposed rule. These protections bear no weight unless captured in the regulations. More should be done to reflect the Preamble's good intentions in the body of the regulations. For example:

> The Preamble discusses providing affected enrollees, prescribers, pharmacists, and pharmacies with written notice when a drug will be removed from the formulary or moved to a different tier for cost-sharing. The regulatory language does not specify that the notice should be in writing. Requirement for written notice is critical and should be specified.
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> The Preamble gives examples of situations when a plan will be required to allow an enrollee to use a non-network pharmacy. These include situations such as when an enrollee's plan does not contract with the long-term care pharmacy which an enrollee in a nursing home must use. The regulations should include the examples CMS discusses in the preamble.

2. There are a number of areas where the law is unclear or contradictory and these areas are creating serious problems for the regulation drafters. CMS should take advantage of the law's provision calling for the submission of technical and corrective amendments. While this was supposed to have been done by June 8, 2004, it should still be done, and Congress should address these issues as soon as possible.

3. Simplicity, as well as additional support for information and counseling, is necessary to ensure that beneficiaries are reached in a comprehensible way. The sheer size and complexity of these regulations is a testament to the fact that this new law is incredibly confusing. If beneficiaries are confused, enrollment and use of the new program will be very difficult, particularly for lower income, sicker, and limited English proficiency beneficiaries. Thus whenever it is possible, CMS should seek to simplify the new program.

Addressing some of our specific concerns:

Subpart B-Eligibility and Enrollment

1. The draft regulations addressing enrollment of beneficiaries into private drug plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDPs) do not adequately address the need for hands-on outreach, particularly to low-income beneficiaries, or to beneficiaries with special needs, such as mental illness. More attention must be given to developing materials and education and enrollment campaigns focused on informing beneficiaries with disabilities, including mental illness and cognitive impairments, and those with other special needs about the new drug benefit and helping them to enroll in the best plan available.

2. Of particular concern, is enrollment of the dual eligibles. Beneficiaries covered by both Medicare and Medicaid are by definition poor and cannot afford to pay privately fo fill any gaps in medication. Congress and the Administration promised that dual eligible beneficiaries would be better off with this new Part D drug benefit than they were receiving drug coverage through Medicaid. To honor this promise, coverage of medications for dual eligibles and other special populations must be grandfathered into the new Part D benefit. In addition, CMS must require plans to establish an alternative flexible formulary for dual eligibles as suggested in the preamble to the proposed regulations. This flexible formulary would incorporate utilization management techniques that focus on improving inefficient and ineffective provider prescribing practices but

do not restrict access to medications through prior authorization, fail first, step therapy, or therapeutic substitution requirements.

3. The regulations do not adequately address how drug coverage for the dual eligibles will be transferred to Medicare on January 1, 2006. There are issues both of timing and implementing the enrollment process in a way that will ensure that these beneficiaries do not confront a loss of benefits or a gap in drug coverage, either of which could have disastrous health consequences. Specific comments on enrollment of dual eligibles and our recommendations appear in our comments on §§423.34, 423.36, 423.48 and on Subpart P.

A. We are concerned with ensuring continuity of care for dual eligibles and access to needed prescriptions. These issues and concerns apply equally to all dual eligibles, and particularly to those with special health care needs, as well as to other populations with specific needs (See our comments in Subpart C, §423.120.)

B. The proposed regulations would force dual eligibles to enroll (or be automatically enrolled) in the "benchmark" or average cost plans in their areas because the low-income subsidy they will receive will only cover the premium for these plans. The formularies for these plans will not be as comprehensive as the drug coverage these individuals currently have through Medicaid. Even though Massachusetts has restricted access to drugs in its Medicaid program with preferred drug lists and prior authorization requirements, Massachusetts has taken many steps to ensure that special populations can readily access medically necessary drugs. For example, individuals who have been stabilized on one antidepressant are not required to try another one.

C. Without access to the coverage they need, dual eligibles will be forced to switch medications, which for certain populations, such as beneficiaries with HIV/AIDS or mental illness can have serious adverse consequences. Also, failing to ensure continuity of care for dual eligibles may benefit the plans, but will undoubtedly lead to Medicare and/or state increased costs for more physician and emergency room visits, and hospitalizations. The regulations do provide a special enrollment period for dual eligibles to use "at any time" (§423.36). However, being able to enroll in a different Part D plan is inadequate to meet the special needs of dual eligibles.

D. In the preamble to the proposed regulations, CMS points to an exceptions process as a means of securing coverage of off-formulary medications (See our comments to **Subpart M-Grievances, Coverage Determination and Appeals**) But the process proposed is extremely complex and cumbersome to navigate for someone having a psychiatric crisis, facing cognitive impairments, or in the midst of aggressive chemotherapy-to list just a few examples. Moreover, the timelines established are inordinately drawn out; for example, an expedited determination could take as long as two weeks. Drug plans are not required to provide an

emergency supply of medications until at least two weeks following a request. Exception, grievance and appeal processes should not be used to substituted for open formulary access to medications.

§423.34 Enrollment Process.

§423.34 (b) Enrollment.
The final rule should provide that an authorized representative may complete the enrollment form on behalf of a Part D eligible individual.

§423.34(c), Notice Requirement.
The notice must be in writing and inform an individual who is denied enrollment of his or her appeal rights, including the right to appeal the imposition of a penalty for late enrollment.

§423.34(d) Enrollment requirement for full benefit dual eligibles.
In the Preamble, CMS requested comments on whether CMS or the states should perform automatic enrollment of dual eligibles. State officials have more readily available data identifying the dual eligibles in their state and they also will be involved in the enrollment process because they are already required to perform low-income subsidy enrollment. In addition, there is an incentive for them to enroll these individuals in Medicare drug plans because without drug coverage they will increase utilization of other Medicaid services. Thus, states should be afforded the ability to conduct auto-enrollment and receive full federal financing for this function. In addition, CMS should develop its own systems for automatic enrollment of dual eligibles in states that do not elect to do so. Also, because the proposed rule leaves unanswered key questions about who will conduct automatic enrollment of dual eligibles and how it will occur, CMS must give the public the opportunity to provide input on any proposal it develops on this issue before publishing a final regulation.

§423.34(d)(1) General Rule.
The draft regulations provide that dual eligibles will be automatically enrolled in a Part D plan if they do not enroll themselves, by the end of the initial enrollment period, which, under §423.36, is May 15, 2006. However, their Medicaid prescriptions drug coverage will end on January 1, 2006. This proposed timeline for automatic enrollment must be changed because it could expose millions of dual eligibles to a four and half month coverage gap that could have serious health consequences for this vulnerable population. Given the difficulty of reaching this population coupled with inadequate provisions for outreach and education, it is almost certain that a substantial number of dual eligibles will face a several month gap in coverage between the end of Medicaid's drug benefit and automatic enrollment. This is untenable, and directly in conflict with Congress' and the Administration's promise that dual eligibles will be better off under Medicare Part D. The transfer of drug coverage from Medicaid to Medicare Part D should be delayed. Absent a delayed transition date for dual eligible drug coverage, however, dual eligibles should be randomly assigned and enrolled in a plan that best suits their needs as early as November 15, 2005 but no later than December 1, 2005. While we would prefer to provide individuals an extended period to make informed choices, it is critical to complete auto-enrollment as early as possible to leave as much time as possible to distribute plan information

and cards to beneficiaries, allow them to switch plans, and educate them about their new drug coverage before January 1, 2006. To make this process work more smoothly, states can begin profiling individual drug histories to prepare for random auto-assignment among plans that are appropriate for the individual even before plan information is released on October 15, 2005. Additionally, CMS should fund a campaign of individualized counseling and assistance both before and after auto-enrollment to explain to individuals their choices and how to enroll in a plan; explain, if applicable, how to get benefits under the plan to which they have been auto-assigned; and explain, if applicable, that they can choose a different plan from the one to which they have been auto-assigned and assist in choosing and enrolling in such a plan.

§423.34(d)(1)(ii)
CMS must develop a solution to the issue of automatic enrollment of dual eligibles who are enrolled in MA plans that have a prescription drug benefit with a premium that is above the low-income benchmark. The solution should be the one least disruptive to medical care and should not force a dual eligible to choose among continued MA enrollment, paying added premiums, or foregoing drug coverage. For institutionalized dual eligibles, the difference between the premium and the premium subsidy should be considered an incurred medical expense and deducted from their monthly "patient paid amount" to the facility. For non-institutionalized dual eligibles, in states with pharmacy assistance programs (SPAPs) which will wrap around Part D coverage and will cover dual eligibles, the SPAPs should be authorized to pay the difference. For medically needy individuals, the cost differential would be an incurred medical expense contributing toward their spenddown, if appropriate. Otherwise, individuals should be counseled about the premium discrepancy and about their right to withdraw from the MA plan and return to original Medicare. Ideally, dual eligibles who want to remain in the MA plan should be allowed to do so and not have to pay any amount by which the MA-PD basic premium exceeds the low-income benchmark amount.

§423.34(d)(2), When there is more than one PDP in a PDP region.
Because not every PDP plan may be appropriate for each dual eligible (for example, due to formulary restrictions), CMS should limit "on a random basis" to "among such plans in the region that meet the beneficiary's particular drug needs." Also, this subsection undermines the §423.859 right of assured access to a choice of at least two qualifying plans, by acknowledging that there may be regions where there is only one PDP in a PDP region with a monthly beneficiary premium at or below the premium subsidy amount.

§423.36 Enrollment Periods.

§423.36(a)(3)(ii) Exception.
It is not clear who these beneficiaries would be.

§423.36(c) Special Enrollment Periods.
This section should be expanded to provide "special enrollment exceptions" for individuals disenrolled by a PDP (such as for disruptive behavior) so that the individual will have an opportunity to join another PDP and continue with necessary medications. These "special enrollment exceptions" are necessary given the high risk of discrimination presented by the

provisions for involuntary disenrollment. CMS should provide a special enrollment period for these beneficiaries. It should include a reasonable time period for plan selection and be exempt from late enrollment penalties. It should also be expanded to make clear that involuntary loss of creditable prescription drug coverage includes loss because the beneficiary, or beneficiary's spouse, stops working; because COBRA coverage ends or because the premiums became unaffordable.

§423.36(c)(4) Special Enrollment Periods and Dual Eligibles.
We support granting dual eligibles special enrollment periods. However, this provision does not adequately address their needs. It is unlikely that there will be much choice of low-cost drug plans in each region, particularly in rural areas which have not historically attracted many Medicare+Choice plans. For example parts of Cape Cod and Western Massachusetts have no Medicare+Choice plans. In addition, these individuals will not have the resources to pay for more comprehensive coverage. Moreover, the special enrollment provisions do not specify that dual eligibles would not be subject to a late enrollment fee if this complex process of disenrollment and reenrollment resulted in a gap in coverage of over 63 days.

In addition, full benefit dual eligibles should receive notice explaining their right to a special enrollment period when they enroll in a plan, and every time their PDP changes its plan in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

§423.36(c)(8)
The regulations should include a special enrollment period similar to the one for dual eligibles for all beneficiaries eligible for a full or partial-low income subsidy. This is necessary because if coverage for a drug is denied, these low-income beneficiaries will be unable to afford to pay for drugs during a period of appeal, or if their appeal is denied and they are locked into a plan that does not cover a drug they need.

Special enrollment periods should also be provided for all institutionalized individuals, not just institutionalized dual eligibles, since their access to needed drugs may be compromised by the design of the plans and by pharmacy access requirements, such as if their long-term care pharmacy is not required to be included in the network of all PDPs. Individuals with life-threatening situations and individuals whose situations are pharmacologically complex should have the same rights as well.

§423.38 Effective Dates.

§423.38(c) Special Enrollment Periods.
Effective date should be first day of first calendar month following special enrollment in which individual is eligible for Part D.

§423.42 Coordination of enrollment and disenrollment through PDPs

§423.42(c)(2)
Notice of disenrollment should be in writing.

§423.44 Disenrollment by the PDP.

§423.44(b)(2)(I)
CMS requested comments about the requirement to involuntarily disenroll individuals from a PDP if they no longer reside in the service area. This raises the issue of "snowbirds"-the large number of Medicare beneficiaries who move for large parts of the year. This is a problem in Massachusetts where many elders winter in warmer climates. The churning-the enrolling and disenrolling-that plans serving this population will face as they apply this section will be enormous. Because of different formularies between plans and problems of coordination, the regulations should seek to minimize plan changes and maintain continuity of care. This section, as written, could result in a significant number of plan changes, disrupting continuity of care.

Some suggested ways to address this issue better would be to require that plans as a condition of participation have a system of visitor or traveler benefits, consider exempting regional PDPs and PDPs with out-of-network services from the disenrollment requirement, require plans to provide prospective enrollees specific information on traveler benefits and "out-of-plan service policies" and clearly define the time period that a plan could consider an enrollee as "no longer resid(ing) in the PDP's service area." such that it accommodates seasonal travelers who maintain a residence in the service area.. In many cases, 90 day mail order service and arrangements with other plans will make enrolling and disenrolling unnecessary. However, beneficiaries must have a clear understanding of how a plan will serve them while temporarily out of the service area; how when they are traveling and need emergency pharmaceutical services their plan will (or will not) reimburse for those services.

§423.44(d)(2)
Provisions in the proposed regulations to allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" create enormous opportunities for discrimination against individuals with mental illnesses, Alzheimer's, and other cognitive conditions. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and accordingly be subject to a late enrollment penalty permanently increasing their premiums. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage. Moreover, CMS lacks statutory authority to authorize PDPs to involuntarily disenroll beneficiaries. Under the MMA, section 1860D-1(b) directs the Secretary to establish a disenrollment process for PDPs using rules similar to a specific list of rules for the Medicare Advantage program. This list does not include reference to section 1851(g)(3)(B) of the Social Security Act which authorizes MA plans to disenroll beneficiaries for disruptive behavior. Thus, these proposed regulations must not be included in the final rule.

Concerns with specific provisions in this section and recommendations for beneficiary protections, which, at a minimum should be provided, are as follows:

§423.44(d)(2)(vi) Reenrollment in the PDP.
In the preamble, CMS appears to be asking for comments on whether a PDP should be allowed to refuse reenrollment of an individual who has been involuntarily disenrolled if there is no other drug plan in the area. As discussed above, it is our position that there is no statutory basis for involuntarily disenrollment. If the regulations allow this for disruptive behavior, then the plans must be required to allow reenrollment. Those individuals most likely to be subject to involuntary disenrollment will not have the resources to pay for their medications out-of-pocket. These individuals are entitled to this benefit. Disruptive behavior does not disqualify you from access to prescription drug coverage and may in fact be an indication that one is in need of medical assistance. Individuals who are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period and may therefore be subject to a late penalty and increased premium as a result. This result is unfair in light of the fact that the disruptive behavior may have resulted from denial of access to needed medications. CMS should therefore provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior, must waive the late enrollment penalty for these individuals, and the regulations must include detailed articulated protections to lessen the risks inherent in authorizing sanctions for "disruptive behavior."

§423.44(d)(2)(vii) Expedited Process.
This provision should be deleted from the final rule. The proposal to establish an expedited disenrollment process in cases where an individual's disruptive or threatening behavior has caused harm to others or prevented the plan from providing services is undefined, and provides no standards, requirements or safeguards. It allows plans to employ this mechanism on the basis of behaviors described in the broadest of terms - terms which could easily be mis-applied or applied capriciously or punitively. Thus, it would undermine all the minimal protections that would otherwise apply.

§423.46 Late enrollment penalty.
CMS should delay implementation of this section for two years. The drug benefit is a new and complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. The Medicare-endorsed prescription drug discount card program has shown that, even with significant outreach, the majority of individuals eligible for the $600 low-income subsidy have not yet enrolled. We disagree that healthy beneficiaries will not apply. We believe that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness and cognitive disabilities. Implementation of the late enrollment penalty should be delayed for individuals eligible for the low-income subsidy who may not understand that they have to apply separately for the subsidy and a drug plan, thinking that application for the subsidy is sufficient.

This section should provide that when the late enrollment penalties are implemented, there will be an opportunity for enrollees to appeal late enrollment penalties; that late enrollment penalties will be coordinated with "special enrollment periods" to ensure that individuals who take advantage of the special enrollment periods do not face late penalties; that individuals who are involuntarily disenrolled are exempt from this penalty; and that if an employer or other entity

providing drug coverage to Medicare beneficiaries fails to provide adequate or correct notice of the creditable status of that coverage or a change in status of that coverage, and that coverage is not creditable, there are no late enrollment penalties.

§423.48 Information about Part D.
Medicare beneficiaries can only exercise an informed choice about their drug plan if they have adequate information about drug plan options available to them. The information should be provided annually, in writing, and include details about the plan benefit structure, cost-sharing and tiers, formulary, pharmacy network, and appeals and exception process. In order to assure that beneficiaries have the required information, the standards should be included in regulations that are binding and enforceable, and not in guidance. Minimally, the regulations should require plans to provide premium information, including whether individuals who receive the low-income subsidy will have to pay a part of the premium and, if so, the amount they will have to pay; the benefits structure and comparative value of the plans available to them; the coinsurance or copayment amounts they will need to pay for each covered Part D drug on the formulary; the specific negotiated drug prices upon which coinsurance calculations will be based and that will be available to beneficiaries if they confront the gap in coverage; formulary structure, the actual drugs on the formulary, and how the formulary can change during the plan year; participating pharmacies, mail order options, out-of-service options; and exception, appeals and grievance processes. Plans should be required to provide this information to potential enrollees in a clear manner using a standard format that will allow beneficiaries to easily compare plans. Plans should be required to provide information on negotiated prices in an easily accessible format.

The regulations should also include specific requirements for plans and states, as well as outline activities CMS will undertake, to ensure that every effort will be made to reach dual eligibles. By summer 2005 CMS and the states should launch a concerted outreach and assistance campaign for dual eligibles to alert them about the need to enroll in a Part D plan and to help them make appropriate choices. The outreach campaign would be intended to prevent default enrollment. In addition, as early as possible, and no later than October15, 2005 (assuming information is available), CMS or the states should mail standardized, easy-to-understand notices to dual eligibles that, among other things: inform them of their eligibility to receive the low income drug benefit if they enroll in a PDP or MA-PD; list choices of health plans (clearly denoting those that meet the benefit premium assistance limit) and contact information for each plan; explain that individuals will be randomly enrolled in a prescription drug plan beginning November 15 (or, if different, the appropriate date) if they fail to opt out or enroll in a plan themselves; explain how they may change their drug plans if they wish at any time; and inform them of where in their community they can go to get help with enrollment. These notices should be tested for readability by focus groups and experts. If the states are required to provide this information, CMS should reimburse 100 percent of the states' costs.

§423.50 Approval of marketing material and enrollment forms.
The marketing rules for the PDPs and MA-PDPs should be developed in the historical context of other Medicare programs. From selective marketing to outright fraud, Medicare programs historically have been afflicted with marketing abuses and scams. We urge that CMS be vigilant to identify and prohibit these problematic areas and practices as it develops final regulations.

§423.50 (e) Standards for PDP marketing.
Telemarketing should expressly be prohibited. Door-to-door solicitation is prohibited under this section and telemarketing presents many of the same dangers. The regulations should specifically prohibit prescription drug plans from initiating telephone or e-mail contact with potential enrollees, unless the potential enrollee requests contact through such means in response to a direct mail or other advertisement.

In the Preamble, CMS asked for comments on whether it would be advisable to permit prescription drug plan sponsors to market and provide additional products (such as financial services, long term care insurance, credit cards) in conjunction with Medicare prescription drug plan services. CMS should not allow plans to market other services, nor should it seek to encourage other entities, such as financial institutions, to participate as PDPs. The potential for abuse—both cherry picking of healthier beneficiaries into plans and avoidance of financial services to less healthy individuals—is enormous. CMS also asked for comments on the applicability of MA marketing requirements for PDP marketing. PDP marketing requirements should be at least as restrictive as MA marketing because of the high potential both for confusion and for individuals to be directed to—and locked-into—plans that do not best meet their needs. Beneficiaries look to providers for balanced, unbiased information, and they should be able to rely on the information that these sources provide. However, if providers or pharmacies are allowed to market plans, there is the potential for aggressive marketing of certain PDPs, regardless of whether or not that PDP is the best for the beneficiary. The adverse consequences of making a bad selection based on promotion from a trusted source are high.

§423.56 Procedures to determine and document creditable status of prescription drug coverage.

§423.56 (e) Notification.
It is essential that beneficiaries understand whether they have creditable coverage. Failure to understand the issue of creditable coverage can lead to a lifetime of higher Part D premiums. CMS must set forth specific requirements that plans provide information to Medicare beneficiaries enrolled in those plans clearly stating whether or not the coverage they have is creditable. Minimally, in 2005, information on whether coverage is creditable or not should be provided in more than one mailing, and included in such documents as quarterly retiree income statements, medical billing correspondence, etc. After 2005, CMS should develop standard notices, through its Beneficiary Notice Initiative, to be used. In years after 2006, when creditable status changes, special notification is needed to insure that beneficiaries know as soon as the decision is made to reduce coverage, so they can begin shopping for a PDP and avoid a lifetime of premium penalties. Because this is such important notification, it should be sent by registered mail, or e-mail with proof of receipt. Additionally where beneficiaries are not adequately informed by an employer or other entity that their coverage is not creditable, CMS should take action on behalf of all the individuals of that employer or other entity to provide a special enrollment period (SEP). Each individual adversely impacted by the failure of the employer or other entity to inform adequately should not have to apply or appeal for a SEP.

Subpart C-Benefits and Beneficiary Protections

§423.100 Definitions.
"Dispensing fee" should be broadly framed, in order to permit the payment of costs associated with home infusion therapy. Of the options provided in the preamble to the proposed rule, we support option 3. We do not believe that a narrowly crafted definition of dispensing fee is appropriate because the conference report at § 1860D-2(d)(1)(B) references negotiated prices in a manner that indicates that Congress intends to define negotiated prices in a way that arrives at the most accurate prices when considering a variety of both concessions and fees. Since the antibiotics, chemotherapy, pain management, parenteral nutrition and immune globulin and other drugs that are administered through home infusion are indisputably covered Part D drugs, and equipment, supplies and services are integral to the administration of home infusion therapies, costs associated with such administration should be included in the definition of dispensing fee, in order to arrive at the most accurate determination of the negotiated price. Option 1 makes an arbitrary and inappropriate distinction between costs associated with dispensing a covered Part D drug and associated costs for the delivery and administration of a covered Part D drug, and option 2 does not capture all the true costs associated with dispensing a covered Part D drug.

"Long-term care facility" should explicitly include ICF/MRs and assisted living facilities.
We recommend that the final rule include a definition of "long-term care facility" that explicitly includes intermediate care facilities for persons with mental retardation and related conditions (ICF/MRs) and assisted living facilities. This is important because many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

§423.104 Requirements related to qualified prescription drug coverage.
The final rule defines "person" so that family members can pay for covered Part D cost-sharing. The law precludes contributions from employer sponsored health plans from being counted as incurred costs and counting toward the deductible or out of pocket limit. Contributions from one employer-sponsored benefit should not receive differential treatment over contributions from another type of employer-sponsored benefit. Contributions from employer-sponsored group health coverage should be counted as an incurred cost, similar to contributions from HSAs, HRAs, and FSAs. The final rule should also count cost-sharing subsidies from AIDS Drug Assistance Programs (ADAPs) as incurred costs. The regulations also specifically state that state-appropriated dollars spent by ADAPs cannot be counted as incurred costs. It is discriminatory and unacceptable to single out state dollars used to provide medications to people living with HIV/AIDS and not allow them to count as incurred costs, while at the same time allowing state dollars paid by State Pharmaceutical Assistance Programs' (SPAPs)to count as incurred costs.

§423.104(e)(2)(ii) Establishing limits on tiered copayments.
The final rule should not allow Part D plans to apply tiered co-payments without limits. Rather, it must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs.

§423.104(h) Negotiated prices.(1) Access to negotiated prices.
No plan should be allowed to impose 100% cost-sharing for any drug. Such cost-sharing should be considered as per se discrimination against the group or groups of individuals who require that prescription.

§423.120 Access to covered Part D drugs.

§423.120(a) Assuring Pharmacy Access.
Pharmacy access standards must be met in each local service area, rather than by permitting plans to apply them across a multi-region or national service area. Permitting plans to meet the access standards across more than one local service area could cause individuals in some local service areas to not have convenient access to a local pharmacy. Also, only retail pharmacies should be counted for the purpose of meeting pharmacy access standards. It would undermine the principle that Medicare beneficiaries will have convenient access to a local pharmacy if the access standards could be met by counting pharmacies that serve only specific populations and which are not available to all parts of the general public. The final rule should require prescription drug plans to offer to contract with Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (I/T/U) pharmacies and make available a standard contract. Should the final rule not contain this requirement and in situations where an I/T/U pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy. The final rule should also require prescription drug plans to offer to contract with all LTC pharmacies and make available a standard contract. Over 80% of nursing home beds are in facilities that require the resident to use a long-term care pharmacy. Should the final rule not contain this requirement and in situations where a LTC pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy. Furthermore, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through higher cost-sharing for out-of-network access.

§1860D-11(e)(2)(D) authority to review plan designs to ensure that they do not substantially discourage enrollment by certain Part D eligible individuals.
CMS should use the authority provided under section 1860D-11(e)(2)(D) to review plan designs, as part of the bid negotiation process, to ensure that they are not likely to substantially discourage enrollment by certain Part D eligible individuals. Previous experience with Medicare+Choice plans shows that private insurers use a variety of techniques to discourage both initial and continued enrollment in a plan by enrollees with more costly health care needs. For example, Medicare+Choice plans have offset reduced cost-sharing for doctors visits with increased cost sharing for services such as skilled nursing facility care, home health care, hospital coinsurance, and cost sharing for covered chemotherapy drugs that are utilized by people with chronic and acute care needs. CMS should thus analyze formularies, cost-sharing tiers and cost-sharing levels, and how cost-sharing (including both tiers and levels) is applied to assure that people with the most costly prescriptions are not required to pay a greater percentage of the cost of those drugs. CMS also needs to assure that a variety of drugs are included in a

formulary at the preferred cost-sharing tier to treat chronic conditions and conditions that require more costly treatments. As stated above, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through higher cost-sharing for out-of-network access.

§423.120(a)(6) Level playing field between mail-order and network pharmacies.
The final rule should ensure that beneficiary out-of-pocket costs used for the purchase of covered Part D drugs count as incurred costs. A key principle of the MMA is that Medicare beneficiaries have convenient access to a local pharmacy. This principle is undermined by permitting plans to charge beneficiaries the cost differential for receiving an extended supply of a covered Part D drug through a network retail pharmacy versus a network mail-order pharmacy. However, notwithstanding this objection, the final rule should permit the cost differential charged to beneficiaries to count as an incurred cost.

§423.120(b) Formulary requirements.
We do not believe it is appropriate for the final rule to constrain prescribers' capacity to prescribe drugs for off-label uses. By not permitting a class to exist in the USP model guidelines solely because all commonly used medications are being used for off-label indications could lead plans to deny coverage for off-label uses. Off-label prescribing has become a common-and accepted-practice across the field of medicine. For example no drugs that are currently used in the treatment of lupus (a serious, life-threatening auto-immune disorder) have the treatment of lupus as an on-label indication. For the treatment of mania, certain anti-convulsants and calcium channel blockers have proven effective and certain anti-convulsants have proven effective for treatment of bipolar disorder, although these uses are not FDA-approved on-label indications. We thus oppose any provisions in the final rule that place new limits on the ability of prescribers to prescribe drugs for off-label uses-or that legitimize the denial of coverage for covered Part D drugs simply because they are used for an off-label indication.
We support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must be protected from tiered cost-sharing that could to these defined populations must be made available at the preferred level of cost-sharing for each drug. We recommend that this treatment apply to at least the following overlapping special populations: dual eligibles, institutionalized populations, persons with life-threatening conditions, and persons with pharmacologically complex conditions.

We recommend that if the final rule limits the notice requirements to persons directly affected by the change, then plans must be required to provide notice in writing, mailed directly to beneficiary, 90 days prior to the change, and the notice must inform the beneficiary of their right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary. We also recommend that the final rule place strict limits on mid-year formulary changes, requiring plans to justify a decision to remove drugs from a formulary such as the availability of new clinical evidence indicating that a particular covered Part D drug is unsafe or contraindicated for a specific use or when all manufacturers discontinue supplying a particular

covered Part D drug in the United States. Should the final rule fail to effect such a restriction, plans should be required to continue dispensing all discontinued drugs until the end of the plan year for all persons currently taking a discontinued drug as part of an ongoing treatment regimen.

§423.124 Special rules for access to covered Part D drugs at out of network pharmacies.
The final rule must establish requirements on plans to dispense a temporary supply of a drug (wherever a prescription is presented, irrespective of whether or not it is at a network pharmacy) in cases of emergency. If the emergency situation involves a coverage dispute, the plan must dispense refills until such time as the prescription expires or the coverage dispute is resolved, through either a plan decision to provide coverage for the drug or through completion of the appeal process. This requirement must also specify that a temporary supply must be dispensed even in cases where beneficiaries are unable to pay applicable cost-sharing.

The final rule should also limit out-of-network cost-sharing to no more than the difference between the maximum price charged to any in-network Part D plan in which the pharmacy participates and the in-network price. While we recommend that this limitation apply in all circumstances, at a minimum, it must be applied through the final rule, to the scenarios described in the preamble to the proposed rule.

§423.128 Dissemination of plan information.

§423.128 (d) Provision of specific information.
It is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center. The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program.

§423.128(e) Claims Information.
In addition to the required explanation of benefits elements in the proposed regulation, the explanation of benefits should also include information about relevant requirements for accessing the exceptions, grievance and appeals processes.

Subpart J-Coordination Under Part D With Other Prescription Drug Coverage

§423.464(e) Coordination with State Pharmaceutical Assistance Programs (SPAPs).

SPAPs and new SPAPs must be able to help beneficiaries 'fill in the donut,' and we appreciate CMS's efforts to coordinate this assistance. To assure that beneficiaries are receiving seamless coverage and not facing undue out of pocket expenses, an exchange of data between the PDP and the SPAP is necessary. This should include (but not be limited to) an exchange of eligibility files, exchange of claims payment and information about the drugs on the PDPs formulary and any changes to it. Also, AIDS Drug Assistance Programs (ADAPs) should be recognized as

State Pharmacy Assistance Programs and allowed to wrap around the Medicare Part D drug benefit.

Subpart M-Grievances, Coverage Determination, and Appeals

The proposed regulations fail to meet the requirements of the Due Process Clause of the Fifth Amendment to the United States Constitution. As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid recipients whose prescription requests are not being honored currently receive a 72-hour supply of medications pending the initial coverage request. They are entitled to notice, face-to-face hearings, and aid paid pending an appeal if their request is denied and they file their appeal within a specified time frame. All state Medicaid appeals processes are completed more expeditiously than Medicare appeals. The appeals process as described in Subpart M does not accord dual eligibles and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity for a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes. While we recognize that the most efficient means of protecting enrollees, amending MMA to provide for an appeals process similar to Medicaid, is beyond the authority of CMS, CMS can take steps in the final regulations to improve notice and the opportunity for speedy review.

Sections 1860D-4(f), (g), and (h) require that Part D plan sponsors establish grievance, coverage determination and reconsideration, and appeals processes in accordance with Sections 1852(f), (g) of the Social Security Act. As will be discussed in more detail below, CMS has failed to comply with the language of those provisions. Overall, the incredibly onerous exceptions process does not comply with the statutory requirements or meet the basic elements of due process. In addition, CMS, in implementing Section 1852(c) and in settlement of *Grijalva v. Shalala*, 153 F.3d 1115 (9th Cir, 1998), *vacated and remanded*, 526 U.S. 1096 (1999), adopted 42 C.F.R. §422.626, which establishes the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review for Part D. CMS needs to incorporate a similar process for Part D in order to establish a process in accordance with Section 1852(c). A similar fast-track process would also be more in keeping with due process requirements.

As a general comment, this entire subpart needs to be made much simpler. To have two tracks, depending on (1) whether one personally pays for a drug and files an appeal or (2) does not obtain the drug and files an appeal, is far too complicated. The time frames, paperwork, and processes should be simplified into one course of action that beneficiaries may hope to understand.

§423.560 Definitions.

This section defines "appeal" to exclude grievance and exceptions processes, and defines “authorized representative” as an individual authorized by an enrollee to deal with appeals. The definition of “authorized representative” needs to clarify that a doctor or representative, including a State Prescription Drug Plan (since the SPAP may be at risk in the event of PDP

actions) can be an authorized representative, and that authorized representatives can deal with exceptions and grievances as well as appeals.

§423.562 General provisions.

§423.562(b)(5)(iii)

Reconsideration by an Independent Review Entity (IRE) should be automatic, as in the Medicare+Choice plans

§423.562(c)(1)

This subsection precludes an enrollee who has no further liability to pay for prescription drugs from appealing. However, it is important to be able to appeal formulary changes. A comprehensive change in this limitation is essential to protect the health of beneficiaries. At a minimum, SPAPs should be able to appeal on behalf of an enrollee and the section should clarify that a low-income institutionalized individual can appeal a determination, even if she has no co-payment responsibilities.

§423.566 Coverage determinations.

§423.566(b) Actions that are coverage determinations.

This subsection needs to clarify further what constitutes a coverage determination. The proposed definition does not include in the list of coverage determinations from which an appeal can be taken a determination by the PDP that a drug is not a covered drug under Part D. An enrollee should be entitled to appeal to determine whether, in fact, a drug the plan claims is not covered under Part D is so covered. The definition should also clarify that denials of enrollment in a Part D plan, involuntary disenrollment from a Part D plan, and the imposition of a late enrollment penalty are coverage determinations subject to the appeals process. Finally, the regulation should state that the presentation of a prescription to the pharmacy constitutes a coverage determination. If the pharmacy does not dispense the prescription, then the request for coverage should be deemed denied, and the enrollee should be entitled to notice and to request a re-determination. Without such clarification, enrollees will not be informed of their rights, and the appeals process will become meaningless.

§423.568, Standard timeframes and notice requirements for coverage determinations.

§423.568(a) Timeframe for requests for drug benefits.

The plan should be required to provide oral notice as soon as it determines that it will extend the deadline for considering whether it will cover a drug, including notice of the right to request an expedited grievance. The oral notice should be followed-up in writing.

§423.568(b) Timeframe for requests for payment.

This section should be eliminated. There should be no distinction in time frames when an enrollee requests payment.

§423.568(c), Written notice for PDP sponsor denials.

Who gives notice? The proposed regulations place the responsibility for providing notice of a coverage determination on the plan sponsor. This presumes a situation in which the person presents a prescription, the pharmacy contacts the plan, and then the plan takes 14 days to decide whether or not to cover a drug. In reality, the pharmacy, in most instances, tells the enrollee that the plan will not cover the drug. Without notice provided by the pharmacy, most enrollees will not know to tell the pharmacy to submit the prescription anyway so they can get a notice from which to appeal. They also may not know or understand their right to seek expedited consideration of the initial coverage determination, or an exception if the drug is not on the formulary or on too high a tier. If the enrollee pays out of pocket and then seeks reimbursement from the plan, she will not be eligible for expedited consideration.

The regulations should require the plan sponsor to develop a notice explaining the right to seek a redetermination, and to ask for expedited review. The pharmacy should be required to give the notice to the enrollee. Any potential burden of such a requirement is reduced by the need to maintain electronic communications between the pharmacies and the plans in order to keep up-to-date with formularies, coinsurance, and calculations of an enrollee's out-of-pocket expenses.

The proposed regulations talk about using "approved notice language in a readable and understandable form." The regulations need to be more specific, including information about what is required to use the exceptions process. We suggest that notice should

Include information about exceptions and appeal rights immediately upon denial (including upon determination that a drug is not covered on formulary and including denials issued by the pharmacist), explain why coverage was denied and provide options in addition to the appeal procedures for obtaining necessary medications;

Include clinical or scientific basis for denial; and

Be available in multiple languages and note the availability of language services.

In addition, all notices need to be available in alternate formats to accommodate people with disabilities, and in languages other than English where a portion of the population is not English speaking. The requirements of plans and the rights of beneficiaries in this area must be spelled out in much more detail. There is also an overarching need to consider literacy problems and encourage simplicity.

§423.568(e) Effect of failure to provide timely notice.
It is nowhere spelled out how the beneficiary is apprised of this right.

§423.570 Expediting certain coverage determinations.

§423.570(a) Request for expedited determination.
CMS requests comments on who should be able to request determinations and re-determinations. An authorized representative should be able to request expedited consideration just as the authorized representative may request a coverage determination. In emergency situations, enrollees with mental health concerns and other vulnerable individuals may need someone else to act on their behalf.

§423.570(c) How the PDP sponsor must process requests.
All coverage determinations and appeals concerning drugs, including those in which the enrollee has paid for the drug, should be treated as requests for expedited review. An enrollee would suffer adverse consequences if required to wait for the longer time periods; many people will simply go without prescribed medications pending the outcome of the review. Doubling the timeframes and disallowing expedited review in cases when enrollees pay for their drugs out-of-pocket could adversely affect the health of those who forego other necessities like food and heat in order to pay for their medicine.

At a minimum, all requests for exceptions should be automatically given expedited consideration. Where someone seeks expedited review of a request to continue a drug that is no longer on the formulary, the plan should be required to process the request in 24 hours under the provision that requires an expedited review to be completed as fast as the beneficiary's condition requires. The enrollee should be given a 72-hour supply of the medicine, which is renewable if the plan decides to take longer than 72 hours. The medicine should be treated as an on-formulary drug.

If requests for an exception are not automatically treated as a request for expedited review, the rules should state that the doctor's certificate requesting expedited review and requesting an exception should be one and the same.

§423.570(d)(2)
A beneficiary should not have to wait for a written notice to learn of the right to file an expedited grievance and the right to resubmit a request with prescribing physician support.

§423.572 Timeframes and notice requirements for expedited coverage determinations.

§423.572 (b) Extensions of timeframe.
The timeframe (of 72 hours) can be extended by the plan up to 14 days on showing that an extension is in the interests of the enrollee. The regulations should be modified to read best interest of the enrollee and define interests of the enrollee to include those situations in which the drug plan seeks additional information to substantiate the enrollee's request, or when the enrollee requests additional time to gather supporting information. The regulations should also require the plan to inform the enrollee of the extension immediately, both orally and in writing, rather than "by the expiration of extension." Also, the written notice should include more than just the reasons for the delay.

There should be no extended time period for requests for payment of drugs already received. This imposes extreme hardship on low-income beneficiaries and those with multiple prescriptions who may choose to unnecessarily spend money on their medications because of the uncertainty and length of the appeals process rather than spend the money on other urgent necessities of life.
It is not clear from the proposed regulations what notice a beneficiary will receive when sometime during the year a plan changes its formulary and the drug(s) it covers. The statute says plans must make the change in information available on the internet, the Preamble discusses a

mailed notice, and the draft regulation simply says 'notice.' A change in formulary, or a change in the tiering of a drug on the formulary should be clearly explained to a beneficiary taking that drug which has been changed. That notice should be written notice and the receipt of that notice should serve as a trigger for the beneficiary's legal rights.

§423.572(d) Content of the notice of expedited determination.
See §423.568(c) comments above.

§423.572(e) Effect of failure to provide a timely notice.
How does a beneficiary know s/he can appeal the lack of timely notice?

§423.578 Exceptions process.
The proposed regulations do not explain how an enrollee will get notice about the exceptions process and/or that a drug is not included on the formulary. The only notice requirement is found in §423.120(b), which requires the plan sponsor to provide at least 30 days notice to CMS, affected enrollees, pharmacies, pharmacist and authorized prescribers before removing a drug or changing a drug's preferred or tiered status. Although the preamble talks about written, mailed notice, and the statute requires posting on the Internet, the regulatory language merely says that notice must be given.

To meet basic due process requirements concerning termination of benefits, the notice of the change must be in writing and must include an explanation of how to use the exceptions process, including the requirements for a doctor's certificate, the right to a hearing, and the reasons why a drug is not included on or removed from the formulary, or why the tier is changing, and the evidence required to establish an exception.

Proposed section §423.120(b) provides insufficient time for the notice, given the substantial burden placed on the enrollee to either get a new prescription or to gather the medical evidence. Many beneficiaries will not be able to get a doctor's appointment within 30 days, and many will not be able to change drugs without a medical evaluation. The final regulations should state that notice must be provided 90 days in advance of the change.

In addition, the exception process section should include a subsection on notice that (1) refers to §§423.120(b) and (2) requires plan sponsors to develop a notice that explains the exceptions process, the situations in which someone may seek an exception, and the information that is required to support an exception request, which the pharmacy will give to an enrollee who requests coverage for a non-formulary drug or requests to be assessed a lower cost-sharing amount.

§423.578 (a)(2).
This subsection fails to meet the statutory requirement that the Secretary establish guidelines for an exception process. The plan statutory language is not permissive; it does not say that plans may establish additional criteria if they wish. It says that the Secretary is to establish criteria and the plans are to abide by them. Plans should have no discretion whatsoever. The fact that they may establish differing tiered structures is not relevant to the statutory right to request an

exception to whatever structure they devise. In fact, the flexibility accorded to plans is why beneficiaries need strong guidelines to protect their interests.

Where the proposed regulations include guidance for criteria, the criteria listed exceed the scope of the statute. The proposed regulations list a "limited number of elements that must be included in any sponsor's exception criteria," but this list includes criteria that do not apply based on the statutory provision that states an exception applies if a physician determines that a preferred drug would not be as effective or would have adverse effects or both.

The proposed rules also fail to provide adequate guidance to physicians concerning whether the standard requiring the doctor to certify that a preferred drug would not be as effective or would cause adverse effects has been met.

The final regulation should require that the lowest co-pay that applies should apply to drugs for which an enrollee has won an exception to the tiered cost-sharing structure. That's the whole point of this process - to infuse some equity upon a showing that none of the other medications covered are as effective or may cause harm.

The final rule should also include the following omitted criteria: regulations permitting continued access to a drug at given price when there is a mid-year formulary change, and regulations requiring sponsors to give enrollees an opportunity to request exceptions to a plan's tiered cost-sharing structure other than on a case-by-case basis.

§423.578(b) Request for exceptions involving a nonformulary drug.
This subsection fails to meet the statutory requirement that the Secretary establish guidelines for an exception process. In the preamble, CMS states that "[r]equiring sponsors to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied" and will help ensure these formularies "are based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs ." However, the proposed regulations give drug plans complete discretion in determining the criteria they will use to determine exceptions requests. In addition, independent review entities "would not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." By failing to adequately define the criteria plans may use to consider exceptions requests or provide any meaningful oversight over these criteria, these proposed regulations would not ensure that formularies are based on scientific evidence and would not establish a transparent process. The regulations as written subvert CMS's stated goals.

The proposed rules set an impossibly high bar for receiving an exception by requiring prescribing physicians to produce clinical evidence and medical and scientific evidence to demonstrate that the on-formulary drug is likely to be ineffective or have adverse effects on the beneficiary. Clinical trials generally do not include older people, people with disabilities and people with co-morbidities. While some such evidence does exist, it has not been developed for all drugs and conditions. However, a physician may have extensive experience treating these kinds of patients with the condition or illness at issue and this experience should be given at least

equal weight in making such determinations. In fact, the statutory standard requires deference to the doctor's determination that all on-formulary medications would not be effective or cause adverse consequences. This required deference is not reflected in the proposed rules. It is also important that the final rules recognize the existence of individual differences in reactions to the same drug and that exceptions be available to someone who can not tolerate or who does not benefit from a drug even though that drug is beneficial to most people.

The NPRM proposes to authorize plans to require a long list of information in the written certification from the prescribing physician that an off-formulary drug is needed. This list is overly long and repetitive and may encourage drug plans to establish burdensome paperwork requirements as a hurdle to prevent physicians and consumers from following through on an exceptions request. Moreover, this proposed rule also leaves the required contents entirely up to the plan's discretion by including the catch-all phrase - "any other information reasonably necessary". The requirements for this written certification should be standardized to facilitate use of the exceptions process by providers and consumers. These standards would also help achieve CMS's stated goal of establishing a transparent process.

An important provision was left out of the requirements for receiving a dosing exception. The proposed rule states that in order to receive an exception, the physician must demonstrate that the number of doses available is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. This rule must also allow exceptions if the prescribing physician demonstrates that the number of doses available would cause an adverse reaction or harm to the enrollee - as provided in the proposed rules for other kinds of exceptions requests.

The final regulation should clarify that formulary use includes not just dose restriction, but the format of the dosage (liquid vs capsule, etc.) and packaging, such as bubble wraps for long-term care facility residents.

§423.578(c)(2) When a sponsor does not make a timely decision.
The regulation provides for a one month's supply of a drug, but only if the plan does not act timely on an exceptions determination. If the request for an exception is not given expedited treatment, the sponsor can take two weeks to issue a decision, meaning the enrollee would wait two weeks before getting the supply of medicine. Even if the exception is treated as a request for expedited review, the enrollee would still have to wait 72 hours (unless s/he could show the decision needed to be made more quickly because of her/his condition.) Most people wait to the last minute to refill a prescription, often because of drug plan and pharmacy restrictions.

It is also unclear how an enrollee knows about these rights when a sponsor does not make a timely decision.

The enrollee should be entitled to a one month's supply upon presenting the request for a refill and upon presenting a new prescription for a non-formulary drug. Plans should be required to make exception determinations and notify the enrollee in 24 hours as required under Medicaid for prior authorization determinations. 42 U.S.C. §1386r-8(d)(5)(A).

We cannot overemphasize the importance of drug coverage and ensuring no gaps in the intake of medication. In mental health and HIV/AIDS, for example, it is essential that medications be available quickly and without interruption. In the HIV/AIDS sector, for example, consistent research proves that the risk of drug resistance and resulting treatment failure significantly increases with each missed dose of therapy.

423.578(c)(3), When an exception request is approved.
The lowest coinsurance amount should apply anytime an enrollee wins an exception through this process because the drug at issues has been determined medically necessary with no on-formulary drug as a suitable alternative. The exception for the non-formulary drug thus meets the criteria for an exception to the tiered cost-sharing structure as well.

The regulation needs to clearly set forth the requirement that notice be provided when a decision is made on an exception request. The notice should explain that the decision is a coverage determination and explain the appeal rights that are available.

We commend CMS for specifying that, once an exception request is granted, a plan sponsor may not require the enrollee to keep requesting exceptions in order to continue receiving the drug. However, we are concerned that the "exception" to this protection which allows the plan to discontinue a drug if safety considerations arise, is too broad. The final regulation should be revised to permit reversal of a previously granted exception only if the FDA determines that the drug is no longer safe for treating the enrollee's disease or medical condition.

We are concerned that the timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed provisions raise similar concerns. It is extremely unfair to require longer time frames if a beneficiary has paid out of pocket for a needed medication when their alternative would be to wait two weeks to a month for a determination or an emergency one-month supply of the needed drug. Beneficiaries' health and safety may well be at risk if they are forced to forego other necessities because of the added, and most likely very significant, expense of paying out of pocket for their medicines. Although the proposed regulations include some provisions for an emergency supply of medications while a plan is considering an exceptions request, it is unreasonable and bad health policy to make beneficiaries wait two to four weeks before the drug plan must provide an emergency supply. In addition, plans should be required to demonstrate that an extension of the standard time frame for exceptions determinations is in the best interest of the enrollee and the final rule must charge independent review entities with exercising oversight over these extensions. Plans should be required to make determinations regarding exceptions requests and notify the enrollee of these determinations in 24 hours as required under Medicaid for determinations regarding prior authorization requests (42 U.S.C. 1396r-8(d)(5)(A)).

§423.580 Right to a redetermination
The proposed regulations only authorize an enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) to request a redetermination or an expedited redetermination. The enrollee's authorized representative must also be allowed to request a redetermination and an expedited redetermination. Since the proposed regulations would allow an enrollee's authorized

representative to file a request for Determinations and Exceptions, it does not make sense to not allow an enrollee's representative to pursue a claim further through the redetermination, reconsideration, and higher levels of appeal. In fact, the proposed regulations define an authorized representative as an individual authorized to act on behalf of an enrollee "in dealing with any of the levels of the appeals process".

§423.584 Expediting certain re-determinations.
The regulations need to describe in detail the notice responsibilities for both standard and expedited re-determinations, including what must be provided in the notice. This is crucial, given that the next level of review to the IRE is not automatic, as it is with Medicare Advantage plans. The notice should explain the reason for the denial, including the medical and scientific evidence relied upon, the right to request review, or expedited review, to the IRE, including timeframes and the right to submit evidence in person and orally.

§423.584(a) Who may request an expedited redetermination.
See §423.580 regarding allowing an individual's authorized representative to request an expedited re-determination.

§423.584(d)(2).
The information in the letter should also be provided orally. The enrollee should not have to wait three days for this information.

§423.586 Opportunity to submit evidence.
The regulations should establish clear criteria for informing the enrollee and the physician that they can submit evidence in person, as well as clear procedures for in-person review.

§423.590 Timeframes and responsibility for making redeterminations.
The regulation should be amended so that a plan can only extend the timeframe for a re-determination if requested to do so by the enrollee, or if the plan can demonstrate that the extension is in the best interest of the enrollee (for example, the plan needs to obtain additional information to support the enrollee's request). As previously stated, all re-determination requests, and particularly those involving exceptions, should be treated as expedited, and plans should not be given more time to resolve re-determination requests involving payment requests.

§§423.590(c) Effect of failure to meet timeframe for standard redetermination and (e) Failure to meet timeframe for expedited redetermination.
Again, how does enrollee know this and know what to do?

§423.600 Reconsideration by an independent review entity (IRE).
CMS needs to clarify in the final regulations that the role of the IRE is to provide independent, de novo review, especially in regard to the exceptions process. The preamble states that "…The IRE's review would focus on whether the PDP had properly applied its formulary exceptions criteria for the individual in question…..the IRE will not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." If the IRE does not review all the

evidence and issue a reconsideration decision based on its own analysis, then enrollees will be denied independent review, and the requirements of due process will not have been met.

Further, because, as noted above, CMS is required by the statute to set standards for the exceptions process, the IRE must have authority to determine whether the PDP's exceptions criteria comply with the statute. Otherwise, enrollees will have no mechanism for review of arbitrary and improper standards.

Since the Part D process is supposed to follow the MA process, the regulations should follow the MA regulations and require that denials automatically be sent to the IRE for reconsideration. The regulations as written create a barrier to the first level of independent review for enrollees who have difficulty following the complicated process. We dispute CMS's statement in the preamble that many of the drug appeals will involve small monetary amounts. Rather, most will involve medications for chronic conditions that enrollees take on an on-going basis; the yearly sum of the cost-sharing will be quite substantial, especially considering the income level of most people with Medicare. In addition, by requiring the enrollee to file a request for ALJ review, the first truly independent review available, CMS can satisfy the statutory requirement that the enrollee files the appeal.

If the final regulations continue to place the burden of requesting a reconsideration on the enrollee, they need to clarify that an authorized representative can act on the enrollee's behalf. Again, without such clarification, enrollees who lack the capacity to file a reconsideration request will be denied their due process rights. In addition, the prescribing doctor should also be permitted to request a reconsideration, especially since the enrollee needs the doctor's statement in order to request IRE review of an unfavorable exception request.

Finally, the enrollee should be allowed to request a reconsideration orally, especially where the request is for an expedited review.

§423.600(b).
We are pleased that CMS is requiring the IRE to solicit the view of the treating physician. We believe the IRE should also be required to solicit the view of the enrollee. However, because in our experience the MA independent contractor is often reluctant and unwilling to accept the views of and evidence from the beneficiary, the final regulation needs to be more specific. The regulation needs to specify how this will occur, including contact by telephone, email, or face-to-face meeting.

§§423.600(d).
The regulations need to establish a set timeframe by which the IRE must issue its decision in order for this process to be transparent. Enrollees will have no knowledge of the contract between CMS and the IRE and thus will not know how long they will have to wait for a reconsideration decision. Also, if contractual, the time frame can change with each new contract, putting enrollees at greater risk of adverse health consequences from being denied needed medicines. The regulation should also state that an enrollee may appeal to an ALJ if the IRE fails to act within the regulatory time frame and how the enrollee will be apprised of this right.

§423.602 Notice of reconsideration determination by the independent review entity.
The language concerning what the notice must entail is ambiguous. The notice must "inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under 423.610." Does this mean that the notice tells you that you can go to an ALJ, but only if your claim is large enough? Or does this mean the IRE only has to tell you about your right to an ALJ hearing if your claim meets the threshold amount? The latter interpretation is problematic for several reasons, including the fact that you can aggregate claims. The final regulation should state that the notice must inform the enrollee of his or her right to an ALJ hearing, and the procedure for requesting such a hearing, including the dollar amount required to request a hearing.

§423.610 Right to an ALJ Hearing.
Congress recognized the special needs of the low income, and how even small copayment amounts can cause many lower income individuals to forgo filling prescriptions. We urge CMS to provide exceptions to the ALJ threshold requirements for those receiving the Medicare subsidy. For example, the amount at controversy for a lower-income individual could be deemed to be the amount that would be at controversy if the individual were a non-subsidy eligible individual receiving the standard benefit.

It is unclear what §423.610(c) intends when it says, "Two or more appeals may be aggregated by the enrollee… if (I) the appeals have previously been reconsidered by an IRE…" Does this mean that an enrollee will have to file a new appeal each month for a prescription to treat an on-going chronic condition? Such a requirement would be unduly burdensome for enrollees, drug plans, the IRE, and the ALJs. The final regulation needs to clarify that when the plan denies coverage, in order to satisfy the jurisdictional amount an enrollee should be able to add up the cost of the medicine for a year, if the medicine treats an on-going chronic condition, or for the number of refills authorized if the underlying condition is not chronic.

Subsection (ii) says the request for the hearing must list all of the appeals to be aggregated and must be filed within 60 days after all of the IRE reconsideration determinations being appealed have been received. If you are consolidating appeals, and the first denial is in April and the last one you need to get to the jurisdictional amount is in August, will you still be timely? Or does it have to be 60 days from the first denial in April?

§423.612 Request for an ALJ Hearing.
The regulation should specify that, if an appeal is filed with the PDP, the PDP must submit the file to the IRE within 24 hours of receipt of the request, and the IRE must transmit the file to the ALJ within 24 hours. Our experience is that, without set time frames, some current reviewing entities take long periods of time, adding to the delay in the processing and resolution of ALJ appeals.

The regulations also need to require the IRE to include all of the information in the file, such as doctor's statements, statements by the enrollee, and any other evidence submitted by the enrollee, including information not relied upon in making its decision. It has been our experience that

contracting entities, including MA plans, often omit evidence submitted by the enrollee when transferring a file to the ALJ or other level of review.

§§423.634, Reopening and revising determinations and decisions and 423.638 How a PDP sponsor must effectuate expedited redeterminations or reconsidered redeterminations.
Subsection (c) in both of these draft regulations allows the PDP to take up to 60 days to implement a reversal by the IRE, an ALJ, or higher. That's totally unacceptable, since further delays may cause increased health consequences to people who have foregone medication pending appeal. Favorable decisions should be implemented in the same 72 hour time period as reversals at earlier levels of review.

Subpart P - Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§432.772 Definitions.
"Family size." We support defining family members as relatives in the household receiving at least half of their support from the applicant or applicant's spouse. In order to minimize burdens on beneficiaries, the regulations should specify that applicants will be able to self-attest to the status of dependents, without providing further documentation.

"Full subsidy eligible individuals." The definition should refer to the language of §§423.773(b) and(c), in order to avoid ambiguity.

"Income." The definition should make clear that income not actually owned by the applicant, even if his or her name is on the check, should not be counted.

"Institutionalized individual." The definition should include those individuals eligible for home and community based services under a Medicaid waiver (see, e.g., definition of "institutionalized spouse" at 42 U.S.C. § 1396r-5(h)(1)(A)), since those individuals must meet the acuity standards for Medicaid coverage in a nursing facility, and should include individuals in ICF-MRs and individuals in any institution in which they are entitled to a personal needs allowance.

The definition should not include the language "for whom payment is made by Medicaid throughout the month" since an individual could conceivably be a full benefit dual eligible recently returned from a hospital stay whose nursing facility stay would be paid for by Medicare Part A for the entire month. Even though in that month all their drugs are likely to be paid for by Medicare Part A, as a practical matter, for continuity and minimum disruption, they should not lose their status as an "institutionalized individual." The same reasoning should apply to a full benefit dual eligible individual who might be hospitalized during an entire month, during which their entire stay would also be paid for by Medicare Part A.

"Personal representative." The portion of the definition that permits an individual "acting responsibly" on behalf of an applicant needs further clarification as to who would determine that the individual is acting responsibly and what circumstances would constitute a per se conflict of interest.

"Resources." We support the limitation of countable resources to liquid assets. However the definitions of liquid assets and what it means to be able to be converted into cash in 20 days need to be clarified. The final rule should include a specific list of countable resources to promote clarity for state and beneficiaries. Resources should not include burial plots, burial funds or life insurance of any value, nor should it include any officially designated retirement account, such as an IRA, 401(k), 403(b) etc. Alternatively, the respective exclusions for the value of life insurance and burial funds should be increased to a reasonable amount, such as $10,000 per asset. Most potential low-income beneficiaries have assets below this level.

Excluding these resources will ease the application process for consumers and eligibility workers, as well as reduce administrative costs by reducing the time and effort required to verify assets. This is consistent with both Congress's and CMS's intent. Resource assessments should not include any consideration of transferred assets, as would otherwise be required under SSI rules.

We note that a current draft of the SSA application for the low-income subsidy inquires whether an applicant has life insurance with a face value of $1,500 or more. CMS must ensure that any proposed SSA application is harmonized with these rules on assets and income. As noted above, life insurance should not count towards assets, and this question should be eliminated.

§423.773 Requirements for eligibility.
We support the proposal to make dual eligibles (both full dual eligibles and those in Medicare Savings Programs (MSPs)) automatically eligible for the low-income subsidy. As we explain below, however, we believe a great deal more specificity is needed in this section. We are particularly concerned that the proposed rule leaves room for ambiguity regarding these beneficiaries' status. We believe that the proposed eligibility rules for partial dual eligibles will result in inequities and confusion. In addition, the draft regulations do not adequately explain how low-income beneficiaries are to be notified about their eligibility, nor do they explain how prescription drug plans are to determine which beneficiaries are enrolled in the low-income subsidy. The proposed rules also do not adequately protect low-income beneficiaries whose enrollment is delayed or is processed erroneously.

§423.773(a) Subsidy eligible individual.
Although the statute defines a subsidy eligible individual as one enrolled in a Part D plan, the requirement in Subpart S that states take applications for the low-income subsidy beginning July 1, 2005, before Part D plans are available to be enrolled in makes it clear that CMS believes people should be able to apply for the low-income subsidy without being enrolled in a Part D plan. This is actually imperative, as otherwise, an individual would be forced to pay a plan premium that the subsidy, in fact, pays for them. The subsidy eligibility determination would be done "conditionally" - conditioned upon the individual enrolling in a Part D plan. The regulations should reflect this reality and clearly direct both SSA and state Medicaid programs determining eligibility that the individual can both apply and be determined subsidy eligible before she or he has enrolled in a plan

§423.773(b) Full subsidy eligible individual.

The indexing of resources should indicate that rounding is always up to the next multiple of $10.

§423.773(c) Individuals treated as full subsidy eligible.
This section should conform to Subpart S § 423.904(c)(3) which requires states to notify all deemed subsidy eligible individuals of their subsidy eligibility. It should specify that the notice must be given by July 1, 2005 for those individuals eligible at that time. For those who subsequently become eligible, notice should be given at the same time the individual is notified of their eligibility for the benefit that qualifies them to be treated as a full subsidy individual. The notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. For those who will lose Medicaid coverage January 1, 2006, the notice should explain their appeal rights as well. Individuals should also be told of their right to appeal the level of subsidy to which they are entitled.

Section 209(b) states and non-1634 states must coordinate with the Social Security Administration to determine how to provide notice to SSI recipients who are not receiving Medicaid and who therefore do not appear on the state's Medicaid rolls.

§423.773 states that both full benefit dual eligibles and MSP beneficiaries are eligible for the low income subsidy, but it does not explicitly state that these beneficiaries are automatically enrolled in the subsidy program. The regulations should be absolutely clear that an individual treated as full subsidy does not have to take any further action with respect to the subsidy (i.e., make application or in any other way verify their status), but only to enroll in a Part D plan. This will help smooth the transition from Medicaid drug coverage for dual eligibles, and should improve participation for others.

§423.773(c)(3).
We support the decision reflected in this proposed subsection to deem MSP beneficiaries automatically eligible for the low-income subsidy. We are concerned, however, that inequities and confusion among beneficiaries may result because SSA will not apply the more generous income and asset MSP eligibility rules in place in some states (for example, Alabama, Arizona, Delaware, and Mississippi, which have eliminated consideration of assets for MSPs). Eligibility requirements should be the same for all subsidy-eligible individuals in a state, regardless of where and how they apply. Under the proposed regulations, in states that have adopted less restrictive income and asset methodology, people whose assets or income are slightly above the limits set in § 423.773 would be enrolled in a less generous subsidy, or have their application rejected entirely, if they apply directly through SSA, because SSA will apply the national guidelines proposed in §423.773. However, the same people would have their application accepted if they applied through their states' Medicaid offices, were screened and then enrolled in an MSP, and were then automatically eligible for the low-income subsidy.

To resolve this problem, we propose that SSA apply state-specific income and asset eligibility rules in determining eligibility for the low-income subsidy, an option discussed, though rejected, in the preamble. This means that for applicants from states that have eliminated the asset test or

increased disregards under §1902®)(2) for MSP eligibility, SSA should apply the state's rules to determine eligibility. This option is permitted under §1860D-14(a)(3)(E)(iv) of the statute.

Alternatively, the regulations should provide that subsidy applicants who appear to have excess assets or incomes would either be screened by SSA for eligibility in an MSP program, or have their applications forwarded to the state Medicaid agency to be screened for MSP eligibility. States would be precluded from requiring beneficiaries to resubmit information, such as income and asset levels, that they have already provided to SSA. Applicants would be enrolled in the appropriate MSP program, and then be enrolled in the appropriate low-income subsidy under proposed § 423.773(c). Adopting this policy, which is not precluded by statute, will ensure that all subsidy applicants are treated equitably, as well as increase participation in MSPs.

As part of this alternative policy, the low-income subsidy application should allow an applicant to opt out of screening and enrollment for an MSP, as some applicants may not wish to participate in an MSP. Under §1860D-14(a)(3)(v)(II) of the statute, beneficiaries who are determined eligible for MSPs may be enrolled in the low-income subsidy. There is no requirement that beneficiaries actually enroll in an MSP. Therefore, applicants who meet eligibility requirements for an MSP, but who decline to enroll in the program, should still be automatically eligible for the low-income subsidy.

Because enrollment in an MSP can affect the amount of assistance a beneficiary may receive through other public assistance program, such as Section 8 housing vouchers or food stamps, there will be a profound need for beneficiary counseling during the enrollment process. We recommend that CMS plan for this need by making funds available to local agencies, including state health insurance assistance programs (SHIPs), and other community-based organizations.

This draft regulation states that a state Medicaid agency must notify full benefit dual eligibles that they are eligible for the low-income subsidy and should enroll in a Part D plan. The regulations do not state, however, when this notice should be issued, or what the notice should say. Consistent with our comments above and those accompanying 423.904(c)(3), the notification should be sent to beneficiaries on or near July 1, 2005, when states will have made the automatic eligibility determinations.

We also suggest that CMS develop model notices based on input from beneficiaries, which would explain the purpose of new subsidy simply and clearly. The notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. It should also explain as simply as possible what level of subsidy the beneficiary will receive, and the beneficiary's appeal rights if she believes the subsidy level is in error.

The draft regulation fails to address eligibility issues for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) state. These beneficiaries should be informed of their likely eligibility for a low-income Medicare subsidy and given an opportunity to enroll. When they have met their spenddown, they should be informed of their entitlement to a lower co-payment, if applicable, as a deemed subsidy eligible.

Our recommendations for redeterminations of these beneficiaries are discussed below, in §423.774.

§423.773(d) Other subsidy eligible individuals.
The indexing of resources should indicate that rounding is always up to the next multiple of $10.

§423.774 Eligibility determinations, redeterminations, and applications.

§423.774(a) Determinations of whether an individual is a subsidy eligible individual.
This subsection provides that determinations of eligibility for the subsidy are to be made by state Medicaid agencies or by SSA, depending on where an individual applies. We believe that in order to ensure prompt enrollment in both the subsidy and ultimately in a plan, the regulations should specify that a determination notice must be sent to the applicant no later than 30 days after the application is filed. Because determinations for the low-income subsidy should be a simple process, very little time should be required to render a decision. Both SSA and states should be required to notify CMS with 24 hours of a individual being determined eligible for the subsidy.

§423.774(b) Effective date of initial eligibility determination.
In order to avoid delays in the ability of beneficiaries to use their subsidy benefits while their application is pending, the final rule should offer beneficiaries the option of applying through a presumptive eligibility system. Such a system would be especially helpful to beneficiaries who have enrolled in a Part D plan but are not yet receiving the low-income subsidy. Applicants can complete a short form at a provider's office or other location in which they declare their family size, income and assets. If their income and assets are below the relevant eligibility levels, they are found presumptively eligible. Applicants may still be required to complete a full application within a prescribed period of time (typically 30 to 60 days) if additional information is required. In the meantime, however, beneficiaries are given temporary cards that they can present to health care providers and receive services immediately. Experience has shown that the error rate for these enrollment systems is very low. In the rare cases where beneficiaries are later found ineligible, they and their providers are held harmless for the benefits they receive during the presumptive eligibility period.

Applicants for the low-income subsidy could be found presumptively eligible at state Medicaid offices, SSA offices, pharmacies, or other providers. If the low-income subsidy application form is simple enough, applicants could complete the form itself and self-attest to their income and assets. If they appear to be eligible, they would be enrolled in the appropriate subsidy while their application is processed. They would receive some form of temporary certification stating that they have been presumptively enrolled, which their pharmacy would accept while their application is processed. Such a system would encourage beneficiaries to apply, as they would be able to see the benefits of the system immediately.

§423.774(c) Redetermination and appeals of low-income subsidy eligibility.
There should be a provision for prompt reconsideration of a subsidy eligibility determination, for beneficiaries who believe they have either been erroneously denied eligibility or approved for the

wrong subsidy category. The provisions applying the appeal rules of state Medicaid plans or SSA do not provide for a prompt reconsideration process. Because obtaining prescription drugs is so vital, and especially because low-income beneficiaries are unable to pay the costs of their prescription drugs out of their own pockets, a quick reconsideration process is essential.

The draft regulation refers to redeterminations and appeals under the state Medicaid plan. This is inadequate, as frequent redeterminations in place in some states will cause some beneficiaries to drop out of the program. To maximize enrollment, the rule should establish that all determinations are for one year, per the Secretary's authority under the statute. We also urge CMS to adopt an annual, passive, and simple redetermination for all beneficiaries, whether they have enrolled through SSA or states. Should it be necessary, the Secretary should direct the Commissioner of SSA to create such a system. Under a passive redetermination system, beneficiaries would be sent a statement of the relevant information on file and asked to respond only if any of that information had changed over the year. If they do not respond, their coverage would continue unchanged for another year.

If states are not required to adopt passive redeterminations, we urge that redeterminations be made as they are under the state's MSP programs, or under the most passive, simplified redetermination process used for any category of coverage under the state plan.

§423.774(d), Application requirements.
This section should make clear to both states and SSA that no documents should be required of the individual as long as the applicant authorizes the agency to verify information from financial and other institutions. Documentation production should be only the absolute last resort.

Also, as we mentioned in our comments to §423.773 above, the proposed rule does not address eligibility determinations and recertification periods for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) state. Once beneficiaries become deemed subsidy eligible individuals by completing their spenddown, they should retain that status for a full year, until their next redetermination for the low-income subsidy, regardless of whether they go off Medicaid. Otherwise, individuals who go in and out of medically needy status, depending on the length of their state's budget period, will have extremely confusing changes regarding their Medicare low-income drug subsidy.

§423.800 Administration of Subsidy.

§423.800(a), Notification of eligibility for low-income subsidy.
We are concerned that there is no provision in §423.800(a) specifying a time period by which CMS must notify a plan that an enrollee is eligible for a subsidy. This is an essential step in the process, because without the subsidy, prohibitive costs will prevent low-income beneficiaries from using their Part D benefits. We propose that CMS be required to inform Part D plans of beneficiaries' enrollment in the subsidy no later than 24 hours after the application for the subsidy is approved. As this will likely be an electronic notification, it should not be burdensome. It is vital that plans know which beneficiaries are enrolled in the subsidy, so that these low-income beneficiaries do not have to pay the full cost of their prescriptions while their subsidy application is process.

§23.800(e), Reimbursement for cost sharing paid before notification of eligibility for low-income subsidy.
The draft reimbursement provisions are inadequate to protect low-income beneficiaries. The proposed regulation would require plans to reimburse low-income beneficiaries for excess copayment and premium amounts made after the effective date of the subsidy application. This is not a realistic solution to the problem facing beneficiaries who have prescription drug needs before their Part D plans are notified that the beneficiaries are subsidy-eligible and need to have their records adjusted accordingly. Low-income beneficiaries will not be able to afford to pay these costs out of their own pockets with the expectation of being reimbursed later. Instead, these beneficiaries will forego prescription drug coverage until their plan processes their subsidy, making the first month or more of their subsidy period meaningless.

Adoption of a presumptive eligibility system recommended above would alleviate this problem. As an additional alternative, the regulations should provide that beneficiaries may present their notice of approval for the subsidy to their pharmacy when they seek prescription drugs. Pharmacies should accept this notice as adequate to relieve the beneficiary from making a co-payment, and instead seek reimbursement for the beneficiary's plan.

Subpart S - Special Rules for States - Eligibility Determinations for Subsidies and General Payment Provisions

§423.904 Eligibility determinations for low-income subsidies.

§423.904(a) General Rule.
This subsection should cross reference the entire Subpart P, or, at a minimum the definitions included in §423.772.

§423.904(b) Notification to CMS.
The rule should direct states to notify CMS of eligibility determinations within 24 hours of making them, as we previously recommended with respect to SSA determinations.

§423.904(c) Screening for eligibility for Medicare cost-sharing and enrollment under the State plan.
The proposed regulation regarding states' obligations to screen subsidy applicants and offer them enrollment in Medicare Savings Programs ("MSPs") are inadequate. In particular, the regulation should specify what "offer enrollment" means. We believe an applicant must be offered the opportunity to enroll during the same visit or contact (in office, by phone, or by mail), without providing any further documentation or completing any additional forms. Only if enrollment is easy and convenient will Congress's intent of increasing participation in MSPs be accomplished. Furthermore, because under the current rules, enrollment in an MSP may be the only entry into the subsidy for some beneficiaries, a quick and easy application for MSP programs is essential. As written, the regulation would permit states to say they have "offered enrollment" simply if they tell applicants that they might be eligible for an MSP and may return another time to complete another application form if they wish to apply. Such an outcome would defeat the

purpose of the screen and enroll provision included in the new §1935(a)(3) established in §103(a) of the statute. Instead, as proposed in our comments to Subpart P, the low-income subsidy application should include an "opt-out" provision, under which qualified applicants would be enrolled in an MSP unless they affirmatively decline to do so. This provision would explain that enrollment in an MSP may be another way to qualify for the low-income subsidy.

As we explained in our comments to Subpart P, because enrollment in an MSP may affect receipt of other public benefits, there is a tremendous need for good quality counseling of beneficiaries. In addition, in order to ensure that enrollment requirements between MSPs and the low-income subsidy are aligned, states should not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective and can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP.

In the interest of further aligning eligibility rules for MSPs and the low-income subsidy and easing administrative burdens, we suggest that CMS direct states to apply the definitions of resources used in Subpart P, §423.772, in making their resource determinations for MSP applicants.

In addition, should CMS adopt a policy, as has been discussed publicly, under which most subsidy applications to state Medicaid agencies would be forwarded to SSA for the actual eligibility determination, the regulations should be clear that the screening for MSP eligibility must take place prior to the processing of the applications to SSA. Potential beneficiaries should not have to wait to be screened and offered enrollment in MSPs. Furthermore, an individual cannot be told, by either SSA or the state that she or he is ineligible for the low-income subsidy until MSP eligibility has been determined (if the individual wishes). It would be incredibly confusing for an individual to receive a notice from SSA that she is ineligible for a subsidy, have her MSP eligibility determined by the state, then receive a notice from the state that she is eligible for both MSP and the subsidy. Whatever the mechanics, the individual must be told that MSPs are a route to subsidy eligibility.

Finally, as we discussed in our comments to §423.773, SSA should also screen subsidy applicants for eligibility in MSPs as well, and develop a system with states to enroll eligible beneficiaries. Applicants should not miss out on the opportunity to enroll in MSPs because they apply through SSA rather than state Medicaid offices. The same concerns about beneficiary education and estate recovery discussed above apply to enrollment through SSA.

The regulations should also ensure that beneficiaries are screened for eligibility for full Medicaid and offered enrollment if they qualify, consistent with 42 C.F.R. §435.404. Ideally, all subsidy applicants would be screened for Medicaid, and offered enrollment if they qualify. Because the importance of maintaining a simple application process for the subsidy is paramount, CMS may wish to consider using a simple screening process based on information obtained through the subsidy application. This screening would trigger a follow-up with applicants who appear to be eligible for full Medicaid.

Many Medicare beneficiaries who are eligible for a low-income subsidy under the Part D Program will also be eligible for other important benefits. Some of these benefits, such as food stamps, are also administered by states and have eligibility rules that very closely correspond with the new eligibility rules for the Part D subsidies. Historically participation by seniors and people with disabilities in these programs has been low, despite the fact that the benefits that low-income Medicare beneficiaries would be able to receive could help them struggle less to make ends meet every month. The Part D enrollment process offers an historic opportunity to connect Medicare beneficiaries to these other programs.

Beyond saying that applications may be filed either with a State's Medicaid program or with SSA, the proposed rule has very little detail about how the application process is likely to work. We urge CMS to specify that the new eligibility process should dovetail with other programs so that low-income Medicare beneficiaries can be enrolled as seamlessly as possible in all the state- or SSA-administered benefits for which they qualify

423.904(d)(3)(ii), Cost-effectiveness of information verification.
This section should be modified to permit states to use the verification process established by the Social Security Administration to verify the income and assets of people who apply for a Part D subsidy through a state Medicaid agency.

PART 403-SPECIAL PROGRAMS AND PROJECTS

Subpart B-Medicare Supplemental Policies

Disclosure notices advising consumers of their statutory rights must be short, simple, easy to understand, and address as few issues as possible. The proposed disclosure notice concerning Medigap policies H, I, and J included in the Preamble is too long, provides unnecessary information, and includes information that may not be accurate for all beneficiaries. We suggest that the letter be modified as follows:

Delete the information about Medicare Part D at the beginning of the disclosure notice;
Delete statements about the value of Part D benefits, which are irrelevant to the issue of changes to Medigap;
Delete the second statement about the need to notify the Medigap issuer if a person later enrolls in Medicare Part D. This information is repetitive; and

Delete the information concerning enrollment issues about Medicare Part D which is unrelated to whether a Medigap policy provides creditable coverage.

In addition, we encourage CMS to develop a different notice for people who will have creditable coverage as their options will be different from those of people whose Medigap policies are not deemed to provided creditable coverage. The specific information this group of beneficiaries will need about their creditable coverage, and any required action, will vary depending on whether their coverage is employer sponsored retiree coverage, a Medigap Plan J, a pre-standard Medigap plan, or a Medigap with a rider or an innovative benefit.

The discussion in the Preamble to the Regulation beginning with Subpart T 4(c)(iii) references the difficulty of determining creditable coverage and the inability to even make that determination in advance of a final rule to implement Part D. We expect there will be confusion on this issue and that mistakes may be made by issuers in applying an actuarial test to groups of policies issued all over the country. We expect additional confusion due to the proposal to modify the definition of Medicare Supplement (Medigap) policies in §403.205 to include riders and freestanding benefits for prescription drugs. We are requesting two remedies for Medicare beneficiaries who are initially notified of creditable coverage when the coverage is no longer or never was creditable: a Special Enrollment Period in Part D and a guaranteed issue right to a Medigap policy without prescription drug benefits. We are also requesting the extension of the right to a guaranteed issue policy to Dual Eligibles who lose their eligibility to Medicaid benefits.

Thank you for the opportunity to submit comments on the proposed rule. We hope that this will not be the final opportunity to do so.

Very truly yours,

Diane F Paulson
Senior Attorney
Medicare Advocacy Project, Greater Boston Legal Services

Linda Landry
Disability Law Center

Deborah Thomson
Massachusetts Law Reform Institute

CMS-4068-P-1258

Submitter : Dr. Eddie Rowe **Date & Time:** 10/04/2004 08:10:27

Organization : Rowe's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

BENEFICIARY ACCESS TO COMMUNITY RETAIL PHARMACIES:
I am concerned about the proposed rul regarding the pharmacy access standard. Under the proposed regulation, each prescription drug benefit plan is allowed to apply the Department of Defense's TRICARE standards on the local (37664)level rather than 'on average' in a regional service area.

To address the situation where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level (no pharmacy in the zip code), the regulation should require that the access standard be the greater of the TRICARE standard or the access equal to that available to a member of the general public living in that zip code.

Requiring plans to meet the standard on a local level is the only way to ensure patients equal and convenient access to their chosen pharmacies.

PROPOSED REGULATION CREATES NETWORKS SMALLER THAN TRICARE:
The proposed regulation also allows plans to create 'preferred' pharmacies and 'non-preferred' pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one 'preferred' pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only 'preferred ' pharmacies shoud count when evaluation whether a plan has met the required TRICARE access standards. The Dept. of Defense network of pharmacies meets the Tricare access standards and has uniform cost sharing for all these network pharmacies. CMS shoould require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan's standards terms should be allowed to provide the same copays to the patient population.

EQUAL ACCESS TO RETAIL AND MAIL ORDER PHARMACIES FOR MEDICARE BENEFICIARIES:
I believe it was the intent of Congress to assure Medicare beneficiaries are able to obtain covered prescriptions drugs and medication therapy management services from the pharmacy provider of their coice. As such, plans must permit beneficiaries to obtain covered outpatient drugs and medication therapy management services at any community retail pharmacy in the plan's network, in the same amount, scope, and duration that the plan offers through mail order pharmacies. According to the proposed regulation, the only difference a beneficiary would have to pay between retail and mail order prescriptions should be directly related to the difference in the service costs, not the cost of the drug product. Under Medicare Part D, all rebates, discounts or other price concessions shoould be credited equally to reduce the cost of prescription drugs no matter where they are dispensed. The benefits from these arrangements shoould be required to be used to directly benefit the Medicare beneficiary in terms of lower cost prescriptions.

Pharmacists are also the ideal health care professionals to provide Medication Therapy Management Program and determine which services each beneficiary needs.

I, also, know that the local pharmacist is the most accessible healthcare provider a Medicare beneficiary has. I have even gone to patients homes to help them with their medications because they couldn't understand the physician's instructions, so how could they possibly understand a mail-order pharmacist on the telephone.

In conclusion, I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.

Sincerely,
Eddie Rowe, DPh.
Rowe's Pharmacy

CMS-4068-P-1259

Submitter : Mr. Michael Starkowski **Date & Time:** 10/04/2004 08:10:44

Organization : State of Ct. DSS

Category : State Government

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

The state of Ct is submitting comments on the entire range of issues not just sections 1-10.

CMS-4068-P-1259-Attach-1.doc

STATE OF CONNECTICUT

File Code: CMS-4068-P

October 4, 2004

Dr. Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) is historic legislation that presents opportunities and challenges for Connecticut. As a state with representation on the State Pharmaceutical Assistance Transition Commission (SPATC) authorized by that law, we are pleased to have been a part of the communication process between the Centers for Medicare and Medicaid Services and certain states that will be impacted by the new Medicare pharmaceutical benefit. We have not repeated all of the recommendations made by the Commission in these comments. However, we want to note that the State of Connecticut supports all of the recommendations outlined by the Commission.

While the SPATC process was certainly a helpful forum for presenting comments of importance to Connecticut, the impact of the Medicare Modernization Act extends beyond the interests of state pharmaceutical assistance programs to include issues relevant to the Medicaid program and to state retirees. The State of Connecticut believes that there are important threshold issues in the rule related to SPAPs. Therefore, we have repeated some of the SPATC comments here to underline the critical nature of these areas.

Accordingly, attached please find comments from the State of Connecticut regarding CMS's proposed rule for implementing the Medicare prescription drug benefit. If you have any questions about our comments, please contact Paul Potamianos at 860-418-6272 (paul.potamianos@po.state.ct.us) or David Parrella at 860-424-5116 (david.parrella@po.state.ct.us).

Sincerely,

Marc S. Ryan
Secretary
Office of Policy and Management

Patricia A. Wilson-Coker, JD, MSW
Commissioner
Department of Social Services

Attachment

A. General Provisions

Section 423.4. Definitions. *PDP Sponsor.* Section 1860D-41(13) of the Act defines a PDP sponsor as a "nongovernmental entity," which is operationalized at Section 423.4 of the proposed rule (p. 46810). We ask that CMS be flexible in its interpretation of the Act and its definition of nongovernmental entity so that states can comply with the law while at the same time allowing for creation of state-sponsored nongovernmental entities or selection of one entity as PDP sponsor for our Medicaid dual-eligible and SPAP populations. Not only would this approach minimize client confusion and ensure continuity of care (since we are familiar with both the medical and pharmaceutical histories of our clients), but it would resolve issues of data-sharing, client notification and client enrollment.

Section 423.6 (p. 46636 of the preamble). Cost-Sharing in beneficiary education and enrollment. It is unclear whether PDPs or MA-PD plans can pass along education and information costs in the form of user fees to states. To the extent that there are education and information costs, these should be borne by CMS and/or PDPs or MA-PD plans, not states.

Section 423.112 (p. 46636 of the preamble). Establishment of prescription drug plan service areas. Because the MMA allows for up to 50 state regions, and because Connecticut is an SPAP state, we believe that CMS should establish PDP regions in a way that allows Connecticut to be its own region. This is of importance to Connecticut because of the need to coordinate between our SPAP and the PDP or MA-PD plans. The needs and concerns of smaller states (especially states with SPAPs) could be subsumed by larger states with different integration needs. Allowing Connecticut to be its own region will help ensure that all PDPs or MA-PD plans will be responsive to meeting Connecticut's needs, and will help maintain continuity of care for Connecticut's vulnerable populations.

Section 423.34(d) (pp. 46638-46640 of the preamble). Enrollment process. *Enrollment requirement for full benefit dual eligibles.* The preamble proposes that full benefit dual eligibles be given until May 15, 2006, to establish initial enrollment before the auto-enrollment process begins. Under this proposal, some full benefit dual eligibles will not be covered by Part D until after May 15, 2006, which would mean either that those individuals have no prescription coverage or that states will be forced to continue coverage through their Medicaid programs for that time period, but without receiving FFP for those Medicaid costs. Indeed, states will incur costs for full benefit duals who do not enroll until May 15, 2006, even beyond that date, since we do not have the administrative and programmatic ability to ensure that those individuals are immediately enrolled in a Part D plan and are accessing Part D prescription drug benefits. States should not be penalized by the fact that many full benefit dual eligibles will likely not be enrolled prior to January 1, 2006; rather, states should be able to receive FFP for prescription costs for duals until initial enrollment is accomplished and individuals are able to access their Part D benefits.

To best address this situation, we believe CMS should implement an auto-enrollment process whereby full benefit dual eligibles are automatically enrolled in a default plan effective January

1, 2006, unless the individual elects to enroll in a different plan prior to that date. In addition, in order for states to implement the most effective, best integrated wrap around program, and to minimize disruption to clients, states should be able to auto-enroll dual eligibles into a preferred PDP (similar to the drug discount card).

Under the rule, a full benefit dual who fails to enroll would be automatically enrolled in a PDP that has a monthly beneficiary premium equal to or below the subsidy amount for low income beneficiaries. While the regulation is clear that states can wrap around for beneficiaries, it is not clear whether a state can elect to enroll a dual (or perhaps SPAP recipient) in a higher premium plan if the state paid the difference and determined it to be cost effective compared to what the state's wrap around cost would otherwise be. In contrast, if a dual elects a higher premium plan as the regulation allows, the beneficiary would cover the cost of the difference (see page 46639 of the preamble). CMS should clarify that there is no obligation for states to cover the differential for duals who enroll in a plan with a premium higher than the premium subsidy benchmark level.

The proposed regulation provides for auto-enrollment for any dual eligible who has not enrolled in a Part D PDP by the end of the individual's enrollment period or upon becoming dual eligible after an initial enrollment period. While the preamble states that full benefit dual eligibles may choose to change enrollment, we believe that they should not be able to disenroll from one plan and enroll in another in a way that would create a break in coverage since this could potentially result in no prescription coverage at all or, for those states that choose to wrap around, it could force states to cover prescription costs through Medicaid at 100% state cost. Such scenarios conflict with CMS's stated rationale for auto-enrollment, which is to ensure that full-benefit dual eligibles receive outpatient drug coverage under Part D (see p. 46638 of the preamble).

If CMS does allow for a break in Part D coverage, protocols need to be in place for the coordination of and payment for drug benefits for any time period that a Medicaid dual eligible is not actually enrolled in a PDP or MA-PD plan. In addition, states need to be notified whenever a dual eligible disenrolls so that state Medicaid programs will know that the individual is no longer covered under Part D. The exposure to state Medicaid programs and SPAPs is significant as many states that choose to wrap around dual eligibles' Part D coverage will find themselves covering 100% of the prescription costs for those dual eligibles that decline enrollment or disenroll from a Part D plan.

Section 423.34 (p. 46639 of the preamble). Enrollment process. CMS is requesting comments on the most appropriate method and entity to perform auto-enrollment of dual eligibles. If the state assumes responsibility for the auto-enrollment of dual eligibles, then the rule should be amended to include an FFP provision. Since Medicare is a federal benefit, we believe that states should be fully reimbursed at 100% of their costs.

B. Eligibility and Enrollment

Section 423.36(a) (p. 46639 of the preamble). Enrollment periods. *Initial Enrollment Period for Part D—Basic Rule*. States with large SPAPs need time to develop and implement a

wraparound. Indeed efforts in this regard are complicated by the fact that many states with SPAPs will also be seeking to integrate their dual eligible populations into their programs to wraparound a dual eligible's minimal Part D costs. In effect, this creates a need to administer two wraparounds. To the degree that CMS will not announce PDP and MA-PD plans until late 2005 and with enrollment not expected until the beginning of November 2005, it is unlikely that all SPAPs will be ready to integrate their programs with the new Part D benefit. In addition, with the late rollout of Part D, there will be little time to educate consumers and help them understand the Part D benefit and its impact on them. If individual SPAPs are not ready to wrap around the federally subsidized drug benefits, SPAP states should have the option to obtain a lump sum transitional payment in FFY 2006 for SPAP recipients or elect to continue under the drug discount card program for SPAP recipients. It is assumed that non-SPAP residents would be enrolled in the nationwide program.

Left open in the preamble (see page 46727) is who will enroll beneficiaries into the Part D benefit. Section 423.774 (page 46855) of the regulation indicates that states may play a role in determining subsidy eligibility for Medicaid duals, but it is unclear if states will be required to or have the flexibility to assume the eligibility and enrollment for both Medicaid duals and SPAP beneficiaries in Part D. Many states would argue that this is the most efficacious way of enrolling beneficiaries. The regulation also leaves open the prospect that states may be the best entities to handle auto enrollment issues for duals that do not enroll in Part D voluntarily. It is noted that states could provide the best and most timely and accurate Medicaid data for determination in these instances.

But, if states are to assume the exclusive role or part of the role in the eligibility and enrollment process, states should be compensated for that cost. States should be offered the opportunity to count all administrative costs, including the costs of determining eligibility and enrollment in Part D plans as eligible Medicaid expenses, whether the beneficiary is enrolled in Medicaid or an SPAP. Consideration should be given to an enhanced reimbursement rate common to all states.

Section 423.48 (p. 46642 of the preamble). Information about Part D. CMS intends to provide information to beneficiaries in advance of initial and annual enrollment periods that would help promote informed beneficiary decisions. However, it could be very confusing for beneficiaries to receive a notice from CMS about monthly premiums and cost sharing requirements, for example, if the beneficiary is also covered by an SPAP or an employer sponsored plan that elects to wrap around the Part D coverage. Connecticut's intention is to ensure that there is no change in benefits or costs to clients of our SPAP or state retirees as a result of Part D, so a notice from CMS about cost-sharing or premiums that the state intends to cover will generate a great deal of confusion on the part of this elderly and disabled population. As an alternative, we believe that notices to beneficiaries covered by SPAPs or covered by a state employee health plan should be coordinated with states so that beneficiary confusion is minimized.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections

Section 423.100 (p. 46646 of the preamble). Definitions. *Covered Part D drug.* It is unclear whether an over-the-counter (OTC) drug currently covered under Medicaid is still subject to FFP

once Part D is implemented. The rule suggests that covered Part D drugs are prescription-only with minor exceptions and must be Medicaid-covered. We believe that dual eligibles should still be able to get non-prescription drug coverage through Medicaid (with associated FFP to the state) because these items are not covered under Part D. It is not a good use of public dollars to have Medicare pay for a more expensive product plus a dispensing fee when a cheaper product is available and is something the client wants. Such a policy could result in doctors prescribing a prescription medication instead of an OTC product so that the client can have it paid for by Medicare.

Section 423.100 (pp. 46648 – 46649 of the preamble). Definitions. *Long-term care facility.* CMS requests comments on how long-term care facilities should be defined in this section and, specifically, whether intermediate care facilities for the mentally retarded should be designated as long-term care facilities. Currently, the rule suggests that the only entities to be defined as long-term care facilities would be skilled nursing or nursing facilities. The CMS justification is that only those facilities are bound to Medicare conditions of participation that result in exclusive contracts with long-term care pharmacies. CMS appears to be willing to reconsider its position on ICF/MRs if evidence is provided that such facilities have pharmacy contracts like long-term care facilities. While ICF/MRs generally may not contract with long-term care pharmacies, it is the case that many state-run ICF/MRs tend to have separate and distinct contracts with pharmacies that are sensitive to the unique needs of these residents. As well, the preamble notes that Medicare does have special coverage related to mentally retarded individuals and that these individuals will need to be assured access to Part D drugs.

We believe ICF/MRs should be designated long-term care facilities for the following reasons:

- Many of these clients have similar health conditions as those in skilled nursing facilities.
- Contracting arrangements are similar to long-term care facilities to respond to residents' unique needs.
- The special coverage in Medicare for the mentally retarded may be better protected through this designation.
- CMS has indicated that it may exempt special needs populations from cost-sharing and formulary restrictions. Residence in a designated long-term care facility would be an appropriate criterion for inclusion in a special needs group, as discussed elsewhere in our comments. Therefore, it is important to define long-term care facilities to include all facilities where individuals live due to health related reasons and also face barriers to their access to pharmacies and drugs due to their living circumstances.

In addition to ICF/MRs, we believe that the regulation should also include group homes under a 1915(c) home and community-based waiver as long-term care facilities for the reasons outlined above. The populations in these facilities are substantially similar to those in ICF/MRs and often are included in state contracts for pharmacy services for ICF/MRs.

Section 423.100 (p. 46651 of the preamble). Definitions. *Incurred costs.* For persons eligible for both ADAP and Medicare, we believe that ADAP expenditures or, alternatively, at least state expenditures for prescription assistance to persons with HIV/AIDS, should count as "creditable"

coverage and should be added to the list of forms of "creditable" coverage under Section 423.56 of the proposed rule (p. 46644 of the preamble). Contrary to the assertion by CMS in the preamble at pages 46650-46651, state funds used to provide prescription assistance to individuals with HIV/AIDS are no different from SPAP expenditures and should count toward that beneficiary's out of pocket costs. We believe that 1860D-24 of the Act gives the Secretary the discretion to define "insurance or otherwise" as described in 1860D-2 in a way that is consistent with our recommendation. The definition of "incurred costs" in Section 423.100 of the proposed rule should therefore be revised accordingly.

Section 423.100. Definitions, or Section 423.104. Requirements related to qualified prescription drug coverage. Since plans can define a one month supply differently (e.g., 30, 31 or 32 days), the proposed rule should establish a consistent definition of supply limits. Without such a definition, one payor may reject a claim saying the refill is too soon, when another would pay. Ensuring a consistent definition will minimize the impact on SPAPs and employer sponsored wrap-around plans, which are likely at risk for covering any charges for early refills.

Section 423.104(h)(1) (p. 46654 of the preamble). Requirements related to qualified prescription drug coverage. *Access to negotiated prices.* The general understanding, based on the language in this section, is that, for a formulary drug, the negotiated PDP or MA-PD plan price will hold through the "donut hole" period and for a non-formulary drug, the SPAP will pay under their pricing structure. Thus, even though it is the SPAP not the PDP or MA-PD plan covering the expense of a formulary drug, the rebate would go to the PDP or MA-PD plan since it is their negotiated rate that is being used and which was most likely developed based on a claims volume that includes the "donut hole" period. By forcing the SPAPs to integrate their programs with all of the plans (see page 46697 of the preamble), there is a disincentive for the states to wraparound. In addition, states lose any bargaining power with manufacturers with regard to rebates if states can no longer guarantee a certain volume or as large a volume. In effect, SPAP costs could now increase during the "donut hole" for a given client as the state no longer has the ability to reduce ultimate costs through significant rebates from a drug manufacturer as the rebate is already being paid to a PDP or MA-PD plan even though the PDP or MA-PD plan is not covering the actual costs of the drugs during the "donut hole." The law and regulation are clear that PDPs and MA-PD plans have to make the discounted price available to beneficiaries even during the "donut hole" period. We recommend that, for states that need the volume to maintain rebates, they be allowed the option of covering prescription costs under their own arrangements (i.e., under existing reimbursement policies and manufacturer rebate agreements), during the "donut hole" period. While a PDP or MA-PD plan may lose some volume discount, states need the leverage.

Section 423.104(h)(3) (p. 46654 of the preamble). Requirements related to qualified prescription drug coverage. *Negotiated prices. Disclosure.* States must have access to the price concession data that CMS says will be required reporting from the PDPs and MA-PD plans despite confidentiality issues. Because states are at risk of losing discounts in both Medicaid and SPAPs, this data will help states determine the financial impact of wrapping around Part D for these populations.

Section 423.112 (p. 46655 of the preamble). Establishment of prescription drug plan service areas. Because the MMA allows for up to 50 state regions, and because Connecticut is an SPAP state, we believe that CMS should establish PDP regions in a way that allows Connecticut to be its own region. This is of importance to Connecticut because of the need to coordinate between our SPAP and the PDP or MA-PD plans. The needs and concerns of smaller states (especially states with SPAPs) could be subsumed by larger states with different integration needs. Allowing Connecticut to be its own region will help ensure that any PDP or MA-PD plans will be responsive to meeting Connecticut's needs, and maintaining continuity of care for Connecticut's vulnerable populations.

Section 423.120(a) (pp. 46658 - 46659 of the preamble). Access to covered Part D drugs. *Assuring pharmacy access.* The proposed rule distinguishes between preferred and non-preferred network pharmacies, where a non-preferred pharmacy is a network pharmacy that offers Part D enrollees higher cost-sharing for covered Part D drugs than a preferred pharmacy. As noted in the preamble, cost sharing can vary not only based on the type of drug or formulary tier, but also on a particular pharmacy's status within the plan's pharmacy network. This adds yet another level of complexity to the plan, especially as SPAPs or employer sponsored plans try to wrap around and coordinate with multiple PDPs and MA-PD plans. Further, while the proposed rule appears to guarantee beneficiaries wide access to pharmacies, a PDP or MA-PD plan could still meet these access requirements but in effect have a very small preferred network that discourages enrollment of certain populations as well as enrollment from certain geographic areas. On page 46659 of the preamble, CMS says it will review the design of proposed plans to ensure that such plans do not "substantially discourage" enrollment. This is important as the current rule does not ensure adequate access to preferred pharmacies and could be used by PDPs or MA-PD plans to shift certain costs back to SPAPs or employer sponsored plans that choose to wrap around the Part D benefit. To maximize access, CMS should establish clear guidelines to ensure the broadest network of preferred pharmacies throughout a PDP's or MA-PD plan's coverage area. We believe this could best be achieved by requiring plans to meet network access standards using preferred pharmacies. In addition, the rule should mandate that CMS approve changes to a PDP's or MA-PD plan's network annually, as well as any substantive midyear changes in plan networks.

Section 423.120. Access to covered Part D drugs. The MMA does not appear to address the issue of continuity of benefits with respect to dual eligibles. Since the existing provisions in Title XIX have not been repealed, CMS will need to clarify whether state Medicaid programs continue to be bound by the requirement to provide non-formulary drugs as dual eligibles transition to Medicare Part D. Similarly, if there is an appeal of a formulary decision, we believe that Medicare should pay for the cost of the requested prescription pending resolution of the appeal, so that Medicaid is not responsible for continuing coverage at 100% state cost.

Section 423.120 (p. 46661 of the preamble). Access to covered Part D drugs. CMS is requesting comments on special needs populations and any special treatment needed for such populations as it relates to flexibility and cost containment in the program. The preamble recognizes the unique health needs of such populations and notes that open formularies are the norm for clients in long-term care facilities. Section 423.782(a)(2)(ii) also exempts individuals in long-term care facilities from cost-sharing.

Skilled nursing facility residents and residents of ICF/MRs appear to be deemed institutionalized under the Act and would be free of cost-sharing requirements. That may not be the case for residents of 1915(c) waiver group homes and other similar facilities for persons with mental illness or mental retardation. Because these special needs populations have substantially similar financial status and health needs as residents of skilled nursing facilities and ICF/MRs, we believe that all of these populations should be treated equally.

While residents of ICF/MRs and group homes and other facilities may have some income disregarded (those in nursing homes do not), their income is still extremely limited. The personal needs allowances (PNAs) in skilled nursing facilities are generally well below $100 in most states, and need only be $30 per month according to federal Medicaid law. These PNAs must cover personal incidentals as well as co-pays and non-formulary drugs. If not deemed institutionalized or otherwise freed of cost-sharing, a medically fragile individual subject to cost-sharing and with multiple prescriptions could not afford even the minor cost-sharing under Part D.

The financial wherewithal of all special needs populations, including those in skilled nursing facilities and ICF/MRs otherwise free of cost-sharing, may not be able to afford their medications or have true access to them if formulary restrictions apply. Formulary restrictions could force such special needs individuals to utilize the majority or all of their monthly income on medications if a needed drug is not on a formulary, and must be purchased out-of-pocket while pursuing an appeal. Indeed, in some cases, their PNA would not be adequate to cover the out-of-pocket cost, resulting in a break in therapy. Furthermore, few of these individuals have the cognitive abilities to deal with appealing a formulary denial and it would be an enormous burden for their group home or case manager to have to navigate the appeals process on behalf of numerous clients.

CMS clearly recognizes in the preamble that such populations may need special treatment because they are more sensitive to and less tolerant of many medications. Also noted is that most long-term care pharmacies have open formularies to respond to this fact. In general, the existence of any formulary restrictions and cost-sharing could easily lead to greater medical costs for non-drug benefits for these exceedingly medically fragile populations. Research published by the Center for Health System Change has documented that barriers to access for drugs for the Medicaid population, including co-payments and prior authorization, have led to reduced adherence to medically necessary drug regimens. Failure to properly comply with medication therapy results in exacerbations of chronic and acute illnesses that, at a minimum, bring these patients back to the physician and, at worst, puts them in a hospital or other institutional setting.

We believe strongly that all special needs populations must be exempt from formulary restrictions and cost-sharing. Formulary exceptions and exemptions from cost-sharing are important for the following groups:

- Residents of skilled nursing facilities and other like entities.
- Residents of ICF/MR facilities.
- Residents of 1915(c) waiver group homes.

- Residents of state-run group homes that operate similarly to 1915(c) waiver group homes but have not technically met federal Medicaid qualifications.
- Those with chronic mental illness, whether they qualified for federal SSI or not. These individuals often are required to have less-than-30-day supplies of prescription drugs because of suicidal tendencies or the need for close monitoring. Formularies and cost-sharing for this population would complicate the already major challenge of drug adherence for many of these individuals, whose very illnesses make it difficult to adapt to change. Furthermore, paying out of pocket for denied drugs would force these individuals to exhaust the vast majority of their income each month. States that have implemented even nominal co-pays on Medicaid recipients have at least anecdotally found that such co-pays have dissuaded the mentally ill from filling prescriptions. This was the case even when Medicaid beneficiaries were told that federal law dictated that the drug could not be withheld due to lack of payment of co-pays. Thus, we know that financial barriers for this population result in under-treatment and consequently larger costs for non-drug services.
- Those with other chronic health conditions, such as HIV/AIDS. These beneficiaries often have multiple prescriptions due to the complex nature of their conditions. As such, they would be unable to afford cost-sharing or the additional financial implications of being subjected to a restrictive formulary.
- Beneficiaries who are otherwise on Medicaid community-based waivers (to avoid institutionalization) and therefore have very limited incomes should also be considered to be free of cost-sharing and certain formulary restrictions. This would apply to individuals on home and community-based waivers for the elderly and disabled or those on Katie Beckett waivers.

Section 423.120 (see also section 423.124) (p. 46657 of the preamble). Access to covered Part D drugs. CMS is seeking comments regarding whether plans should be required to contract with long-term care pharmacies. Section 1860D-4(b)(1)(C)(iv) of the law gives the Secretary discretion to require plans to contract with long-term care pharmacies. We would recommend that section 423.120 of the rule be modified to include access to all long-term care pharmacies.

Section 423.120 (p. 46659 of the preamble). Access to covered Part D drugs. The proposed regulation provides for fairly stringent rules to ensure that beneficiaries have access to medically necessary drugs. While section 1860D-4(b)(3)(A) of the Act requires that the formulary be "developed and reviewed" by a P&T committee, it is CMS' interpretation that the P&T committee may establish and change drugs on a formulary and that the committee's decision is binding on the plan. Section 423.120 of the regulation, however, requires only that a PDP's and MA-PD plan's formulary be reviewed by a P&T committee. The regulation should be amended to adopt CMS' intent about the binding nature of the P&T committee's decisions.

Section 423.120(a)(6) (p. 46649 of the preamble). Access to covered Part D drugs. *Level playing field between mail-order, and network pharmacies.* The proposed rule provides that those who choose an extended supply of a Part D drug through a retail pharmacy would be responsible for the differential between the retail pharmacy's negotiated price and the network's mail-order

negotiated price. We are concerned about this policy because, if that amount is greater than the amount the SPAPs or employer sponsored wrap-around plans would have paid for the extended supply, then costs are being shifted to the states.

CMS is seeking comments on their proposal that this price differential be counted as an incurred cost against the annual out-of-pocket threshold. We support this position and recommend that the rule clearly state that this differential counts towards out-of-pocket expenditures.

Section 423.120(b)(2) (p. 46660 of the preamble). Access to covered Part D drugs. *Inclusion of drugs in all therapeutic categories and classes.* There is a requirement that PDPs and MA-PD plans have at least two drugs in each class as well as have generics available. The regulations are not clear, however, whether generics can be one of the two drugs. We believe two brands plus a generic (when available) should be the minimum requirement.

Section 423.120(b)(5) (p. 46819 of the preamble). Access to covered Part D drugs. *Provision of notice regarding formulary changes.* Section 1860D-4(b)(3)(E) of the Act states: "Any removal of a covered Part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists." Of concern is that CMS has interpreted "appropriate notice" to mean 30 days. Specifically, section 423.120 (page 46819) of the proposed rule reads: "A PDP sponsor or MA organization offering an MA–PD plan must provide at least 30 days notice to CMS, affected enrollees, authorized prescribers, pharmacies, and pharmacists prior to removing a covered Part D drug from its plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug." CMS may maintain that any arbitrary change is unlikely as it has a requirement for all formulary changes to go through a P&T committee that meets specifications and the approval of CMS. The issue is not that changes might be made arbitrarily, but it simply does not allow enough time for the SPAPs to respond to or integrate the formulary change in their programs. Therefore we recommend that, at a minimum, PDPs be required to grandfather-in coverage of a deleted drug for anyone who was taking the medication prior to the deletion, unless the deletion is due to the new availability of a generic substitute or due to the FDA's removal of the drug from the market due to safety reasons. This should not be construed as prohibiting a PDP from asking physicians to voluntarily switch their patients to less costly drugs, in a therapeutic substitution initiative. In the alternative, we believe that any formulary change should require 90 day notice to all beneficiaries as well as SPAPs and state retiree plans.

Section 423.120(b)(5) (p. 46661 of the preamble). Access to covered Part D drugs. *Provision of notice regarding formulary changes.* CMS proposes that PDPs and MA-PD plans only inform those taking a drug affected by a formulary change of such a change. We believe that all beneficiaries and all parties, including SPAPs and state retiree plans, should be notified of formulary changes.

Section 423.124 (p. 46662 of the preamble). Special rules for access to covered Part D drugs at out-of-network pharmacies. In the preamble, CMS details four scenarios where out of network access would be guaranteed. A fifth scenario for out-of-network access should be added that specifically identifies those retirees who reside in different parts of the country during the year

("snowbirds") and are outside of the service area, (e.g., they reside for several months at a time in Connecticut and in Florida). Regional plans may not be sufficient for snowbirds. Even if a plan's service area does cover both areas of the country where the snowbird resides, the plan may not use the same contracting pharmacies in the dual locations, thereby subjecting the retiree to pay higher costs from out-of-network pharmacies during a portion of the year. This is an important consideration for employers who currently have (or are required to have per union agreements or otherwise) prescription drug coverage that is nationwide or covers entire regions of the country and are deciding whether to switch to a plan that has Medicare Part D as the primary payer for prescription coverage.

D. Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

Section 423.153 (p. 46667 of the preamble). Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste. CMS requests comments regarding a proposed requirement that cost-savings strategies be under the direction and oversight of a Pharmacy and Therapeutics Committee. We support this proposal.

Section 423.153 (p. 46670 of the preamble). Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste. For states to run successful disease management programs, it is important that they retain the ability to access prescription history for dual eligibles. In addition, in order to minimize prescription abuse by clients who are in lock-in status, states need the ability to continue to track a client's prescription history. The exchange of data between PDPs / MA-PD plans and states is critical. Limiting the number of plans (see our comments in Subpart J) would facilitate integration and allow the state to better coordinate care.

Section 423.153(c). Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste. *Data Sharing/ Quality Assurance.* To ensure an effective drug benefit program, quality assurance and evaluation are essential. In particular, SPAPs and state retiree plans must have access to data to evaluate program performance. As a result, we believe CMS should share Medicare evaluation data with SPAPs and state retiree plans to allow states to make decisions regarding ongoing quality improvements. We also believe CMS should issue an annual report assessing the effectiveness of the Part D drug benefit program. The report should include detailed information on claim denials; exceptions and appeals and their outcomes; the turnaround times for PDP processing of prior authorization requests, exception requests, and re-determination requests; and, the percent of the total negotiated drug costs paid by the PDP versus the beneficiary, SPAP, or state retiree plan.

F. Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation

Sections 423.104 and 423.272 (p. 46681 of the preamble). Review and negotiation of bid and approval of plans submitted by potential PDP sponsors or MA organizations planning to offer MA–PD plans. The general understanding, based on section 423.104 of the proposed rule and page 46654 of the preamble, is that, for a formulary drug, the negotiated PDP or MA-PD plan price will hold through the "donut hole" period and for a non-formulary drug, the SPAP will pay under their pricing structure. Thus, even though it is the SPAP not the PDP or MA-PD plan covering the expense of a formulary drug, the rebate would go to the PDP or MA-PD plan since it is their negotiated rate that is being used and which was most likely developed based on a claims volume that includes the "donut hole" period. By forcing the SPAPs to integrate their programs with all of the plans (see page 46697 of the preamble), there is a disincentive for the states to wraparound. In addition, states lose any bargaining power with manufacturers with regard to rebates if states can no longer guarantee a certain volume or as large a volume. In effect, SPAP costs could now increase during the "donut hole" for a given client as the state no longer has the ability to reduce ultimate costs through significant rebates from a drug manufacturer as the rebate is already being paid to a PDP or MA-PD plan even though the PDP or MA-PD plan is not covering the actual costs of the drugs during the "donut hole." The law and regulation are clear that PDPs and MA-PD plans have to make the discounted price available to beneficiaries even during the "donut hole" period. We recommend that, for states that need the volume to maintain rebates, they be allowed the option of covering prescription costs under their own arrangements (i.e., under existing reimbursement policies and manufacturer rebate agreements), during the "donut hole" period. While a PDP or MA-PD plan may lose some volume discount, states need the leverage.

Section 423.272 (p. 46681 of the preamble). Review and negotiation of bid and approval of plans submitted by potential PDP sponsors or MA organizations planning to offer MA–PD plans. This section allows CMS to reject any bid if it finds that it will "substantially discourage enrollment by certain Part D eligible individuals." In the preamble, CMS asks for comments on how to evaluate the proposed formularies in bid proposals. We believe a reasonable formulary should assure that 90% of patients with any particular diagnosis could find their medication on the formulary. CMS should therefore establish a formulary evaluation criterion that would trigger a much more detailed evaluation of the adequacy of the formulary if a drug plan failed to offer enough medication choices to assure that 90% of the beneficiaries will be able to continue on their current therapies. A formulary that requires vast numbers of elderly to switch or appeal will result in the potential for numerous interruptions in drug therapy that result in other medical cost and quality problems. It will also result in significant costs for SPAPs that will wrap around Part D by picking up the costs of drugs that are denied as non-formulary drugs.

Section 423.293(a) (p. 46685 of the preamble). Collection of monthly beneficiary premiums. *General rule.* The regulation allows for payment of premiums directly to PDPs or MA-PD plans. Because CMS will have the most up-to-date information about which plan a beneficiary is enrolled in, SPAPs should pay premiums directly to CMS. One mechanism that could be used is to parallel the existing programs whereby states pay QMB and SLMB cost-sharing to the federal government through Medicaid reimbursement withholds.

The regulation also allows for the collection of beneficiary premiums through withholding from Social Security checks. However, in the case where an SPAP state wishes to wrap its SPAP

benefit around the Part D benefit, such withholding is inappropriate. Once again, we want the option of paying premiums directly to CMS. Such payments could be made similar to the way Medicare buy-in payments are made for dual eligibles. With state payment of premiums, we would want to ensure that there are beneficiary protections to prevent disenrollment of the beneficiary if a federal-state payment dispute arises.

G. Payments to PDP Sponsors and MA Organizations Offering MA-PD Plans for All Medicare Beneficiaries for Qualifies Prescription Drug Coverage

Section 423.336 (p. 46693 of the preamble). Risk-sharing Arrangements. *Plan spending below target*. In the preamble, CMS writes "if plan spending fell below the target, plans would share the savings with the government." Because states are contributing toward the cost of running the Part D program through the clawback, any savings that accrue to "the government" should be shared with states.

I. Organization Compliance With State Law and Preemption by Federal Law

No comments.

J. Coordination Under Part D Plans With Other Prescription Drug Coverage

Section 423.464(a) (p. 46700 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *General rule*. This section addresses the data sharing that should occur with SPAPs as to coordination of benefits, calculation of out-of-pocket requirements, etc. In our view, the regulation is weak with respect to safeguarding states' needs for coordination because it says that PDPs "must permit" SPAPs to coordinate with PDPs. We believe that the rule should be modified to read that PDPs and MA-PD plans "are required to coordinate with SPAPs." We also believe that, once the initial coordination is in place, language requiring ongoing coordination needs to be added to the rule. In addition, we believe explicit language in the contracts of PDPs and MA-PD plans (see section 423.505 of the rule) must be included to ensure the proper data sharing and coordination, especially if PDPs and MA-PD plans are responsible for TrOOP calculation, as opposed to a separate vendor contracted by CMS. We have offered additional comments under Subpart K, below, regarding contractual language that would help effectuate the requirement for PDPs and MA-PD plans to coordinate with SPAPs.

Section 423.464(a). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *General rule*. While this section of the regulation requires PDPs and MA-PD plans to permit SPAPs to coordinate with plans, the detail is insufficient to address the significant continuity of care concerns raised by SPAP plans on behalf of their beneficiaries. The regulation needs to be stronger on the requirements of PDPs and MA-PD plans to share data and enter into agreements regarding continuity of care and coordination of such things as prior authorization, generic substitution and formulary changes. The regulation should make clear that PDPs and MA-PD plans are required to work with SPAPs and give some deference to the controls,

processes, and limitations (e.g., preferred drug list, prior authorization and generic substitution decisions) already established by SPAPs. We recommend that state rules addressing patient access to drugs should govern PDPs and MA-PD plans. To protect continuity of care, procedures should be put in place before the January 2006 start date to mandate dialogue concerning SPAP clients that have already been prior authorized for certain brand drugs.

Section 423.464(e)(ii) (p. 46697 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Non-discrimination.* Section 1860D-3 of the Act requires the Secretary to ensure that each Part D eligible individual has a choice of at least two qualifying plans or, if necessary, the opportunity to enroll in a fallback prescription drug plan. Section 1860D-23(b)(2) prohibits SPAPs from working with a subset of plans available in the region (the so-called "anti-discrimination" requirement), which means that SPAPs must coordinate with multiple plans. Section 426.464(e)(1)(ii) operationalizes the Act by requiring SPAPs to provide assistance "to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls." Section J of the preamble (page 46697) states:

> "We are interpreting the nondiscrimination language to mean that SPAPs, if they offer premium assistance or supplemental assistance on Part D cost sharing, must offer equal assistance by all PDPs or MA–PD plans available in the State and may not steer beneficiaries to one plan or another through benefit design or otherwise. State programs cannot, for example, use the threat of withholding SPAP enrollees to negotiate coverage, premium or formulary changes with PDPs or MA–PD plans. Violations of the non-discrimination rule will jeopardize the program's special status with respect to true out-of-pocket costs. That is, a State program that discriminates does not qualify under the definition of an SPAP, and consequently, its contributions to cost sharing do not count toward the out-of-pocket limit."

CMS indicated in an 8/4/04 conference call that the actual operational details were not yet defined. For administrative ease, efficiency and cost effectiveness, states need the ability to limit the number of PDPs with which they need to coordinate to one or two. The states need to have ways to ratchet down their costs, especially in light of no guarantee of reimbursement for ongoing administrative costs, the strong likelihood of a loss of drug rebate dollars in SPAP and Medicaid programs, and the ongoing "donut hole" costs to states. More to the point, continuity of care can be maximized (and costs to the state and federal governments minimized) if states have the ability to work with one or two preferred PDPs. Further, many SPAPs will be providing some form of wrap around coverage or will be subsidizing a plan's premiums. As a result, it is essential that SPAPs be given the opportunity to steer their beneficiaries away from those PDPs requiring disproportionately high premiums without providing any clear benefits to their enrollees. The language in section 423.464 of the regulations should be broadened to allow states to contract with one or two PDPs as long as the contracts are competitively bid and limiting the number of PDPs would be in the best interest of state SPAP clients because the state clearly defined what it was looking for during the bidding process. We believe that states would still be able to meet the anti-discrimination test with this process. As an alternative, states should be allowed to design a wrap around and limit enrollment of its SPAP and dual-eligible clients in those plans that agree to the state's contractual requirements. As a further alternative, states should have the right to auto-enroll any SPAP clients who are required as a condition of enrollment in an SPAP to enroll in Part D but fail to do so (or duals that either refuse to enroll voluntarily or disenroll from Part D) in a state's preferred PDP vendor(s). Indeed, section 423.34

of the regulation refers to states potentially doing an automatic and random enrollment function with regard to duals that do not voluntarily enroll. We believe that allowing states to enroll SPAP clients and dual eligibles in default plans, but then allowing those enrollees to choose another PDP if they do not want to be in the default plan, will meet the test of anti-discrimination.

Section 423.464(f)(3) (pp. 46696-46700 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Imposition of fees.* While SPAPs are not required to coordinate with PDPs (see page 46701 of the preamble), section 423.464(a) of the regulation says PDPs "must permit" SPAPs to coordinate with PDPs and MA-PD plans. The rule allows Part D plans to impose fees on SPAPs for required coordination, including enrollment, claims processing, payment of premiums, and administrative processes (see page 46700 of the preamble). Because no funding is provided to states for this coordination, such fees should not be imposed on the states. While 1860D-11(j) of the Act says that fees unrelated to the cost of coordination are not to be imposed, we believe that CMS has the authority to interpret this language to prevent unnecessary and unreasonable fees from being charged at all. Instead, CMS should establish a baseline requirement of coordination that is applicable nationwide, with any costs related to that coordination factored into a plan's bid and paid by CMS. Only extraordinary costs related to a state's unique situation that are beyond the scope of normal, reasonable national-standard coordination requirements should be borne by the state, and even then we seek the ability to negotiate such costs in concert with CMS before plan contracts are executed. Additionally, it is important that the regulations and the PDP and MA-PD plan contracts signed with CMS be clear and specific on the level of coordination that PDPs and MA-PD plans must have with SPAPs, and that any state-specific requirements be included in the contracts executed by CMS and the plans. Without these protections, there is absolutely no incentive for plans to negotiate in good faith with states, and states could be subjected to unreasonable and excessive fees as a result of needing to coordinate SPAP and retiree coverage with the plans. (We have made related comments on contract protections in Subpart K.)

Section 423.464(f)(ii) (pp. 46698 – 46699 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Employer Options*. If employers pick an option that requires their retirees to enroll in Part D with Medicare as the primary payer, the final rule should contain special access and financial protections to safeguard those employers with significant numbers of "snowbird" retirees. As discussed in our comments on Subpart C, above, this segment of the retiree population has access issues that must be addressed. This is particularly important because there is still uncertainty over how many plans that currently offer nationwide drug discount cards will participate in Part D due to the notion of presumed risk.

Section 423.464(d) (p. 46701 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Cost Management Tools.* Section 423.464(d) of the proposed rule and section 1860D-24(c)(1) of the Act allow PDPs and MA-PD plans to continue to use cost-containment strategies even as they relate to SPAPs or other drug plans providing wrap-around or supplemental coverage. CMS seeks comments in the preamble on how CMS "can ensure that wrap-around coverage offered by SPAPs and other insurers does not undermine or eliminate the cost management tools established by Part D plans." The greater concern may be how to ensure that Part D plans are not incentivized to cost shift to SPAPs and state retiree plans. If states are

paying for coverage for SPAP enrollees who are also Medicare Part D beneficiaries (regardless of whether the PDP or MA-PD plan is directly providing the additional benefits under contract with the SPAP or whether the SPAP is coordinating such wrap around coverage with the PDP or MA-PD plan), we believe CMS should help support state laws and policies regarding SPAP coverage. States are as interested in cost management as CMS—but we are also mindful of the impact on vulnerable populations and the need to ensure continuity of care. The rule makes no attempt to prevent PDPs and MA-PD plans from controlling or overruling SPAP decision-making when coverage is paid for by SPAPs, particularly in the "donut hole." Section 423.464(d) of the rule should be modified to require that PDPs and MA-PD plans accede to SPAP rules where SPAPs are paying for beneficiary coverage.

Section 423.464(e)(2) (p. 46702 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Special treatment under out of pocket rule*. CMS indicates it is interested in comments on whether SPAPs should be required to provide feedback on how much TrOOP they have paid. Because PDPs know how much of the claim they have paid and because beneficiary and SPAP expenditures both count as TrOOP costs, it is irrelevant how much of that claim is SPAP related. There are enough administrative and coordination requirements in MMA without imposing more. The rule should be modified by deleting the phrase "collect information on and" from Section 423.464(e)(2). PDPs should count any non-PDP costs for SPAP enrollees as out of pocket for purposes of TrOOP calculation.

Section 423.464(e)(2) (pp. 46706 and 46789 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Tracking TrOOP*. CMS seeks comments on whether a single, central entity or multiple PDPs are best suited to tracking TrOOP. Because of coordination requirements with SPAPs, we recommend that one central entity (CMS) maintain a data system rather than having multiple PDPs maintaining separate systems.

K. Proposed Application Procedures and Contracts With PDP Sponsors

Section 423.505. Contract Provisions. (cross reference Section 423.464. Coordination of Benefits). Section 423.464 of the rule and page 46700 of the preamble address the data sharing that will occur with SPAPs as to coordination of benefits, calculation of out-of-pocket requirements, etc. See our comments under Subpart J, above, regarding strengthening the rule by requiring PDPs to coordinate with SPAPs. CMS has proposed no specific contractual language for PDPs and MA-PD plans that would describe the required coordination. Section 423.505 of the proposed regulation only states that PDPs would need to "comply with the coordination requirements…in subpart J". In order to implement this requirement, we believe explicit language in section 423.505 of the rule as well as in the contracts of PDPs and MA-PD plans must be included to ensure the proper data sharing and coordination, especially if PDPs and MA-PD plans are responsible as opposed to a separate vendor contracted by CMS.

Section 423.505. Contract Provisions. (cross reference Section 423.464. Coordination of Benefits). *Fees*. CMS has proposed no specific contractual language for PDPs and MA-PD plans that would prevent unreasonable or excessive fees from being imposed (see comments to Section 423.464 under Subpart J). Section 423.505 of the proposed regulation only states that

PDPs would need to "comply with the coordination requirements…in subpart J". Because no funding is provided to states for coordination, such fees should not be imposed on the states. While 1860D-11(j) of the Act says that fees unrelated to the cost of coordination are not to be imposed, we believe that CMS has the authority to interpret this language to prevent fees from being charged at all, or at a minimum the imposition of unnecessary and unreasonable fees. Instead, CMS should establish a baseline requirement of coordination that is applicable nationwide, with any costs related to that coordination factored into a plan's bid and paid by CMS. Only extraordinary costs related to a state's unique situation that are beyond the scope of normal, reasonable, national-standard coordination requirements should be borne by the state, and even then we seek the ability to negotiate such costs in concert with CMS before plan contracts are executed. Additionally, it is important that the regulations and the PDP and MA-PD plan contracts signed with CMS be clear and specific on the level of coordination that PDPs and MA-PD plans must have with SPAPs, and that any state-specific requirements be included in the contracts executed by CMS and the plans. Without these protections, there is absolutely no incentive for plans to negotiate in good faith with states, and states could be subjected to unreasonable and excessive fees as a result of needing to coordinate SPAP and retiree coverage with the plans. (We have made related comments on contract protections in Subpart J.)

Sections 423.509 and 423.510. Termination of contract by PDP or CMS. Currently, SPAPs are not among the parties specifically delineated as requiring notification by either PDPs or CMS. Given the significant impact Part D plans will have on SPAPs and state retirees, states must be included as parties to be notified of the termination of PDP contracts. At a minimum, SPAPs should be allowed greater notice than to the public in order to coordinate coverage as well as current and future enrollment. Sections 423.507 through 423.510 of the proposed rule should be amended to include timely notification to SPAPs and state retiree plans of termination of a PDP contract. (Similar notification requirements should be imposed by CMS on MA-PD plans.)

L. Effect of Change of Ownership or Leasing of Facilities During Term of Contract

Sections 423.551(c) and 423.552(a)(1) (pp. 46716-46717 of the preamble). Advance Notice Requirement. Currently, states are not among the parties specifically delineated as requiring notification by either PDPs or CMS. Given the significant impact Part D plans will have on SPAPs and state retirees, states must be included as parties to be notified of changes in ownership. To ensure continuity of care and minimize disruption of coordinated benefits, the advanced notification requirements in sections 423.551 and 423.552 of the proposed rule should be amended to include states, especially SPAP states.

M. Grievances, Coverage, Reconsiderations, and Appeals

Section 423.562. General Provisions. (cross-reference Section 423.44 (p, 46641 of the preamble). Disenrollment by the PDP). Section 423.44 of the proposed rule allows for the disenrollment of beneficiaries whose behavior is "disruptive, unruly, abusive, uncooperative or threatening." Because of the special needs of the dual eligibles, as well as the elderly and disabled served under our SPAP, an adequate appeals process needs to be established as well as

provisions to ensure that there will be no lapse in coverage since lack of coverage would threaten their health needs.

Sections 423.560 to 423.638. To protect continuity of care, procedures should be put in place before the January 2006 start date to mandate dialogue between states and PDPs and MA-PD plans concerning SPAP clients that have already been prior authorized for certain brand drugs. In Connecticut, atypical antipsychotic drugs are exempt from prior authorization for clients currently on them – only newly prescribed atypical antipsychotics that have at least three A-rated generics available for substitution are required to get prior authorization, and then for initial scripts only. The regulation should be modified to ensure that PDPs honor the existing prior authorization and generic substitution decisions made by SPAPs. This will help maintain continuity of care.

Section 423.560. Definitions, and Section 423.562. General Provisions. *SPAPs as Authorized Representatives, and Data Sharing*. While the definition of an authorized representative under section 423.560 could be interpreted to include an SPAP acting on behalf of an SPAP client, the regulation should be clarified. For both administrative and programmatic reasons, it is important that SPAPs be allowed to be the authorized representatives for SPAP clients.

For example, regarding step therapy, SPAPs may have claims history to show that the PDPs and MA-PD plans preferred drug was previously tried. PDPs and MA-PD plans should be required to coordinate with SPAPs and share claims history because SPAPs may have the longest and most complete clinical history. This is especially important because people may change PDPs and MA-PD plans every year, but the SPAP will remain consistent.

SPAPs and PDPs / MA-PD plans need to coordinate or at least share clinical criteria for prior authorization and also generic substitution. It is important both to avoid having two entities undertake prior authorization but also to protect continuity of care.

It will be confusing for SPAPs that have full benefit plans to know whether they should pay under their wrap-around when a PDP or MA-PD plan denies coverage. For example, when denials occur for a DUR reason, how will an SPAP know not to pay for a contraindicated drug? Certainly, SPAPs will want to continue with their own DUR programs to both protect their clients as well as prevent unnecessary costs. This will be challenging if the PDP or MA-PD plan and SPAP DUR programs don't have the same system edits.

Again, the rule must be clarified to ensure that the definition of "authorized representative" includes SPAPs and retiree plans acting on behalf of a beneficiary. We also recommend that CMS add requirements to Section 423.562 to ensure that PDPs are required to share data with SPAPs, at no cost to SPAPs, to ensure coverage is coordinated to promote continuity of care.

Section 423.566 (pp. 46718-46721 of the preamble). Coverage determinations. A phase-in period for formulary denials by PDPs and MA-PD plans for new enrollees is needed. This would ensure that new enrollees don't first discover that they aren't covered for a drug when they have run out and are seeking a refill – leaving them no time to pursue a switch or to appeal. This is especially important for individuals taking multiple drugs who may discover that more

than one medication needs to be switched. Good clinical practice calls for not switching multiple drugs at once, but rather doing them one at a time, so that it is clear which drug is causing side effects, if any show up. An exception should automatically be granted any time an individual is running into more than one denial for non-formulary drugs. Otherwise, SPAPs and employer sponsored wrap-around plans will wind up paying for all of these denials.

Section 423.568(a). Standard timeframe and notice requirements for coverage determinations. The proposed rule allows PDPs up to 14 days to issue a decision on the request for an exception. This timeframe, however, is far too lengthy and is inconsistent with current industry practice as well as Medicaid standards. If adopted, this standard could put vulnerable populations, particularly those with chronic illnesses, at significant risk. PDPs should be required to render a decision on a request for an exception within 48 to 72 hours. While an exception request is pending, the beneficiary should receive the requested prescription (at a minimum, a 3-day supply if a 48-72 hour timeframe for PDP review of exception requests is adopted).

Section 423.578. Exceptions process. We have a number of recommendations regarding the proposed exceptions process. First, the final regulation must ensure that exceptions processes dovetail with SPAP prior authorization processes. Second, SPAPs must be allowed to be authorized representatives for the individual during the exception appeal. Third, while an exception is pending for dual eligibles, Medicare should pick up the full cost of the requested prescription until a decision is rendered so that states are not forced to pick up the costs as a potential Medicaid and SPAP continuity of care issue. This is particularly important because of restrictions on limiting Medicaid state plan services for the dual eligible population. Fourth, PDPs should be required to grandfather-in coverage of a deleted drug for anyone who was taking the medication prior to the deletion, unless the deletion is due to the new availability of a generic substitute or due to the FDA's removal of the drug from the market due to safety reasons. This should not be construed, however, as prohibiting a PDP from asking physicians to voluntarily switch their patients to less costly drugs as part of a therapeutic substitution initiative. Finally, we urge inclusion of language to guarantee access to lower co-pays when midyear increases are made by the PDPs.

Section 423.600 (p. 46722 of the preamble). Reconsideration by an Independent review entity (IRE). Connecticut supports the proposal for establishing an independent review entity for reconsideration of PDP redeterminations.

Sections 423.560 to 423.638. Grievances, Coverage Determinations, and Appeals. As an alternative to the dispute resolution framework presented in the proposed rule, we offer a potential retrospective dispute settlement framework. Under this alternative, a drug is authorized in favor of continuity of care while the dispute resolution process takes place. The system could be modeled after several Medicare demonstration programs operating in states dealing with home care coverage in the Medicare and Medicaid programs.

N. Medicare Contract Determinations and Appeals

No comments.

O. Intermediate Sanctions

No comments.

P. Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Section 423.772 (pp. 46725-46726 of the preamble). Definitions. *Family Size.* In addition to applicant and his/her spouse, the household includes "individuals who are related to the applicant or applicants…and who are dependent on the applicant or the applicant's spouse for at least one-half of their financial support." As the preamble indicates, this rule is dissimilar to the SSI as well as eligibility determination rules for Transitional Assistance under the current drug discount card program. By requiring the consideration of a household member other than a spouse, complexity is added to the process, increasing the administrative burden on states performing eligibility determinations for low income subsidy individuals. It is also very different than how eligibility is determined for our SPAP, and as such, it increases the administrative burden involved in wrapping around the Part D benefit. The rule should be changed to have greater consistency with existing government programs.

Section 423.772. Definitions. *Resources*. The proposed rule at Section 423.773 includes resource limits (also known commonly as "asset limits") for "full subsidy eligible" and "other low-income subsidy" eligible individuals. The definition for resources under Section 423.772 of "other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act" is problematic because it is vague. It is not clear how this 20-day liquidation rule should be interpreted. The regulation should provide a specific list of instruments and asset types that are excluded. For example, cash surrender value of life insurance should be totally excluded. Providing a clear list of excluded "non-liquid" resources will foster uniform eligibility determination and ease the administrative burden for SPAPs.

Section 423.772. Definitions. *Institutionalized individual.* (cross reference Section 423.782. Cost-sharing subsidy.) While institutionalized persons have no cost sharing for covered Part D drugs covered under their PDP or MA-PD plans, the definition of "institutionalized" is problematic. Individuals in residential care homes, group homes, etc. are vulnerable populations and their care is typically paid for or subsidized by states and the federal government. The imposition of cost-sharing on these individuals could have the unintended effect of encouraging institutionalization in order to provide prescription coverage under Part D. The incentive should be for the client to choose the community option, not the institutional option. Community settings such as residential care homes and group homes should be included in the definition of "institutionalized individual."

Section 423.782(a)(2)(ii) (p. 46729). Cost-sharing subsidy. *Full subsidy eligible individuals.* Consistent with the MMA statute, this section rules out any cost-sharing for institutionalized beneficiaries, although page 46729 of the preamble may not completely comport with the outlined section. The preamble refers to 1902(q)(1)(B) of the Social Security Act:

(B) In this subsection, the term "institutionalized individual or couple" means an individual or married couple—

(i) who is an inpatient (or who are inpatients) in a medical institution or nursing facility for which payments are made under this title throughout a month, and

(ii) who is or are determined to be eligible for medical assistance under the State plan.

It would appear that the SSA section above does define ICF/MRs as institutions, so those clients would not be subject to cost sharing. It is less clear whether individuals in 1915(c) waiver group homes, assisted living facilities, residential care homes, boarding homes and other such entities would be defined also as "medical institutions." For the reasons outlined in our comments on special needs populations (section 423.120), we strongly believe that all of these individuals need to be exempt from cost-sharing. Thus, the proposed rule should be clarified to include in the definition of "institutionalized beneficiary" all individuals in 1915(c) waiver group homes, assisted living facilities, residential care homes, boarding homes and other such therapeutic residential facilities.

Q. Guaranteeing Access to a Choice of Coverage (Qualifying Plans and Fallback Plans)

See our comments under Subpart J regarding nondiscrimination and use of preferred plans.

Section 423.855 (p. 46638 of the preamble). Definitions. *Eligible Fallback Entity or Fallback Entity*. If the fallback option must be implemented because not enough PDPs or MA-PD plans express interest in serving in a state, the definition of an eligible fallback entity should be modified so that an SPAP can serve as the fallback plan for SPAP clients (and all others would go to the Part D fallback provider).

R. Payments to Sponsors of Retiree Prescription Drug Plans

Section 423.884 (pp. 46741 – 46743 of the preamble). Requirements for qualified retiree prescription drug plans. *Definition of Actuarial Equivalence.* CMS' concern over windfalls, though justifiable, could drive sponsors from participating in the subsidy or worse yet drive them to drop their employer-sponsored drug coverage completely. CMS is so concerned that employers could impose the full cost of the benefit package on employees through employee premiums or contribute a smaller amount toward the financing of the package and still be eligible for subsidy, that they don't realize their proposed requirements to qualify for the subsidy are too stringent for most employers.

Three tests for actuarial equivalency have been proposed. Option 1 is the creditable coverage gross test or one prong approach. Option 2 proposes to limit the amount of the retiree drug subsidy so that it could not exceed the amount paid by plan sponsors on behalf of their retirees. Option 3 proposes a two- prong gross and net test that employers must satisfy. We do not support the proposals under Options 2 and 3 as they contradict the intent of the MMA to slow the decline in employer-sponsored retiree insurance. In addition, CMS stated in the preamble that, "we have questions about the adequacy of the legal basis" for the proposed policies in Options 2 and 3. If

a limit on the subsidy is imposed, there is no incentive for employers that offer a retiree drug benefit that exceeds the proposed Part D coverage to continue to provide high-quality prescription drug coverage to their Medicare eligible retirees. The two-prong approach under Option 3 places an undue burden on employers by requiring them to meet both tests in order to qualify for the subsidy. The unnecessary burden of meeting the net test may force employers to not apply for the subsidy, discontinue its coverage and make Medicare Part D the primary payer for its retiree drug costs.

For all these reasons stated above, we believe the gross test for actuarial equivalency proposed as Option 1 is more than sufficient. It meets the policy goal established by Congress in that it will minimize the administrative burdens on employers. By minimizing the administrative burdens, more employers will retain their sponsored drug coverage for its retirees and thereby fulfill two other goals of Congress to maximize the number of retirees retaining employer-sponsored drug coverage and minimize the costs to the government of providing retiree drug subsidies.

Section 423.888 (pp. 46745 – 46746 of the preamble). Payment methods, including provision of necessary information. *Plan Year versus Coverage Year Issues.* Cost threshold and cost limits are calculated for plan years that end in 2006 yet the subsidy amount for a qualifying covered retiree is based on coverage year (calendar year). Connecticut is a state that has a July 1 through June 30 plan year. As such we would encounter the situation identified where for the plan year July 1, 2006 through June 30, 2007, our actuarial attestation would be due on April 1, 2006. However, the cost threshold and cost limit for 2007 would most likely not be calculated. This is a major issue for employers. How can employers provide evidence of actuarial equivalency without knowing the cost limit and cost threshold that will be in place during the plan year? It is unreasonable and unrealistic to expect that this can be done.

A second aspect of this issue is specific to the first year of implementation. How should CMS handle plan years that begin in 2005 with respect to the subsidy payment? The options are to: 1) start counting gross costs for prescriptions filled after January 1, 2006; 2) determine a subsidy amount as if the sponsor were authorized to receive subsidy payments for the entire plan year and then prorate this amount based on the number of plan year months that fall in 2006; or 3) determine subsidy amounts on a monthly basis as if the sponsor were authorized to receive subsidy payments for the entire plan year but would then pay only the amounts for the plan year months that fall in 2006. Of the three options presented the preference is for either Option 1 or Option 3. Because our plan year begins July 1, 2005, the same results would be achieved under either scenario.

Section 423.888 (pp. 46746 – 46748 of the preamble). Payment methods, including provision of necessary information. *Payment Methodology.* The proposal is for CMS to make monthly payments with adjustments for over/under payments to subsequent periodic payments and a final reconciliation 45 days after the end of the calendar year. This requires plan sponsors to certify by the 15th of the following month the total amount by which actual drug spending exceeds the cost threshold and yet remains below the cost limit. CMS based this method on the assumption that plan sponsors use PBMs and PBMs routinely adjudicate claims on a real-time basis with very limited claims or payment lags. This may be true, but what does a sponsor do if it can't get the data in a timely fashion from the plan? The State of Connecticut utilizes the services of one PBM

for the collection of prescription claims data for all employees, including retirees. The prescription benefits are on a fully insured basis with employees contributing a set dollar amount for a co-payment. The state has encountered problems with respect to receiving timely information from the PBM. The expectation to require sponsors to certify the prior month's amounts by the 15th is idealistic and is a goal that the state would be unlikely to meet. A more realistic goal would be to allow sponsors to certify within the range of 45 – 60 days after the end of the month.

Section 423.888 (p. 46748 of the preamble). Payment methods, including provision of necessary information. *Data Collection*. Of the options proposed, we recommend the first option that requires the sponsor (or group health plan designated by the sponsor) to submit the aggregate total of all allowable drug costs of all of the qualifying covered retirees in the plan for the time period in question. This choice does not place excessive burdens on the employer and is the most protective of the retiree's privacy. CMS states that this option may be the most problematic in terms of assuring the accuracy of the subsidy payment but we disagree. Even though the aggregate cost submitted to CMS would not be broken down to each qualifying retiree, the sponsor (or group health plan) must maintain the claims data to support and verify its submission for audit purposes for at least six years after the end of the plan year.

The remaining options require a sponsor (or group health plan) to submit the aggregate allowable costs for each qualifying covered retiree. Even if this data is required for only the first two years as proposed in one option, there are still privacy issues. Therefore the remaining options are not recommended as they impinge on a retiree's privacy. This infringement is to the point where the submission of costs broken down to each retiree does not appear to comply with the government's own HIPAA requirements.

S. Special Rules for States—Eligibility Determinations for Low-Income Subsidies, and General Payment Provisions

Section 423.904 (p. 46751 of the preamble). Eligibility determinations for low-income subsidies. (See also Section 423.744 (p. 46727 of the preamble)). We request clarification of the language on page 46751 of the preamble regarding eligibility determinations for low-income subsidies being conducted "consistent with the manner and frequency" that Medicaid determinations and redeterminations are conducted. While Section 1860D-14(a)(3) of the Act and the proposed rule at Section 423.774(a) say that eligibility determinations for low-income subsidies are made "by the State under its State plan under title XIX if the individual applies with the Medicaid agency," this is inconsistent with the language on page 46751 of the preamble. Also, if a state were to consider using a contractor for the eligibility determination and redetermination process, we would want costs associated with the contractor to be eligible for FFP.

The state is seeking clarification as to whether CMS would approve a State Plan Amendment that eliminates prescription drugs as a covered benefit for full duals (because of the availability of the Part D benefit), without violating equal amount, scope and duration requirements. In other words, can states limit pharmaceutical coverage in Medicaid to non-duals? Without this ability, states will be faced with providing prescription drug coverage for dual eligible Medicaid

recipients who decline enrollment or disenroll at 100% state cost. If CMS will not approve such an amendment, the state will be open to coverage at 100% state cost of Part D non-formulary drugs pending the outcome of an appeal.

Section 423.906(a) (p. 46751 of the preamble). General payment provisions. *Regular Federal matching*. The proposed rule indicates that states could receive the regular federal match for administrative costs in determining subsidy eligibility and for notification. However, the preamble also indicates that states would be responsible for periodic redeterminations. We therefore believe that the rule should be modified to clarify that FFP for redeterminations is permitted.

In addition, ongoing financial support should be provided for states' operational and administrative costs once transitional grants end in/after FFY 06. Specifically, in addition to the provision that allows states to gain federal financial participation on their administrative costs associated with determining a dual eligible's subsidy, states and SPAPs should be eligible to count the following as eligible reimbursement costs in the Medicaid program: costs of enrolling dual eligibles in the Part D program; enrollment and eligibility costs of SPAP recipients in the part D program; and all administrative costs associated with administering a wraparound for both dual eligible and SPAP recipients.

Section 423.910. Requirements. If Connecticut determines that it is in their best interest – from both a financial and continuity of care standpoint – to run their own prescription drug program for their dual eligibles at 100% state cost (e.g., through our SPAP), can we waive the auto-enrollment process for dual eligibles? It appears that under this scenario, the state would not be subject to the phase-down state contributions provisions.

Section 423.910(b)(1) (p. 46752 of the preamble). Requirements. *State contribution payment. Calculation of payment*. The 2003 base year is artificially high because it fails to account for changes in utilization and pricing that were implemented through Connecticut law to bring down pharmacy costs in the Medicaid program for dual eligibles (e.g., MAC pricing, prior authorization, generic substitution, dispensing fee changes, preferred drug list and supplemental rebates). We believe that the law (Section 1935(b), page 2157 of MMA) gives the Secretary the discretion to make adjustments to the 2003 base. In determining the gross per capita Medicaid expenditures for prescription drugs, the Secretary shall "use data from the Medicaid Statistical Information System (MSIS) and other available data" (emphasis added). We believe the Secretary could use actuarial analyses or other data to evaluate the changes to state drug expenditures (as described above) to consider adjustments to the 2003 baseline. We ask that you consider this and adjust the proposed rule accordingly.

Section 423.910(b)(2) (p. 46752 of the preamble). Requirements. *State contribution payment. Method of payment.* The rule specifies that state payments for the "phased-down state contribution" would be made in a manner similar to the mechanism by which states pay Medicare Part B premiums for dual eligibles. If Connecticut can make its contribution in the same manner as we are currently doing for our dual eligibles, this methodology is acceptable. If the Secretary were to require that we submit a check or make an electronic transfer payment,

there would be significant implications for Connecticut's constitutional and statutory expenditure cap.

T. Part D Provisions Affecting Physician Self-Referral, Cost-Based HMO, PACE, and Medigap Requirements

No comments.

CMS-4068-P-1260

Submitter : Ms. c c **Date & Time:** 10/04/2004 08:10:46

Organization : c

Category : Individual

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

lkjkl kjllkj lkjlkj lkjlkjlkj

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
DEPARTMENT FOR REGULATIONS & DEVELOPMENT

Please note, the attachment to this document has not been attached for several reasons, such as:

1. Improper format,
2. Submitter did not follow through attaching the document properly,
3. The document was protected and would not allow for CMS to attach the attachment to the original message.

We are sorry that we cannot provide this attachment to you at this time electronically, but you can view them here at CMS by calling and scheduling an appointment at 1-800-743-3951.

Submitter : Dr. Paul Wettengel **Date & Time:** 10/04/2004 08:10:00

Organization : FirstChoice Healthcare

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Thank you for your attention to this matter.

CMS-4068-P-1261-Attach-1.rtf

To CMS Officials,

FirstChoice Healthcare is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

FirstChoice Healthcare is licensed to provide home health care nursing, palliative care and I.V. therapy services in 25 Central and Eastern Nebraska counties as well as a wide geographic area in Western Iowa. Approximately 20% of referred infusion therapy patients return home to their local community to finish their prescribed intravenous regimen.

As FirstChoice Healthcare provides a complete range of intravenous therapies, enteral therapies, home health services and palliative care services, demographics are quite diverse: pediatric, adult, geriatric, surgical oncology, AIDS, infectious diseases, OB/GYN, the terminally ill, cardiology, immuno-compromised, pulmonary, and the solid organ and bone marrow transplantation population.

FirstChoice Healthcare appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD

community, his new coverage under Part B *has not resulted in additional access to home IVIG under Medicare.* We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm .

CMS should establish **specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies** to ensure adequate enrollee access to home infusion therapy under Part D.

CMS should require **specific standards for home infusion pharmacies** under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

CMS should adopt the **X12N 837 P billing format** for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

CMS should **mandate that prescription drug plans maintain open formularies for infusion drugs** to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Paul J. Wettengel, PharmD
President/CEO
FirstChoice Healthcare
8710 F Street, Suite 118
Omaha, NE 68127-1532

CMS-4068-P-1262

Submitter : Mr. Randall Binning **Date & Time:** 10/04/2004 08:10:38

Organization : Mr. Randall Binning

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS,

I write this comment in hopes that you will consider the role pharmacists can play in the improvement of healthcare given to the clients covered by medicare and medicaid.

Pharmacists are in an important position to manage medication therapy for patients who need to take chronic medications. Pharmacists are highly accessible, as well as most patients pick up medications monthly.

Currently pharmacists get paid to dispense medications regardless of the amount of time or information that is given to the patient. FOr the most part there is little incentive for pharmacists to make sure patients are using their medications properly. If pharmacists are given reimbursement for their services, patients with chronic conditions could be monitored on a monthly, or some other regular basis that would improve the medication therapy.

In the new CMS bill, I believe there needs to be a definition of what pharmacy management of medication therapy is and it must not be left up to the pharmacy benefit managers (PBM) to determine what this reimbursement is.

This medication management is already in place but could be vastly improved if reimbursement for it was appropriate.

It is also important that all pharmacists would be elligible to receive reimbursement if medication therapy management is given. Please do not allow the PBMs to dictate which pharmacist can give the management.

In closing, pharmacies can be an integral component of the new Medicare benefit. Medicare recipients often rely on their pharmacist for advice and counsel. Pharmacists will be able to assist in making this new benefit successful or they will speak out against it. Medicare must make specific requirements of the plan sponsors otherwise many of the nation?s foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacists must be allowed to participate equally and fully. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program.

Thank you for your consideration.

Sincerly,

Randall Binning PharmD (graduated 2004)
Pharmacy Resident

CMS-4068-P-1263

Submitter : Mr. John Bynon **Date & Time:** 10/04/2004 08:10:48

Organization : TVA Retirees Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attached letter.

CMS-4068-P-1263-Attach-1.doc

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8014

Re: File Code CMS-4068-P
Comments to Proposed Rules for Medicare Prescription Drug Benefit

Dear Sir or Madam:

The following are the comments of the Tennessee Valley Authority Retirees Association on the proposed rules to implement the new Medicare Prescription Drug Benefit. We appreciate the opportunity to provide comments on these important issues.

The TVA Retirees Association seeks to represent the views of retirees of TVA, who are not eligible for coverage in the Federal Employees Health Benefits Program, but who instead are covered by medical plans sponsored by TVA.

For the most part, TVA retirees pay for their TVA-sponsored retiree medical benefits out of a TVA-funded pension supplement provided by the TVA Retirement System and not directly by TVA. This unique way of providing employer assistance for retiree medical benefits was adopted in part to assure that retirees would continue to receive an employer-funded vested benefit, which the retirees could choose to use for the retiree medical benefits of their choice.

According to the proposed rules, employers will have several options available to them, one of which is to continue to sponsor retiree prescription drug coverage that is actuarially equivalent to Medicare Part D benefits while accepting a retiree drug subsidy (the "Primary Coverage Option"). It is our understanding that CMS is leaning toward the "two-prong" test for determining actuarial equivalence. Based on the unique way in which a portion of the TVA plan premiums may be paid with the use of retiree pension subsidies, TVA is concerned that the TVA plan may not satisfy the second "net value" prong as currently proposed. In light of the Medicare Part D program, the inability to qualify for the Primary Coverage Option would be a disincentive to TVA to continue providing the TVA plan as primary coverage to its Medicare-eligible retirees. Such a result would be contrary to CMS's express goals of maximizing the number of retirees retaining employer-based drug coverage while minimizing the administrative burdens on beneficiaries and employers.

The TVA Retirees Association supports adoption of a final rule which would give TVA the flexibility to adopt the Primary Coverage Option if such an option is desired by and beneficial to TVA's Medicare-eligible retirees and achieves CMS's goals with respect to employer-based drug coverage. We request that CMS draft the final rules to allow employers like TVA, which have retiree drug plans with benefits at least as equivalent to the Part D benefit but which are financed in unique ways such as with pension subsidies, to satisfy the actuarial equivalence test

or to provide the flexibility to work with CMS in order to qualify for the Primary Coverage Option.

Sincerely,

John S. Bynon, Sr.
Chairman, Insurance Committee
TVA Retirees Association
224 West Hills Road
Knoxville, TN 37909

CMS-4068-P-1264

Submitter : Mr. Timothy Schuerch **Date & Time:** 10/04/2004 08:10:51

Organization : Alaska Native Tribal Health Consortium

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please find enclosed MS Word document containing comments applicable to a number of provisions of the proposed Part D regulations; dd

CMS-4068-P-1264-Attach-1.doc

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM
Administrative Offices 4141 Ambassador Drive
Anchorage, Alaska 99508
Telephone: 907-729-1900
Facsimile: 907-729-1901

FILE CODE: CMS-4068-P

Comments To Proposed Medicare Part D Regulations

I. INTRODUCTION: The Alaska Native Tribal Health Consortium

The Alaska Native Tribal Health Consortium (ANTHC) is the largest privately operated Indian health program in America, managing over $125 million annually in IHS program and project funds, and with total revenues in excess of $300 million per year, all of which is devoted exclusively to providing health services to Alaska's 100,000+ Alaska Natives.

We are organized under the Alaska Non-profit Code, and enjoy tax-exempt status under Section 501(c)(3) of the Internal Revenue Code. Our three primary sources of revenue are (1) compacted IHS funds; (2) third party reimbursements, including private insurance, Medicare and Medicaid; and (3) federal grant funds. Our vision is *"a unified Native health system, working with our people, achieving the highest health status in the world."*

Pursuant to our charitable public health mission, we employ over 1,600 staff, including over 600 Indian Health Service (IHS) employees assigned to us under the Intergovernmental Personnel Act (IPA), and over 100 Commissioned Officers of the Public Health Service assigned to us under 42 USC 2004b in accord with 42 USC 215(d).

Our services encompass the Alaska Native Medical Center (ANMC), a JCAHO-accredited 150-bed acute care hospital in Anchorage, which we operate in cooperation with the Southcentral Foundation under the authority of Section 325 of P.L 105-83.

The ANMC Pharmacy is a large I/T/U pharmacy providing an array of services to our customer-owners, including Medicaid covered services, Medicare Part A covered services, Medicare Part B covered services, and Medicare Part D covered services. The ANMC Pharmacy serves many thousands of Medicare Part D eligible AI/AN, a significant percentage of which are subsidy eligible AI/AN.

Thus the treatment of AI/AN under the Medicare Part D regulations, especially AI/AN receiving services from I/T/U pharmacies, will have a significant impact on our third party reimbursements, which we heavily rely upon to support the provision of services to our AI/AN customer-owners.

II. KEY POLICY CONSIDERATIONS

(1) Aligning Part D regulations, as permitted by statute, with the Departmental AI/AN policy goal of narrowing the American Indian/Alaska Native health disparities gap, e.g., by lowering AI/AN barriers to access to pharmacy services.

(2) Consistent with Departmental AI/AN policy goals, and as permitted by statute, maximizing participation of Part D eligible AI/AN in the Part D program by ensuring that AI/AN, and the I/T/U pharmacies serving AI/AN, are consistently and uniformly treated in a manner that reflects Departmental AI/AN policy goals.

(3) Consistent with Departmental AI/AN policy goals, and as permitted by statute, maximizing participation of Part D eligible AI/AN by tailoring the regulations to prospectively avoid Secretarial findings for AI/AN under 42 USC 1860D-11(e)(2)(D)(i), with regard to any PDP, that "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan."

(4) Consistent with Departmental AI/AN policy goals, and as permitted by statute, mitigating the financial burden on I/T/U pharmacies and States resulting from transition of payment for Part D covered services for subsidy eligible AI/AN from 100% FMAP-paid State agencies to the Medicare Part D system, which allocates costs for subsidy eligible AI/AN between I/T/U pharmacies, CMS and States.

(5) Consistent with Departmental AI/AN policy goals, and as permitted by statute, avoiding penalization of I/T/U pharmacies for providing services to AI/AN on an IHS-prepaid basis, without charge to the patient (per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)).

III. COMMENTS

SUBPART A—GENERAL PROVISIONS

(NO COMMENTS)

SUBPART B—ELIGIBILITY AND ENROLLMENT

COMMENT WITH REGARD TO THE SUBPART AS A WHOLE: In order to ensure maximum participation of AI/AN in Part D; in order to ensure that the Part D regulations treat AI/AN and the national network of I/T/U pharmacies serving AI/AN in a uniform manner that is consistent with Departmental AI/AN policy goals; and in order to minimize the likelihood of Secretarial findings for AI/AN under 42 USC 1860D-11(e)(2)(D)(i), with regard to any PDP or MA-PD, that, "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan," **ANTHC feels the Secretary should consider amending the provisions of Subpart B of the proposed regulations to reflect the following comprehensive statutory approach to access and enrollment of AI/AN in PDPs and MA-PDs:**

(1) The Secretary should exercise his statutory discretion under 42 USC §1860D-1(b) and 42 USC §1395w-21(b)(1)(A) to waive, in the case of AI/AN, the requirement that Part D eligible individuals may only enroll in a plan that encompasses that PDP's or MA-PD's geographic region;

(2) Through the bidding and approval processes of 42 USC §1860D-11 (PDPs) and §1854(a) (MA-PDs), the Secretary should establish a small number of PDPs and/or MA-PDs that, in addition to providing coverage for all Part D eligible individuals in their respective PDP or MA-PD area(s) who choose to enroll in that plan, would also provides coverage for AI/AN on a national basis for all Part D eligible AI/AN who choose to enroll in each such plan, as permitted by 42 USC §1860D-11(a)(3).

(3) In preparation for PDP and MA-PD bidding processes, the Secretary should develop and publicize, in close consultation with the CMS Tribal Technical Advisory Group (CMS TTAG), an **AI/AN supplemental information packet**. The packet would solicit PDP sponsors and MA-PD organizations to consider including in their bids one or more plans that would provide coverage for Part D eligible AI/AN on a national basis. It would contain information on Part D eligible AI/AN and the national network of I/T/U pharmacies serving AI/AN, in sufficient detail to allow bidders to fairly assess whether they should include in their bids the information required under 42 USC §1860D-11(b)(2), with regard to any plan(s) in the bid proposing to provide coverage for Part D eligible AI/AN on a national basis. The packet would also set forth any "additional information" that the Secretary (in close consultation with the CMS TTAG) would require to be included in bids containing one or more plans to provide national coverage to Part D eligible AI/AN, as permitted under 42 USC §1860D-11(b)(2)(F). Specific types

of information that the Secretary might consider including in the **AI/AN supplemental information packet** might include general information on AI/AN and AI/AN health issues, as carefully and compellingly set forth in **the National Indian Health Board comments to these regulations.** Consideration should also be given to describing in detail the national network of I/T/U pharmacies serving AI/AN, including:

- who they serve (AI/AN, per 25 USC §1680c);
- the basis on which services are provided (IHS-prepaid without charge to the AI/AN);
- where they are located (in I/T/U facilities near the AI/AN served);
- the way they buy drugs (FSS or 340B programs);
- the way they dispense drugs (with much more patient consultation than in the private sector due to the high risk of culture and/or language barriers impeding instructions);
- the information system used track drug and reimbursement information (RPMS);
- the charitable mission served (providing pharmacy services to a population group and in geographic areas characterized by failure of competitive market dynamics); and
- the way Medicare reimbursements are processed (via a nationally centralized system).

(4) In reviewing and negotiating bids (under 42 USC §1860D-11(d)) that contain one or more plans proposing to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such review and negotiation is conducted in a manner consistent with Departmental AI/AN policy goals.

(5) In approving or disapproving any plan (under 42 USC §1860D-11(e)) that proposes to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such approval or disapproval is made in a manner consistent with Departmental AI/AN policy goals, especially with regard to the requirement of 42 USC §1860D-11(e)(2)(D) that the Secretary approve a plan only if he "does not find that the design of the plan and its benefits (including any formulary or tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan."

(6) The Secretary has already successfully adopted a centralized national model similar to that proposed above for processing Medicare Part A and Part B payments to I/T/U facilities, through the use of a single Carrier for I/T/U providers nationwide. With I/T/U facilities already possessing the capacity to be reimbursed for Part A-covered drugs, and on the verge of gaining the capacity to be reimbursed for Medicare Part B-covered drugs and biologicals under §630 of the MMA, the Secretary may wish to consider the efficiencies and improved coordination of benefits in the administration of the various Medicare drug programs as they apply to I/T/U providers that would likely result from adopting a similarly centralized, national system for processing Part D drug benefit payments to I/T/U facilities. For example, Trailblazer LLC has done a fair job of coordinating Part A and Part B payments to I/T/U facilities since the passage of the BIPA. Organizations like Trailblazer might prove to be efficient and effective sponsors of

PDP or MA-PD plans providing Part D coverage to Part D eligible AI/AN on a national basis.

(Additional Comments to SUBPART B, ELIGIBILITY AND ENROLLMENT):

42 CFR 423.44 DISENROLLMENT BY THE PDP

COMMENT: Because I/T/U pharmacies provide services to AI/AN on an IHS-prepaid basis without charge to the AI/AN, per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)), the financial burden of disenrollment of a Part D eligible AI/AN receiving services from an I/T/U pharmacy will fall squarely on the I/T/U pharmacy, rather than the AI/AN. Moreover, the cost and expense of reenrollment of the Part D eligible, including payment of some or all of the premiums that may be owing, will also fall on the I/T/U pharmacy. Thus ANTHC feels the Secretary should consider adding a new subsection to 42 CFR 423.44 to clarify that in the case AI/AN, the Secretary reserves the discretion to waive or amend the disenrollment and reenrollment provisions of the section.

42 CFR 423.48 INFORMATION ABOUT PART D

COMMENT: This section requires each PDP and MA-PD plan to provide to CMS on an annual basis "the information necessary to enable CMS to provide current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage." For PDP or MA-PD plans providing coverage for Part D eligible AI/AN on a national basis, the Secretary should require this information to also be provided to the CMS TTAG and the IHS for distribution to AI/AN through the national network of I/T/U pharmacies.

42 CFR 423.50 APPROVAL OF MARKETING MATERIALS AND ENROLLMENT FORMS

COMMENT: CMS should consult closely with the CMS TTAG and the IHS in carrying out its review and approval of the marketing materials and enrollment forms of PDP and MA-PD plans providing coverage for Part D eligible AI/AN on a national basis.

42 CFR 423.56 PROCEDURES TO DETERMINE AND DOCUMENT CREDITABLE STATUS OF PRESCRIPTION DRUG COVERAGE

COMMENT: Subsection (a)(9) properly includes as creditable prescription drug coverage "coverage provided by the medical care program of the IHS, Tribe or tribal organization, or urban Indian organization (I/T/U)." However, we feel there are significant administrative burdens and inefficiencies with the approach of the proposed regulations to require, before coverage provided by I/T/U providers may be considered creditable prescription drug coverage, that coverage provided by I/T/U providers must meet the general requirement of subsection (a) that "the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles…." Because I/T/U pharmacies uniformly provide services to AI/AN on an IHS-

prepaid basis, without charge to the AI/AN, and uniformly only scale back services as a last resort when funding falls short, it is highly likely that coverage provided by I/T/U providers will nearly always equal or exceed the actuarial value of standard Medicare Part D prescription drug coverage. And, in those few instances when it may not, it will likely nearly always be because program funding was inadequate, in which case the I/T/U provider providing coverage would especially not be in no position to divert scarce resources away from direct services in order to pay for expensive actuarial analyses. Thus we believe significant public health policy interests weigh in favor of amending this section to waive the actuarial equivalence requirements in the case of coverage provided by I/T/U providers.

SUBPART C—BENEFITS AND BENEFICIARY PROTECTIONS

42 CFR 423.100 DEFINITIONS

Definitions of "INCURRED COSTS" and "INSURANCE OR OTHERWISE:

COMMENT: A bona fide question of statutory interpretation exists with regard to whether (1) amounts up to the annual deductible limit paid by an I/T/U pharmacy on behalf of non-subsidy eligible AI/AN, (2) cost-sharing expenses above the annual deductible limit up to the initial coverage limit waived or absorbed an I/T/U pharmacy on behalf of a non-subsidy eligible AI/AN, and (3) amounts exceeding the initial coverage limit paid by an I/T/U pharmacy on behalf of a non-subsidy eligible AI/AN, should be treated as *"incurred costs"* under 42 USC §1860D-2(b)(4)(C)(ii), and thus be counted by CMS towards the non-subsidy eligible AI/AN Part D enrollee's annual out-of-pocket threshold, which in 2006 will be $3,600.

It is fairly clear that under the preceding subsection at 42 USC §1860D-2(b)(4)(C)(i), all three of these cost categories must be treated consistently, i.e., either all three are "incurred costs" in cases where an I/T/U pharmacy pays or waives them on behalf of a non-subsidy eligible Part D AI/AN enrollee, and thus counted towards the AI/AN's annual out-of-pocket threshold, or all three are "insurance or otherwise," and not counted towards the AI/AN's out-of-pocket threshold.

Given his statutory discretion in this matter, the Secretary may wish to consider the likely, reasonably foreseeable outcomes of the latter, more restrictive of the two interpretations, and determine whether those outcomes are consistent with Departmental AI/AN policy goals.

If in 2006, an I/T/U pharmacy were to provide services to a non-subsidy eligible AI/AN Part D enrollee on an IHS-prepaid basis, without charge to the AI/AN, per its charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)), it would likely want to calculate the costs vs. benefits of paying the $250 deductible on behalf of the AI/AN.

If the AI/AN were to use up $1,250 worth of covered drug benefit in the year, then the I/T/U pharmacy might well decide to pay the $250 deductible, because after it was paid, the PDP or MA-PD would pay 75% of the remaining $1,000 ($750) with the I/T/U pharmacy paying the

remaining 25% ($250). In other words, between the deductible payment and its 25% cost-sharing obligation, the I/T/U pharmacy would pay or waive a total of $500 on behalf of the AI/AN, in return for which it would receive $750 from the PDP or MA-PD, or 60% of the AI/AN's total covered drug costs for the year.

If the AI/AN were to use up $2,250 worth of covered drug benefit in the year, topping out but not exceeding the initial coverage limit for the AI/AN in the year, then the I/T/U pharmacy would get a slightly better deal: it would pay $250 for the deductible, plus waive 25% of the remaining $2,000, for a total cost of $750. In return, it would receive from the PDP or MA-PD 75% of the $2,000 of drug costs in excess of the deductible, or $1,500, or 66.67% of the AI/AN/s total covered Part D drug costs for the year.

If the AI/AN were to use up $3,250 worth of covered drug benefit in the year, then the I/T/U pharmacy's benefit received from the PDP or MA-PD, as a percentage of payment for the AI/AN's total costs for covered Part D drugs for the year, would fall significantly: The I/T/U pharmacy would pay $250 for the deductible ($250), plus bear the cost of waiving the 25% cost-share for next $2,000 worth of covered drug benefit usage ($500), plus bear 100% of the cost of the remaining $1,000, because that is the amount by which the AI/AN's covered drug benefit costs for the year exceed his/her initial coverage limit ($1,000), for a total cost to the I/T/U pharmacy of $1,750, in return for which it would receive from the PDP or MA-PD 75% of the $2,000 ($1,500) of covered drug costs exceeding the deductible amount but less than the initial coverage limit, or 46.15%.

And, to the degree the AI/AN were to use up ever higher amounts of covered drug benefit in the year, the I/T/U pharmacy's benefit received from the PDP or MA-PD, expressed as a percentage of payment for the AI/AN's total costs for covered Part D drugs for the year, would continue to decline ad infinitum, since neither the deductible amounts paid by the I/T/U pharmacy, nor the cost-sharing amounts waived by the I/T/U pharmacy, nor the payment by the I/T/U pharmacy on behalf of the AI/AN of costs in excess of the initial coverage limit would be counted as "incurred costs" for purposes of calculating when that AI/AN's out-of-pocket threshold for that year. In other words, the out-of-pocket threshold amount for that year for that AI/AN would never be reached, nor could the out-of-pocket threshold ever be reached in any year for non-subsidy eligible AI/AN Part D enrollees.

Thus the reasonably foreseeable net effect of treating I/T/U pharmacy payment and waiver amounts as "insurance or otherwise," and not as "incurred costs," is a modest benefit if the AI/AN uses up no more than a few thousand dollars per year in covered Part D drug benefit, but a complete absence of any additional benefit for amounts exceeding the initial coverage limit, which in 2006 will be $2,250. The stop-gap benefits that would normally come into play for amounts of the covered Part D drug benefits in excess of the annual out-of-pocket limit, $3,600 in 2006, would be completely eliminated. In other words, with regard to the significant stop-gap benefits that would otherwise be available to non-AI/AN non-subsidy eligible Part D enrollees, AI/AN non-subsidy eligible Part D enrollees, and the I/T/U pharmacies that serve them, are severely penalized precisely because the I/T/U pharmacy providing services to that AI/AN does

so on an IHS-prepaid basis, without charge to the patient (per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)). **In other words, the proposed regulations, as written, subject AI/AN and the I/T/U pharmacies that serve AI/AN to severe financial penalties in comparison to non-AI/AN and non-I/T/U pharmacies precisely for doing nothing more than fulfilling their public health mission and carrying out the Departmental policy objective of narrowing the AI/AN health disparities gap via, e.g., lowering AI/AN barriers to access to pharmacy services.**

We also agree with and incorporate by reference into these comments the excellent, well-thought-out public health policy discussion regarding these definitions in **the National Indian Health Board comments** to the definitions of "incurred costs" and "insurance or otherwise" in 42 CFR 423.100 of the proposed regulations.

42 CFR 423.100 DEFINITIONS (continued)

Definition of "Network Pharmacy:"

COMMENT: ANTHC feels consideration should be given to amending this definition, or otherwise clarifying in regulation, policy, PDP or MA-PD contract, and/or in "additional information" the Secretary might require of certain plans in their bid documents, that PDP or MA-PD plans that provide coverage for Part D eligible AI/AN on a national basis be required to include as "network pharmacies" all pharmacies in the national I/T/U pharmacy network.

Definition of "Person:"

COMMENT: ANTHC strongly urges the Secretary to amend this definition by adding an additional sentence that affirmatively assures the inclusion of all I/T/U pharmacies, regardless of whether operated by the IHS, a Tribe or tribal organization, or an urban Indian organization. The significance of this definition is that it would clarify that costs paid or waived by I/T/U pharmacies on behalf of AI/AN are "incurred costs" for purposes of calculating the annual out-of-pocket limit for all AI/AN Part D enrollees under 42 USC §1860D-2(b)(4)(B)(ii), including non-subsidy eligible AI/AN.

Definition of "Preferred Pharmacy:"

COMMENT: ANTHC feels consideration should be given to amending this definition, or otherwise clarifying in regulation, policy, PDP or MA-PD contract, and/or in "additional information" the Secretary might require of certain plans in their bid documents, that PDP or MA-PD plans that provide coverage for Part D eligible AI/AN on a national basis be required to treat all I/T/U pharmacies as "preferred pharmacies."

42 CFR 423.112 ESTABLISHMENT OF PRESCRIPTION DRUG PLAN SERVICE AREAS

(NO COMMENTS)

42 CFR 423.120 ACCESS TO COVERED PART D DRUGS

Subsections (a)(1) and (3):

COMMENT: We feel consideration should be given to creating an additional waiver under subsection (a)(3) of the pharmacy access requirements of subsection (a)(1) in the case of the national I/T/U pharmacy network. The national I/T/U pharmacy network has been established by the IHS, Tribes and tribal organizations, and urban Indian organizations for the express purpose of maximizing AI/AN pharmacy access within the constraints of the limited resources available to I/T/U pharmacies. To impose the generally applicable access requirements of (a)(1) on I/T/U pharmacies would be inequitable, costly, and have the effect of penalizing the more remote and underfunded I/T/U pharmacies by creating incentives for PDP and MA-PD plans to de-select them and otherwise attempt to exclude them from their respective networks. In other words, it is precisely because I/T/U pharmacies tend to serve populations and geographic areas characterized by failure that what would normally be generally applicable market assumptions implicit in subsection (a)(1) would not hold true. Again, without such a waiver, PDPs and MA-PDs will in many cases avoid dealing with I/T/U pharmacies, which in turn will result in sub-optimized participation of AI/AN, particularly those in remote or impoverished areas, in the Medicare Part D benefit, contrary to Departmental AI/AN policy goals.

Subsection (a)(5), Discounts for Preferred Pharmacies:

COMMENT: We feel consideration should be given to amending this subsection to clarify that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis must treat all I/T/U pharmacies as "preferred pharmacies," to ensure that in all cases, I/T/U pharmacies will receive the best negotiated PDP or MA-PD reimbursement available, assuring that IHS-funded I/T/U pharmacies, and thus taxpayers, will in all cases be able to take advantage of the financial benefits of the MMA's competition-assurance provisions, as well as assuring that the Department policy goal of narrowing the AI/AN health disparities via lowering AI/AN barriers to access to pharmacy services is well-served.

Subsection (b)(1), Formulary Requirements—Development and Revision By a Pharmacy and Therapeutic Committee:

COMMENT: This provision requires that a PDP sponsor's or MA organization's formulary "must be reviewed by a pharmacy and therapeutic committee" that meets certain requirements. We feel consideration should be given to amending this subsection to require that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis must include on their respective pharmacy and therapeutic committees at least one pharmacist or physician selected by the IHS; at least one pharmacist or

physician selected by Tribes and tribal health organizations; and at least one pharmacist or physician selected by urban Indian organizations.

Subsections (b)(4), (5), and (7), Periodic Evaluation of Protocols; Provisions of Notice Regarding Formulary Changes; Provider and Patient Education:

COMMENT: We feel consideration should be given to clarifying in the regulatory language or in Secretarial policy that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis be required to engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies in the protocol evaluation requirement of subsection (b)(4); the provisions of notice regarding formulary changes requirement of subsection (b)(5); and the provider and patient education requirement of (b)(7).

Subsection (c) Use of Standardized Technology:

COMMENT: We feel consideration should be given to clarifying in the regulatory language or in Secretarial policy that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis be required to engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies in the technology standardization requirements of this subsection.

42 CFR 423.128 DISSEMINATION OF PLAN INFORMATION

COMMENT: We feel consideration should be given to clarifying in the regulatory language or in Secretarial policy that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis be required to engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies regarding the plan information dissemination requirements of this section.

42 CFR 423.132. PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS

COMMENT: We strongly urge the Secretary to consider amending this section to provide an exception from this requirement in the case of I/T/U pharmacies. I/T/U pharmacies provide services to AI/AN on an IHS-prepaid basis, without charge to the patient, per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)). Thus it is the I/T/U pharmacies, and not the AI/AN receiving services, that bear the cost of PDP or MA-PD formulary choices, obviating the need for AI/AN receiving services from I/T/U pharmacies to have such price-comparison information.

SUBPART D: …

(NO COMMENTS)

SUBPART F: SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL

COMMENT: COMMENT WITH REGARD TO THE SUBPART AS A WHOLE: In order to ensure maximum participation of AI/AN in Part D; in order to ensure that the Part D regulations treat AI/AN and the national network of I/T/U pharmacies serving AI/AN in a uniform manner that is consistent with Departmental AI/AN policy goals; and in order to minimize the likelihood of Secretarial findings for AI/AN under 42 USC 1860D-11(e)(2)(D)(i), with regard to any PDP or MA-PD, that, "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan," **ANTHC feels the Secretary should consider amending the provisions of Subpart F of the proposed regulations to reflect the following comprehensive statutory approach to access and enrollment of AI/AN in PDPs and MA-PDs:**

(7) The Secretary should exercise his statutory discretion under 42 USC §1860D-1(b) and 42 USC §1395w-21(b)(1)(A) to waive, in the case of AI/AN, the requirement that Part D eligible individuals may only enroll in a plan that encompasses that PDP's or MA-PD's geographic region;

(8) Through the bidding and approval processes of 42 USC §1860D-11 (PDPs) and §1854(a) (MA-PDs), the Secretary should establish a small number of PDPs and/or MA-PDs that, in addition to providing coverage for all Part D eligible individuals in their respective PDP or MA-PD area(s) who choose to enroll in that plan, would also provides coverage for AI/AN on a national basis for all Part D eligible AI/AN who choose to enroll in each such plan, as permitted by 42 USC §1860D-11(a)(3).

(9) In preparation for PDP and MA-PD bidding processes, the Secretary should develop and publicize, in close consultation with the CMS Tribal Technical Advisory Group (CMS TTAG), an **AI/AN supplemental information packet**. The packet would solicit PDP sponsors and MA-PD organizations to consider including in their bids one or more plans that would provide coverage for Part D eligible AI/AN on a national basis. It would contain information on Part D eligible AI/AN and the national network of I/T/U pharmacies serving AI/AN, in sufficient detail to allow bidders to fairly assess whether they should include in their bids the information required under 42 USC §1860D-11(b)(2), with regard to any plan(s) in the bid proposing to provide coverage for Part D eligible AI/AN on a national basis. The packet would also set forth any "additional information" that the Secretary (in close consultation with the CMS TTAG) would require to be included in bids containing one or more plans to provide national coverage to Part D eligible AI/AN, as permitted under 42 USC §1860D-11(b)(2)(F). Specific types of information that the Secretary might consider including in the **AI/AN supplemental information packet** might include general information on AI/AN and AI/AN health issues, as carefully and compellingly set forth in **the National Indian Health Board comments to these regulations.** Consideration should also be given to describing in detail the national network of I/T/U pharmacies serving AI/AN, including:

- who they serve (AI/AN, per 25 USC §1680c);
- the basis on which services are provided (IHS-prepaid without charge to the AI/AN);
- where they are located (in I/T/U facilities near the AI/AN served);
- the way they buy drugs (FSS or 340B programs);
- the way they dispense drugs (with much more patient consultation than in the private sector due to the high risk of culture and/or language barriers impeding instructions);
- the information system used track drug and reimbursement information (RPMS);
- the charitable mission served (providing pharmacy services to a population group and in geographic areas characterized by failure of competitive market dynamics); and
- the way Medicare reimbursements are processed (via a nationally centralized system).

(10) In reviewing and negotiating bids (under 42 USC §1860D-11(d)) that contain one or more plans proposing to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such review and negotiation is conducted in a manner consistent with Departmental AI/AN policy goals.

(11) In approving or disapproving any plan (under 42 USC §1860D-11(e)) that proposes to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such approval or disapproval is made in a manner consistent with Departmental AI/AN policy goals, especially with regard to the requirement of 42 USC §1860D-11(e)(2)(D) that the Secretary approve a plan only if he "does not find that the design of the plan and its benefits (including any formulary or tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan."

The Secretary has already successfully adopted a centralized national model similar to that proposed above for processing Medicare Part A and Part B payments to I/T/U facilities, through the use of a single Carrier for I/T/U providers nationwide. With I/T/U facilities already possessing the capacity to be reimbursed for Part A-covered drugs, and on the verge of gaining the capacity to be reimbursed for Medicare Part B-covered drugs and biologicals under §630 of the MMA, the Secretary may wish to consider the efficiencies and improved coordination of benefits in the administration of the various Medicare drug programs as they apply to I/T/U providers that would likely result from adopting a similarly centralized, national system for processing Part D drug benefit payments to I/T/U facilities. For example, Trailblazer LLC has done a fair job of coordinating Part A and Part B payments to I/T/U facilities since the passage of the BIPA.

SUBPART G: PAYMENT TO PDP SPONSOR AND MA ORGANIZATIONS OFFERING MA-PD PLANS FOR ALL MEDICARE BENEFICIARIES FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

42 CFR §423.329 DETERMINATION OF PAYMENT

Subsection (b), Health Status Risk Adjustment:

COMMENT: We feel that for PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis, the Secretary should engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies in the establishment of risk adjustment factors, data collection of risk adjustment factors, development of methodologies to measure risk adjustment factors, and publication of risk adjustment factors as required under this section.

…

SUBPART P: PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

42 CFR 423.772 DEFINITIONS

Definition of "Resources:"

COMMENT: Many AI/AN hold interests in real property that is held in one or more types of trust status by the U.S. Government. Given the statutory restrictions that these real property interests are subject to by definition, we feel consideration should be given to amending this definition to make clear that real property interests of AI/AN individuals held in some form of trust status by the U.S. Government are excluded from this term. **We incorporate by reference the excellent, well-researched National Indian Health Board comments on this definition**.

Definition of "Income:"

COMMENT: Under the MMA, the Secretary has the option to permit a State to make subsidy eligibility determinations using the methodology set out at section 1905(p) of the Act if the Secretary determines that this would not result in any significant difference in the number of individuals who are made eligible for the subsidy. This in turn would permit a State to use the same resource methodologies that it uses to determine Medicaid eligibility for QMBs, SLMBs, and QIs if the Secretary determines that the use of those methodologies would not result in any significant differences in the number of individuals who are made eligible for a subsidy. This includes the less restrictive methodologies a State may use under section 1902(r)(2) of the Act to determine eligibility for QMBs, SLMBs and QIs.

The Secretary has proposed not to exercise this option at all under the proposed regulations, for two reasons: First, allowing States this greater flexibility to establish their own income determination standards would detract from the policy objective of achieving uniformity in the low-income subsidy determination process. Second, allowing States this flexibility would result in significant administrative burdens and complexity in administering the Medicare Part D low-income subsidy eligibility determination process.

Given the Departmental policy goal lowering barriers to access to services to narrow the AN/AI health disparities gap, and given the well-documented barriers of poverty, distance, high incidence of disease experienced by many Medicare-eligible AN/AI, and given the scarce resources and escalating costs experienced by all I/T/U pharmacies, we feel significant public health policy considerations weigh heavily in favor of the Secretary exercising his statutory discretion granted to him at under 42 USC §1860D-14(a)(3)(C)(iv) of the Act to amend this proposed regulatory definition of "income" in a way that would allow States to employ the less restrictive methodologies of 1902(r)(2) in making subsidy eligibility determinations for AI/AN.

The policy interest of maintaining uniformity would still be well-served, because the exception to the rule that would be created would be miniscule in comparison to the entire Part D program; the exception would only apply to a very defined population group; and in creating their own income determination standards under 1902(r)(2), States would still be constrained by the limits inherent in 1902(r)(2) and related statutes.

The policy interests of assuring economy and efficiency and avoiding unnecessary complexity and administrative burdens in carrying out the Part D program would also be well-served because State programs are already quite familiar with AI/AN populations; the I/T/U pharmacies that serve them; and are quite capable of working closely with I/T/U pharmacies to identify AI/AN beneficiaries and appropriately calculate their income for purposes of subsidy eligibility determination in a way that balances the need to control health care costs with the Departmental policy objective of lowering barriers to health services for AI/AN.

It should also be noted that should the Secretary choose to exercise his statutory discretion under the MMA to allow States 1902(r)(2) flexibility with regard to calculation of AI/AN income for purposes of subsidy eligibility determination, that approach would be consistent with the Secretary's exercise of statutory discretion in similar situations, e.g., such as in 2002, when the Secretary exercised his discretion to not subject I/T/U providers to the Medicaid 100% upper payment limit requirements of 42 CFR 447.272.

42 CFR 423.773 REQUIREMENTS FOR ELIGIBILITY

Under Subsection (c)(3), a State agency must notify individuals treated as full benefit dual eligible individuals that they are eligible for a full subsidy of Part D premiums and deductibles. Individuals to receive such notification would include QMBs, SLMBs, and QIs. We feel consideration should be given to providing such notification to the I/T/U pharmacy serving such subsidy-eligible individuals as well.

AI/AN receiving services at an I/T/U pharmacy are likely to include many individuals who are to be treated as full subsidy eligible individuals, all of whom would be receiving care from such

I/T/U pharmacies on an IHS-prepaid basis, with no charges to the individual, pursuant to the public health mission of I/T/U pharmacies.

In these cases, it is the I/T/U pharmacy, rather than the full-subsidy AI/AN that would bear financial responsibility for the payments and waivers that would apply if there were no subsidy. Therefore, we feel consideration should be given to amending subsection (c)(3) to require that in the case of AI/AN served by an I/T/U pharmacy, notice also be given to the I/T/U pharmacy.

42 CFR 423.780 PREMIUM SUBSIDY

Subsections (a) and (b):

I/T/U pharmacies provide services to AI/AN on an IHS-prepaid basis, at no charge to the AI/AN, pursuant to the Departmental public health policy goal of lowering barriers to health services for AI/AN. For this reason, we feel consideration should be given to amending these subsections to expressly clarify that I/T/U pharmacies may pay Part D premium amounts on behalf of the AI/AN that might not be fully covered by the premium subsidy available to full subsidy eligible AI/AN or other low-income subsidy eligible AI/AN. In addition to this, we feel consideration should be given to amending these subsections to make clear that for AI/AN receiving services from I/T/U pharmacies, the I/T/U pharmacies may pay any other unsubsidized premium amounts on behalf of other low-income subsidy eligible AI/AN, as well as on behalf of unsubsidized AI/AN Part D beneficiaries.

We feel this approach would have a significant positive impact on the participation of AI/AN in the Medicare Part D drug benefit.

It should be noted, however, that we feel strongly that such charitable, public health-oriented premium payment amounts (as well as cost-sharing amounts) by I/T/U pharmacies on behalf of AI/AN MUST be counted as "incurred costs," as defined in the proposed regulations at 42 CFR 423.100, as noted at length above in our comments addressed to that section.

42 CFR 423.800 COST-SHARING SUBSIDY:

Subsections (a) and (e):

I/T/U pharmacies provide covered services to low-income subsidy eligible individuals on a IHS-funded, pre-paid basis, with no out-of-pocket charges to the low-income subsidy eligible AI/AN, pursuant to the public health mission of I/T/U pharmacies of reducing barriers to health services for AI/AN, in furtherance of the Departmental AI/AN policy goals.

The Congress has expressly approved this practice in the MMA itself, at Section 101, Part D, Subpart 5, by amending 42 USC 1320a-7b(b)(3) to permit, in the form of a statutory exception to the federal anti-kickback statute,

> "…(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under Part D of Title XVIII, if the conditions described in clauses (i) through (iii) of section 1128A(i)(6)(A) are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1860D-14(a)(3), section 1128A(i)(6)(A) shall be applied without regard to clauses (ii) and (iii) of that section)."

In light of this very recent, unmistakeably clear statutory expression of the Congress, and in light of the compelling public health mission served by I/T/U pharmacies in lowering barriers to access for AI/AN by providing covered Part D drugs to AI/AN on an IHS-funded, pre-paid basis, we believe consideration should be given to amending subsections (a) and (e) to require that in all cases in which an I/T/U pharmacy waives or reduces cost-sharing amounts that would otherwise have been paid as out-of-pocket costs by a low-income subsidy eligible individual, the reimbursement that would otherwise be paid by the individual shall be paid to the I/T/U pharmacy.

42 CFR 423.800 ADMINISTRATION OF SUBSIDY PROGRAM:

Subsections (c) and (d):

Payment to a PDP sponsor or MA organization for cost-sharing subsidies made on a capitated basis may be inappropriate with regard to payments made on behalf of AI/AN to PDP sponsors or MA organizations for PDPs or MA-PDs primarily serving I/T/U pharmacy beneficiaries. Although such a capitated payment system may work well for the private sector, we believe such a payment system inappropriately creates incentives for PDP sponsors or MA organizations to attempt to maximize profits at the expense of reducing the scarce resources necessary for I/T/U pharmacies to carry out the Secretary's stated goal of narrowing the AI/AN health disparities gap.

We would ask that consideration be given to amending these subsections to reflect that PDP sponsors or MA organizations with PDPs or MA-PDs that serve a significant number of AI/AN would not have available to them the option of having the cost-sharing subsidies reimbursed to them on a capitated basis.

SUBPART P: SPECIAL RULES FOR STATES IN MAKING ELIGIBILITY DETERMINATIONS FOR SUBSIDIES

423.902 DEFINITIONS

Definitions of "STATE MEDICAL ASSISTANCE PERCENTAGE," and "PHASED-DOWN STATE CONTRIBUTION PAYMENT"

The proposed regulatory definition of State medical assistance percentage is identical to the statutory definition at section 1935 of the Act: "The proportion equal to 100% minus the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs."

This definition requires the Secretary, in determining each State's medical assistance percentage to first determine "the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs."

Unfortunately, under the Act's FMAP provisions at 42 USC 1396d(b), a State's FMAP can vary.

On the one hand, a State's FMAP for a given fiscal year could be calculated using the default FMAP formula set out in the first paragraph of subsection (b).

On the other hand, the plain language of the 1935 reference to 1396d(b), under well-established principles of statutory interpretation, ould be read more broadly to include ALL of subsection (b), including (b)(1), (b)(2), (b)(3) and (b)(4).

We feel that the correct reading of §1935 should follow well-established principles of statutory interpretation, and in a manner that weighs in favor of achieving the Departmental AI/AN policy goal of narrowing the AI/AN health disparities gap by lowering AI/AN barriers to access to covered Part D drugs, by allowing States to calculate their SMAP for purposes of §1935 by factoring in the 100% FMAP reimbursement amounts received for the applicable year, weighted in proportion equal to that State's overall proportion of 100% FMAP-paid reimbursement in comparison to the overall reimbursement amounts received in that year at otherwise-applicable FMAP percentages.

For example, if New Mexico's established FMAP percentage for a given year were 50%, but 20% of the total value of Medicaid reimbursements paid by the Secretary to New Mexico for that year were paid at 100% FMAP (due to those reimbursements being made for services provided to AI/AN), then 80% of the total value of paid Medicaid claims for that year were reimbursed at 50% FMAP, and 20% of the total value of paid Medicaid claims for that year were reimbursed at 100% FMAP.

So if New Mexico's total value of paid Medicaid claims in a given year were $1 billion, the actual FMAP experienced by New Mexico would be ($800 million x 50% FMAP) = **$400 million + $200 million** ($200 million x 100% FMAP) = $600 million, or 60%, rather than the published FMAP rate of 50%.

This difference, in turn, significantly impacts the amount of New Mexico's phased-down State contribution payment to the Secretary under the statutory formula.

Under the formula, New Mexico's monthly contribution amount is equal to 1/12 of the product of the base year (2003) Medicaid per capital expenditures for covered Part D prescription drugs

for full-benefit dual eligible individuals, multiplied by the State medical assistance percentage (which is the inverse percentage amount of the FMAP percentage), the applicable growth factor, the number of the State's full-benefit dual eligible individuals that month, and the phased-down state contribution factor.

We feel consideration should be given to accepting the plain language of section 1935 on its face, and to assign an FMAP value to each State for each fiscal year using State's FMAP value

As is pointed out in the General Provisions accompanying the proposed regulations at 69 FR 46638, 3rd column:

> "General principles of statutory interpretation require us to reconcile two seemingly conflicting statutory provisions whenever possible, rather than allowing one provision to effectively nullify the other provision. Consequently, when a statutory provision may reasonably interpreted in two ways, we have an obligation to adopt the interpretation that harmonizes and gives full effect to competing provisions of the statute."

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(END OF ANTHC COMMENTS TO PROPOSED PART D REGULATIONS)

Submitter : Ms. Jennifer Dripps **Date & Time:** 10/04/2004 08:10:01

Organization : UNC School of Pharmacy

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

I believe patients should be able to choose the pharmacy and pharmacists they prefer. Limiting medicare patients to preferred pharmacies takes away there freedom to choose!

CMS-4068-P-1266

Submitter : Mr. William von Oehsen **Date & Time:** 10/04/2004 08:10:18

Organization : Public Hospital Pharmacy Coalition

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

PHPC wishes to submit the attached comments. If you have questions, please contact William von Oehsen or Ted Slafsky at (202) 466-6550.

CMS-4068-P-1266-Attach-1.pdf

PHPC
Public Hospital Pharmacy Coalition
www.phpcrx.org
(A Coalition of the National Association of Public Hospitals and Health Systems)

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4068–P
P.O. Box 8014
Baltimore, MD 21244–8014

Re: Comments to Proposed Medicare Prescription Drug Benefit; Docket ID CMS–4068–P

Dear Dr. McClellan:

The Public Hospital Pharmacy Coalition (PHPC) would like to take this opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the proposed Medicare Prescription Drug Benefit. PHPC is an organization of over 200 safety net hospitals and health systems that participate in an outpatient drug discount program established under Section 340B of the Public Health Service Act. The Coalition was formed to increase the affordability and accessibility of pharmaceutical care for the nation's poor and underserved populations. PHPC submits these comments for three reasons. First, it wants to ensure that prescription drug plans (PDPs) and Medicare Advantage (MA) organizations do not discriminate against or otherwise obstruct participation of pharmacies that are based in 340B providers, such as disproportionate share hospitals (DSHs) and federally-qualified health centers (FQHCs). Second, PHPC recommends that CMS actively encourage PDPs and MA plans to include 340B provider pharmacies in their pharmacy networks, especially in connection with any medication therapy management program that the plans choose to offer. Third, we seek assurance that PDPs and MA plans are permitted to offer separate co-branded drug benefit programs to beneficiaries who are existing patients of a 340B provider and are therefore eligible to receive 340B-discounted pricing. This alternative model for offering and financing a Medicare prescription drug benefit should improve both the affordability and continuity of pharmaceutical care for low-income Medicare patients. These three recommendations are discussed in greater detail below.

BACKGROUND

Established by Congress and signed into law by President George H.W. Bush in 1992, the Public Health Service 340B program was designed to assist federally-funded safety net providers and programs expand access to pharmaceutical care by giving them access to deeply discounted pharmaceuticals. 340B discounts are approximately half of average wholesale prices. In addition to eleven categories of federal grantees and sub-grantees, a number of disproportionate share hospitals that provide large volumes of indigent care are eligible to participate in the 340B program. These hospitals are either owned by state or local government or have a contractual relationship with state or local government to provide care to low-income populations. There are currently over 200 DSH hospitals participating in the 340B program and most of them are teaching facilities.

Although 340B hospitals constitute less than 5 percent of all hospitals in the United States, they provide over 25 percent of the uncompensated health care for Americans. Participating DSH hospitals also provide an enormous volume of care to Medicare beneficiaries, particularly low-income beneficiaries who often lack pharmaceutical coverage. Close to two million Medicare patients are treated at 340B hospitals each year and 340B hospital pharmacies are responsible for almost all of the pharmaceutical care for these patients. Due to the existing relationships between 340B hospital pharmacists and their patients, these professionals are in a unique position to monitor drug utilization, provide culturally sensitive pharmacy counseling services, and ensure compliance with drug regimens. Yet, 340B hospitals face ever-increasing budgetary constraints which, when coupled with significant increases in pharmaceutical costs, have forced many of them to consider limiting access to medically necessary drugs for the indigent and vulnerable populations that they serve.

COMMENTS

The intersection of the 340B program and the new Medicare Part D drug benefit both raises concerns and creates opportunities which are the subject of PHPC's comments below. For each comment, we have identified the relevant proposed regulation and quoted the applicable language therein.

Section 423.120(a)(4)

Pharmacy network contracting requirements. In establishing its contracted pharmacy network, a PDP sponsor or MA organization offering qualified prescription drug coverage—

> (i) Must contract with any pharmacy that meets the prescription drug plan's or MA–PD plan's terms and conditions; and
>
> (ii) May not require a pharmacy to accept insurance risk as a condition of participation in the PDP plan's or MA–PD plan's network.

Comment:

340B hospitals have historically faced barriers to being included in pharmacy networks established by pharmacy benefit mangers (PBMs) and managed care plans. The refusal of manufacturers to give rebates to PBMs and managed care plans for drugs that have already been deeply discounted under the 340B program creates a disincentive for these sponsors to offer participation agreements to 340B hospitals and other covered entities. PHPC has received reports from some members that they have encountered similar barriers to signing up for the Medicare drug discount card program. Because the new Part D benefit will be administered in large part by PBMs and managed care organizations, we are concerned that the subtle forms of discrimination against 340B pharmacies over the past decade will be perpetuated in the new Part D program. PHPC requests CMS's assistance in addressing this concern.

On its face, Section 423.120(a)(4) appears to protect pharmacies from potential discriminatory conduct by Part D plans. However, plan sponsors can devise certain "terms and conditions" that, whether intentional or not, have the effect of excluding 340B provider pharmacies from plan networks. For example, a condition of participation that the pharmacy serve all plan enrollees would conflict with a covered entity's obligation under the 340B statute not to sell or otherwise transfer its 340B-discounted drugs to anyone other than its own patients. If enrollees who are not patients of the 340B provider are permitted to fill prescriptions at the 340B pharmacy, the 340B provider would be saddled with having to choose between two equally unattractive options: augment the 340B pharmacy's infrastructure to allow it to maintain two inventories of drugs (340B and non-340B) or violate the 340B prohibition against dispensing discounted drugs to non-patients. Price disclosure requirements or billing terms could also be used by PDPs and MA plans to exclude 340B pharmacies. PHPC therefore asks that CMS add to Section 423.120(a)(4) a statement that PDP sponsors and MA organizations be prohibited from developing any terms or conditions that have the effect of discouraging or barring 340B provider pharmacies from participating in the plans' pharmacy networks.

In promoting the Medicare discount card program, CMS has already recognized the vital role that FQHCs, DSH hospitals, and other 340B providers play in caring for low-income seniors and disabled Americans. Indeed, CMS issued specific guidance urging drug card sponsors to reach out to FQHCs and other 340B providers in building their pharmacy networks. These same 340B pharmacists are in a unique position to educate low-income Medicare patients about the new Part D benefit and to help them navigate through the various choices. If 340B pharmacies are excluded from the networks of Medicare Part D plans, continuity of care will be compromised and patients may suffer adverse health consequences which, among other things, could end up increasing costs to the Medicare program. PHPC therefore urges CMS to continue its policy of promoting use of the 340B program by Medicare patients. It can communicate this policy by regulation – in which case Section 423.120(a)(4) appears to be the relevant provision – or it can notify PDP and MA sponsors by less formal means.

Section 423.104(h)(1)

Negotiated prices. (1) *Access to negotiated prices.* Under qualified prescription drug coverage offered by a PDP sponsor or an MA organization, the PDP sponsor or MA organization is required to provide its enrollees with access to negotiated prices for covered Part D drugs included in its plan's formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for covered Part D drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit.

Comment:

Section 423.104(h)(1) states that PDP and MA sponsors must give enrollees access to prices that the sponsors have negotiated. Although PHPC supports this pricing policy, it believes that CMS needs to clarify the regulation with respect to pharmacies participating in the 340B program. The discounts available to the 340B provider will often be larger than the range of discounts negotiated by Part D plans through the use of formularies and market share agreements. To accommodate the lower prices available through the 340B program, PHPC asks that CMS clarify that 340B pharmacies are permitted, but not required, to sell at lower prices than the Part D negotiated prices. Access to lower 340B prices should save money for both the Medicare program and beneficiaries. PHPC's request, therefore, reflects sensible policy.

Section 423.120(a)(5)

Discounts for preferred pharmacies. A PDP sponsor or MA organization offering a prescription drug plan or an MA–PD plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs (relative to the copayments or coinsurance applicable when those covered Part D drugs are obtained through a non-preferred pharmacy) when a Part D eligible individual enrolled in its prescription drug plan or MA–PD plan obtains the covered Part D drug through a preferred pharmacy. If the prescription drug plan or MA–PD plan provides actuarially equivalent standard coverage, the plan must still meet the requirements under §§ 423.104(e)(2) and (5). Any cost-sharing reduction must not increase CMS payments under § 423.329.

Comment:

PHPC supports giving PDP and MA sponsors the flexibility of establishing preferred and non-preferred pharmacies in their Part D pharmacy networks. However, as mentioned in our first comment, we are concerned about potential discrimination against 340B provider pharmacies. The flexibility that Part D plans enjoy under this section could be used to discourage use of 340B pharmacies by relegating them to non-preferred status. We therefore ask that CMS prohibit plans from using criteria to accept pharmacies into preferred networks that are more difficult for 340B providers to satisfy than non-340B pharmacies. We would prefer that an explicit statement to this effect be added to Section 423.120(a)(5).

Section 423.153(d)

(d) *Medication therapy management program.* (1) *General rule.* A medication therapy management program—

(i) Must assure that drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Must, for the targeted beneficiaries described in paragraph (d)(2) of this section, reduce the risk of adverse events, including adverse drug interactions;

(iii) May be furnished by a pharmacist; and

(iv) May distinguish between services in ambulatory and institutional settings.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the medication therapy management program described in paragraph (d)(1) of this section are enrolled Part D eligible individuals who—

(i) Have multiple chronic diseases;

(ii) Are taking multiple covered Part D drugs; and

(iii) Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level that CMS determines.

(3) *Use of experts.* The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program under section 1807 of MMA.

(5) *Considerations in pharmacy fees.* An applicant to become a PDP sponsor or an MA organization wishing to offer an MA–PD plan must—

(i) Describe in its application how it will take into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing medication therapy management services for covered Part D drugs under a prescription drug plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for medication therapy management services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

Comment:

PHPC strongly supports the establishment of a medication therapy management program within the Medicare program. Most 340B hospitals are academic medical centers that rely heavily on clinical pharmacies for identifying and delivering treatment options. Hospital pharmacists are part of the professional team that evaluate and recommend patient-specific therapies. We therefore want to ensure that 340B hospital pharmacies have a fair chance to participate in the new medication therapy management program and are not subject to conditions of participation that directly or indirectly discriminate against them. In addition to the proposed requirement that such medication management therapy programs are developed in cooperation

with licensed and practicing pharmacists and physicians, we also strongly recommend that the regulation require that these programs are under the supervision of a licensed pharmacist and that such a pharmacist is reasonably reimbursed for his or her services.

Section 423.272(b)(2)

Plan design. CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. If the design of the categories and classes within a formulary is consistent with the model guidelines (if any) established by the United States Pharmacopeia, that formulary may not be found to discourage enrollment on the basis of its categories and classes alone.

Comment:

Since the launch of the Medicare drug discount card several months ago, several 340B providers have partnered with discount card sponsors to develop a co-branded discount card giving cardholders access to 340B-discounted pricing. These specialized card programs are built around a 340B provider – typically a DSH hospital, FQHC or a combination of DSHs and FQHCs – that is already serving a large population of low-income Medicare patients. Initial reports suggest that these co-branded care programs have been successful in promoting continuity of care for low-income Medicare patients while lowering the cost of drugs well below the discounts advertised on the CMS website. These co-branded discount card partnerships between 340B providers and card sponsors would like to transition into the Part D program in 2006. PHPC is concerned about application of Section 423.272(b)(2) because access to the co-branded card is limited to the subset of cardholders who are "patients" of the 340B partner within the meaning of the 340B statute and implementing guidelines. The prohibition in Section 423.272(b)(2) against discouraging enrollment by certain Part D eligible individuals could be construed as prohibiting the co-branded partnership model that both 340B providers and prospective PDPs would like to establish in the Part D program.

With respect to discount card programs in which a 340B entity offers a co-branded discount card option, CMS has already endorsed in writing that the card sponsor can limit enrollment into the co-branded card option to only those cardholders who are "patients" of the 340B entity. CMS endorsement of this policy was essential to the success of the 340B-based discount card model because, under the 340B anti-diversion provision, the 340B providers are prohibited from selling or otherwise transferring their discounted drugs to anyone other than their own patients. PHPC simply seeks an extension of this policy to the new Part D benefit so that PDPs can offer special 340B-based drug benefits to enrollees who are patients of 340B providers. There are at least three advantages to this model.

First, if the target Medicare population chooses to sign up with the 340B provider's co-branded drug benefit, patients could continue using the 340B entity's pharmacy during the so-

called donut hole or during other gaps in coverage when the enrollees would otherwise find themselves unable to afford retail pharmacy prices, even at the PDP's discounted rates. In the absence of such a program, many low-income Medicare beneficiaries will have to change pharmacies after their coverage is depleted, returning to their original 340B pharmacy providers, where they are assured of getting their prescriptions filled. Unlike retail pharmacies, DSH and FQHC pharmacies are required by law to serve all patients, regardless of their ability to pay. Allowing patients within this vulnerable population to keep their pharmacy "home" at the 340B provider will avoid the inevitable switching of pharmacies during gaps in coverage. This, in turn, will avoid disruptions in pharmaceutical care, especially since a change in pharmacies may end up forcing patients to change drugs because of the different formularies maintained by the pharmacies.

The second advantage of a DSH- or FQHC-based discount card is that the covered entity's pharmacy will almost always be able to offer prices at or below the discounted prices typically available to low-income Medicare beneficiaries who sign up for the Part D benefit. 340B discounts will likely be deeper than the discounts that non-340B pharmacies will be able to offer to enrollees. Not only would beneficiaries benefit from these deeply discounted rates, manufacturers would not have to pay rebates to help card sponsors make their drugs more affordable. The affordability of the drugs available through the DSH or FQHC benefit would result from their acquisition through the 340B program, not from the use of manufacturer rebates to lower a participating pharmacy's drug costs.

The third reason why CMS should support a 340B-based co-branded benefit program is that it would help strengthen this nation's safety net. DSH hospitals and FQHCs represent the backbone of our country's health care system for the poor. As the number of uninsured Americans climbs and availability of taxpayer revenue to pay for health care shrinks, 340B providers often find themselves at the brink of financial collapse. It is therefore not surprising that these safety net institutions want their Medicare patients to use drug benefit dollars on their own pharmacy services rather than using their coverage elsewhere. Helping to direct this new source of federal revenue to 340B providers would further the mission of safety net institutions in meeting the needs of the underserved, both today and for future generations.

In summary, PHPC asks that CMS clarify Section 423.272(b)(2) in order to facilitate, or at least not hinder, partnerships between approved PDPs and 340B entities so that the 340B drug discount program could be used to fund a specialized co-branded benefit for enrollees who are patients of the 340B entities.

We hope that CMS will work with PHPC in pursuing this exciting model for expanding pharmaceutical access and stretching scarce resources for low-income Medicare beneficiaries.

* * * *

PHPC appreciates this opportunity to submit comments. Please do not hesitate to contact

me at (202) 466-6550 if you have any questions or need additional information.

Sincerely,

William H. von Oehsen
Counsel

Correspondence should be sent to:

William H. von Oehsen
Public Hospital Pharmacy Coalition
1875 Eye Street, N.W.
12th Floor
Washington, D.C. 20006

Submitter : Mr. Nelson Soltman **Date & Time:** 10/04/2004 08:10:46

Organization : Legal Assistance Foundation of Met. Chicago

Category : Individual

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

III. Subpart J: ?423.464(e)(1): Requirements to be a State Pharmaceutical Program.

Many elderly Medicare beneficiaries in Illinois participate in the SeniorCare program for pharmaceutical assistance. Illinois estimates that about 200,000 participants age 65 and over are in SeniorCare, which provides comprehensive prescription drug coverage. Seniors in Illinois with incomes at or below 200% FPL, and who otherwise meet the eligibility standards for Medicaid, may use SeniorCare. Cost sharing is generally minimal with no premiums, $4 copays for brand name drugs and $1 copays for generics for the first $1,750 of drug spending. After $1,750 of drug spending has been reached, a senior pays a coinsurance of 20 percent in addition to the copays.

SeniorCare is more generous than the proposed Part D program, according to estimates by the Illinois Department of Public Aid (IDPA), Illinois? Medicaid agency. CMS should allow for the continuation and renewal of the Senior Care Program, and should not mandate that the Senior Care population switch its coverage to Part D. CMS should provide flexibility for Illinois to modify SeniorCare to coordinate benefits with Medicare Part D to maximize coverage and minimize costs for beneficiaries.

Part D should be implemented to protect and maintain these beneficiaries? current ability to access affordable prescription drugs. The definition of SPAP should be modified to provide for the continuation of Illinois? SeniorCare program, and to assure that SeniorCare participants are not penalized for participation in SeniorCare. The SeniorCare structure has been in operation for several years, and works well for beneficiaries. They should be able to continue to benefit from SeniorCare.

ELIGIBILITY, ELECTION, AND ENROLLMENT

I. Transition of Dual Eligibles: 423.34(d) Enrollment requirement for full benefit
dual eligibles

Transition of the dual eligibles to Part D coverage is a major problem. CMS should eliminate any potential gap in coverage between the time that Part D takes effect (January 1, 2006) and the end of the initial enrollment period, when auto-enrollment would occur (May 15,2006). The Part D dual eligible population does not generally have experience in choosing prescription plans. They will have been on Medicaid, without the need for making such a choice. Some, such as those with cognitive impairments, may find it especially difficult to make such choices.
CMS? proposed delayed timeline for automatic enrollment could expose dual eligibles to a four and half month coverage gap that would cause hardship and could have serious health consequences for this vulnerable population. Creating such a gap will also run the risk of increasing hospital costs nationwide for services provided to beneficiaries hospitalized due to the deterioration of their health resulting from the gap in prescription coverage.

To prevent these consequences for dual eligibles, the transition of drug coverage for dual eligibles should be delayed for at least six months. Dual eligibles will need this long, given their higher prescription use, increased incidence of cognitive impairment, and need for individualized counseling and assistance, to select the most appropriate Part D coverage.

In addition, CMS should fund a comprehensive campaign of individualized counseling and assistance to explain to individuals in advance of their required enrollment what their choices are and how to enroll in a plan; if applicable, to explain how to get benefits under the plan to which they have been auto-assigned; and, if applicable, explain that they can choose a different plan from the one to which they have been auto-assigned and assist in choosing and enrolling in such a plan.
II. Section 423.46: Late enrollment penalty.

CMS should delay implementation of this section for all enrollees for at least one year. Part D is a new and particularly complex program. Many

beneficiaries will be confused about the program, not understand that they must choose a plan and enroll, or not be able to complete the enrollment steps. Many who require prescription drug coverage and are eligible for it do not necessarily know how to access it. For instance, Illinois estimates that almost 360,000 Illinois seniors are eligible for SeniorCare, but only about 200,000 are enrolled.

The people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness. Many Medicare beneficiaries will need more than six months to understand the program, understand how Part D coordinates with other drug coverage they may have, and choose the drug plan that is right for them. Beneficiaries should not be penalized because of the complexity of Part D and its implementation.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

IV. Subpart M: Grievances, Coverage Determinations and Appeals

This subpart should be simplified. The timeframes, required paperwork, and procedures should be simplified into one system, understandable to beneficiaries, that meets the requirements of the Due Process. The current system does not meet that test. The appeals process described in Subpart M does not provide dual eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity to a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes. It should be modified to meet those requirements.

CMS-4068-P-1268

Submitter : Mrs. Gerald Shea **Date & Time:** 10/04/2004 08:10:49

Organization : AFL-CIO

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4068-P-1268-Attach-1.pdf

VIA ELECTRONIC DELIVERY

October 4, 2004

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014
Http://www.cms.hhs.gov/regulations/ecomments

Dear Sirs/Madams:

In response to the notice by the Centers for Medicare and Medicaid Services (CMS) of a proposed rule implementing the new Medicare Prescription Drug Benefit (69 Fed. Reg. 46632), the American Federation of Labor-Congress of Industrial Organizations (AFL-CIO) and the National Education Association (NEA) are submitting the following comments regarding the payment of retiree drug subsidies to sponsors of retiree prescription drug plans and related issues.

The AFL-CIO is a voluntary federation of 60 national and international labor unions, representing approximately 13 million working women and men and more than 3 million retirees of every race and ethnicity and from every walk of life. The mission of the AFL-CIO is to improve the lives of working families—to bring economic justice to the workplace and social justice to our nation. The achievement of a reasonable level of health security in retirement is an important component of economic justice. The NEA is the nation's largest professional employee organization. Its 2.7 million members are represented throughout the field of public education, including elementary and secondary teachers, education support professionals, higher education faculty, and retired educators who belong to 51 state-level affiliates. The NEA believes that "affordable, comprehensive health care, including prescription drug coverage, is the right of every resident."

The law passed by Congress and signed into law by the Administration last year includes a number of serious structural flaws and shortcomings. Too few beneficiaries will receive the help they need, while insurance companies are given an advantage over the traditional fee-for-service Medicare program -- a structure that is sure to undermine the guaranteed Medicare benefits upon which tens of millions of our nation's elderly and disabled have come to depend. In addition, the True Out of Pocket provision discriminates against beneficiaries with retiree health benefits, making it nearly impossible for retirees to qualify for Medicare's catastrophic coverage. In fact, the Congressional Budget Office (CBO) found this inequitable treatment is a significant factor in their estimate that 2.7 million retirees could lose their employer-sponsored prescription drug coverage as a result of the new law. And the additional funds provided for the employer subsidy

in the conference agreement -- $18 billion to make the subsidy tax free – provided absolutely no additional benefit to non-taxable entities such as public sector employees and multiemployer plans that provide retiree health benefits.

Implementation of the retiree drug subsidy provisions of the Medicare Modernization Act (MMA) will have enormous and far-reaching implications for Medicare-eligible retirees with existing prescription drug benefits provided through a former employer. While the statute was prescriptive in certain respects, it also left to the Administration broad authority to implement many of the provisions, particularly with regard to the employer subsidy. Establishing the standards employers must meet to qualify for the subsidy can either exacerbate or mitigate the harmful provisions of the underlying statute – making the number of retirees who are helped rather than hurt relatively better or worse. In order to prevent employers from using the standards as an excuse to significantly reduce the coverage they now provide – even with the financial assistance of the federal subsidy – CMS must adopt and enforce strong retiree protections. In those instances in which the Secretary concludes he lacks the statutory authority to issue adequate protections for retirees, it is incumbent upon him to propose to the Congress specific legislative changes that would give him that authority, or that would otherwise protect retirees.

General Provisions

In the Preamble CMS described Congress's key policy goals for the Medicare retiree drug subsidy program and stated that the new Medicare law gives the Secretary of Health and Human Services the authority to achieve them. According to CMS, these goals are:

- Maximize the number of retirees retaining employer-based drug coverage through the retiree drug subsidy program;
- To not create windfalls, whereby retirees might receive a smaller subsidy from retiree drug plan sponsors than Medicare Part D would provide on their behalf (i.e., the employer would receive a greater subsidy than what it contributes to its retiree drug plan);
- Minimize the administrative burdens on beneficiaries, employers, and unions; and
- Minimize costs to the government of providing retiree drug subsidies and not exceed the budget estimates.[1]

Under the MMA, employers have several options for continuing to provide prescription drug coverage to Medicare-eligible retirees: retain actuarially equivalent coverage and receive a federal subsidy; "wrap around" or supplement the Medicare Part D benefit; or contract with or become a prescription drug plan (PDP) or Medicare Advantage (MA) plan. The primary focus of our comments is on the employer subsidy, and, in particular, what to measure in considering an employer-sponsored prescription drug benefit, what standard that benefit must meet in order to qualify for the subsidy, and how to ensure the subsidy is used to preserve retiree health benefits.

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[1] 69 Fed. Reg. 46741 (August 3, 2004).

I. Determining "Actuarial Equivalence," or Equal Value, for Alternative Coverage through Employer Sponsored Retiree Drug Plans

Under the new Medicare prescription drug law, the federal government will pay a cash subsidy to employers and other plan sponsors[2] that provide retiree prescription drug coverage that is at least equal in value to Medicare's new Part D prescription drug coverage. Coverage under these retiree prescription drug plans is meant as a substitute for coverage under the standard Medicare Part D prescription drug plan. The drug subsidy payable to the employer would be 28 percent of a retiree's total covered drug costs between $250 and $5,000 per year, which translates to a maximum subsidy payment to an employer of $1,330 per retiree.

The standard Part D benefit design enacted by Congress and signed into law by President Bush, while providing for partial government financing of the new benefit, still requires retirees to pay a substantial part of the costs of prescription drugs.[3]

In order to qualify for the federal subsidy, the employer's drug benefit does not have to look exactly like the standard Part D prescription drug benefit; it just has to be of equal or greater value. For example, the employer retiree drug plan might require each retiree to pay a $50 monthly premium (instead of the estimated 2006 $35 Part D premium) but other variations in the benefit design more favorable to retirees could make it of equal or greater value to the standard Part D benefit.

The law defines this test of equal value as one of "actuarial equivalence," which makes it possible to compare the value of different benefit designs. Actuarial equivalence looks at the expected cost of a benefit for a typical person, not how much it will actually cost for any given individual. This is important because a person who has greater health care needs obviously will cost more than one who is healthier.

CMS will have to create a standard for determining whether an employer retiree drug benefit is actuarially equivalent to the standard Part D benefit. It does not do this in the proposed rules.

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[2] Throughout these comments, the term "employer" is used as shorthand for all plan sponsors under the MMA.

[3] The basic features of the standard Part D benefit are as follows;

- Retirees who choose to enroll in a PDP will pay a monthly premium that will be set by the PDP but is estimated to begin in 2006 at $35 per month and increase from that point.
- The PDP will decide which prescription drugs to cover, as long as they meet certain requirements specified by Congress in the new law.
- A retiree will pay all of the first $250 of covered drug costs each year out of her own pocket.
- A retiree will pay 25 percent of covered drug costs between $250 and $2,250 during the year.
- A retiree will pay 100 percent of covered drug costs between $2,250 and $5,100 during the year.
- A retiree will pay no more than 5 percent of covered drugs costs that exceed $5,100. To be eligible for this "catastrophic" coverage, an individual retiree must pay $3,600 in covered prescription drug costs. Costs covered by a third-party, such as a group health plan, would not count toward this so-called "true out-of-pocket" amount.

Instead, CMS lays out several very different options and asks the public to comment on which standard is the right one and which ones are not appropriate. The standard CMS ultimately chooses will determine how good a benefit employers must offer retirees and how big a share of the benefit employers can require retirees to pay and still qualify for the federal subsidy.

In the preamble to the proposed rules CMS describes the different versions of the actuarial equivalence standard being considered by the government. Below is a brief description of each of these:

- Single Prong Test: Under this test, also known as the "gross value test," an employer's benefit is good enough to qualify for a federal subsidy if on average the total value of the benefit is at least equal to the total value of the standard Part D benefit. It does not matter what share of the benefit, if any, the employer pays. Under this test, the employer could contribute nothing and require the retiree to pay the full cost of the plan, yet the employer would still be paid the federal subsidy.
- Single Prong/No Windfall Test: As with the test above, an employer's benefit is good enough for a subsidy if on average the total value of the benefit is at least equal to the total value of the standard Part D benefit. However, the dollar amount of the subsidy paid to the employer cannot be greater than the dollar amount the employer pays toward the retiree coverage. The employer could design the plan so that it pays nothing towards retiree drug coverage after taking the federal subsidies into account.
- Two-Prong Test: This test begins with the single prong test but applies a second test in which the employer would also have to show it is paying for at least a specific minimum share of the total benefit. CMS offers several examples of the level at which it could set the minimum share or amount the employer must pay under the Two-Prong Test. These include:

    - The average per person amount Medicare would expect to pay as a subsidy to employers during the year, estimated by CMS to be $611 in 2006 when the program begins.
    - The expected amount of paid claims under the standard Part D prescription drug plan minus the monthly Part D premiums paid by the retiree, estimated by the CBO to be approximately $1,200 in 2006.
    - The after-tax value of the average per person amount Medicare would expect to pay as a subsidy to employers during the year. For employers subject to the federal corporate income tax, this would be higher than the $611 estimated subsidy payment and will vary depending on the employer's tax rate.

One of Congress's policy goals under MMA is to ensure that the subsidy is used to preserve retiree benefits and not used simply to improve the employer's bottom line or for other non-health care uses. The preamble to the proposed regulation endorses the principle that the subsidy should be passed through to the retirees to pay for retiree prescription drug benefits. In particular, the preamble states:

> "The intent of the MMA retiree prescription drug subsidy provisions is to slow the decline in employer-sponsored retiree insurance. By providing a special subsidy payment

to sponsors of qualifying plans, the MMA provides employers with extra incentives and flexibility to maintain prescription drug coverage for their retirees. Our intention is to make these subsidy payments as reasonably available to plan sponsors as possible. We wish to take into account as much as possible the needs and concerns of plan sponsors, consistent with necessary assurances that Federal payments are accurate and in accordance with statutory requirements, that the interests of retiree-beneficiaries are protected, and that employers do not receive ''windfalls'' consisting of subsidy payments that are not passed on to beneficiaries."[4]

The structure of the statute promotes cost shifting to retirees. Employers are allowed to shift to retirees the difference between what they are currently paying for retiree drug coverage and the amount necessary to meet actuarial equivalence. If the employer reduces benefits by shifting this extra cost to retirees, the employer is not disadvantaged, because the employer's subsidy under Part D is based upon the total spending for prescription drugs paid by both the employer and the employee. The ability to shift costs to retirees can only be blunted by adopting the highest rational standard for actuarial equivalence.

Our own bargaining experience and recent published data suggest that most employer-sponsored coverage currently exceeds the estimated value of the Medicare Part D benefit. For example, the Business Roundtable recently reported that typically, but not universally, medium and large employers sponsor health benefits that supplement Medicare, including drug benefits. According to testimony presented to the Senate Finance Committee on September 14, 2004, "A May 2003 survey found that of the 65 Business Roundtable companies that responded, all offer retiree benefits that supplement Medicare. The benefits average $2,333 per year per beneficiary, of which an average of $1,498 is spent on outpatient prescription drug coverage."

The CBO estimates the value of the Medicare Part D drug benefit is approximately $1,600 in 2006, of which approximately $1,200 will be paid by the Part D program and $400 will be paid by the beneficiary in a monthly premium. Consequently, the average spending found in the Business Roundtable study (approximately $1,500) is significantly higher than the expected government spending on each Part D beneficiary for 2006 (approximately $1,200). As a result, even if $1,200 were chosen as the figure employers are required to contribute to achieve actuarial equivalence, employers would have significant discretion to shift to their retirees all or part of the difference between what they now contribute and $1,200 and still qualify for the subsidy. Any figure lower than $1,200 would significantly exacerbate this inequity.

We have the following recommendations regarding the actuarial equivalence test that we believe are consistent with CMS's goals.

- CMS should adopt the Two-Prong Test for actuarial equivalence, which requires the portion of the prescription drug plan financed by the employer to be at least equal to the portion of the Part D benefit that is financed by Medicare. Only this test is consistent with the letter and intent of the MMA to provide for alternative drug coverage that is

[4] 69 Fed. Reg. 46737 (August 3, 2004).

actuarially equivalent to the standard Part D benefit. The comparison of the employer plan to the Part D benefit should be based on the benefits provided, not the cost.

- All of the other standards described by CMS in the preamble to the proposed rules could penalize retirees covered under a retiree drug plan and should be rejected. The Single Prong Test, the Single Prong/No Windfall Test, and the two versions of the Two-Prong Test that permit the employer to limit its contribution to the average subsidy amount it would expect to be paid from Medicare could all require a retiree to pay more for her drug coverage than she would if she were covered under a Medicare Part D prescription drug plan.

- In order to achieve the policy goals of Congress and CMS, the regulations should prohibit windfalls to employers. In no instance should the subsidy exceed the subsidy an employer provides for the retiree prescription drug benefit.

    - The maximum potential subsidy an employer may receive is $1,330 (28% of costs between $250 and $5,000). This may exceed the employer's contribution even if the standard is set at the net actuarial value of the Medicare Part D benefit (valued by CBO at $1,200 in 2006).

    - Other tests being considered by CMS would allow for even greater windfalls to an employer. The Single Prong (or Gross Value) Test would allow for enormous windfalls to employers since it would permit an employer to pay nothing toward the drug benefit and still collect federal subsidies. This option has been roundly criticized in the press, is inconsistent with the intent of Congress, and would undermine the integrity of the Medicare drug program.

    - CMS also should reject the Single Prong/No Windfall Test that would limit the amount of the subsidy the employer receives to the amount paid by an employer for retiree drug coverage. This test would allow an employer to effectively pay nothing toward retiree coverage (once the federal subsidy is taken into account) and massively shift costs to retirees at the same time.

    - Where the anti-windfall protections would prohibit an employer from claiming the largest possible retiree drug subsidy payable under the law, CMS should provide a mechanism permitting the plan sponsor to claim the larger subsidy, so long as it passes through to the affected retirees the value of the subsidy exceeding the employer contribution in the form of improved prescription drug benefits.

- Where a plan is fully insured, the regulations should require the insurance carrier to provide to the plan sponsor the information necessary to apply for the subsidy.

II. Definition of "Plan"

CMS indicated in its proposed regulation that it was aware of the fact that employers may have a tiered plan in which retirees receive different contributions based on different levels of service. In response to this issue, CMS proposed the following:

- As with the final COBRA rules, all health benefits provided by a group health plan sponsor will be presumed to be under a single plan unless it is clear from the plan instruments and instrumental operation that the plans are separate plan arrangements.

- Group health plan sponsors should apply the actuarial equivalence test to the group health plan as a whole. The preamble states that the standard will be met if, on average, the actuarial value of retiree drug coverage under the plan is at least equal to the value of standard prescription drug coverage under Part D.

The rules should give employers some flexibility when considering multiple plan offerings and sub-groups within a plan. However, the regulations must include strong protections against employers manipulating plan design and valuations in order to minimize the extent to which classes of retirees are offered, and employers receive a subsidy for, a plan that is inferior to the Medicare Part D standard. In the case of a collectively bargained plan, where benefits are negotiated with the union representing retirees who were part of the collective bargaining unit, CMS can say with certainty that the benefits constitute a separate plan.

Because the plan sponsor has the ability to define the nature of a "plan" it is critical to require that the plan definitions be clearly set forth in the plan documents and summary plan descriptions that are made available to the plan's retirees. Moreover, the regulations should prevent manipulation of the plan definition specifically for the purposes of obtaining a subsidy (e.g. prohibit manipulation that is not consistent with the definition used for COBRA purposes). This can be accomplished by adopting by reference the language of the entire COBRA regulation, which prohibits manipulation to avoid legal responsibilities. Significant changes in methods in any year should be disclosed in the plan sponsor's annual actuarial attestation. This would reduce the chance of errors and limit the risk that some employers will game the system. In addition, whatever approach an employer adopts should be documented and followed in future years.

III. Transparency

In order to protect the integrity of the program, CMS must adopt measures to ensure that the implementation and administration of the subsidy payments to employers are transparent to retirees, their bargaining representatives and the public. Such requirements are essential to achieving Congress's and the President's objectives that these substantial new subsidy payments be used to preserve and possibly improve retiree drug coverage, that no windfalls be created and that costs to the government be minimized.

Safeguards are particularly important for several reasons. First, because the actuarial equivalence test is applied to the average of all subgroups within a retiree health plan offered by an employer, there is the potential for significant variation in such subgroups and, by extension, the use of different plan designs to encourage higher cost beneficiaries to enroll in Part D plans. Second, if the plan is measured according to projected benefits as opposed to benefits received, projections can clearly be unrealistic. Third, due to differences in plan designs, an employer may offer some benefits to subgroups that are actuarially equivalent and others that are not. Retirees

should be able to confirm how the employer calculated actuarial equivalence for their particular subgroup.

Despite these potential abuses, the proposed regulations do not include a process for retirees to challenge an employer's attestation that its plan is actuarially equivalent, nor does it require transparency in regard to plan sponsors' attestations or the underlying assumptions and projections. Providing for such transparency and attestation challenges is critical to empowering retirees and other interested parties to act as guardians of this new federal subsidy.

We recognize that CMS has resource limitations on the extent to which it can review the accuracy of employer Attestations and claims for subsidy. CMS also has broader responsibilities to insure the integrity of the entire Medicare program, which may require vast resources to audit managed care plans and PDPs. By opening the employer subsidy process to scrutiny from retirees and their unions, CMS can allow them to serve as watchdogs with respect to employer retiree drug benefits.

We have the following recommendations to provide greater transparency and to ensure the integrity of the program:

- In general, all reporting and disclosure should be made public in a manner that is timely and permits easy access to the information.

- A Plan's Sponsor's "Attestation" of actuarial equivalence should include the assumptions and methods used to determine the plan's actuarial equivalence and should be available for public inspection shortly after it is filed with CMS. In considering the appropriate form for this disclosure, CMS should look to reporting and disclosure rules of the Employee Retirement Income Security Act (ERISA), with which most plan sponsors and their professional advisors are extremely familiar.[5] In particular, the annual Form 5500 Schedule B can be a useful model for disclosure formats, although we would oppose relying on the time frames required for ERISA disclosures, because the significant time lags in ERISA reporting typically mean that the information provided is out of date.

- If the public is to have any ability to measure the effect of the subsidy on preserving retiree health benefits, CMS must at a minimum require employers to report to retirees and unions the value of the subsidy received, as well as the aggregate claims data used to make the subsidy payments. To have the desired effect, such notices must be provided as soon as possible after the conclusion of the calendar year.

- Retirees and their unions should have the right to an appeals process regarding employers' actuarial equivalence attestations and subsidy amounts received.

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[5] Only private-sector and multiemployer plans are governed by ERISA. State and local government plans are not. However, the same principles of reporting and disclosure and open access to information are familiar to governmental plans due to the public environment in which they operate.

- The employer must be required to notify retirees who are being offered a drug benefit that is inferior to the standard Part D benefit. This situation could arise in at least two situations: first, if CMS adopts an actuarial equivalence standard that permits the actuarial value of the benefit not financed by a retiree to be less than the value of the standard Part D design not financed by a retiree; and second, if CMS adopts a "plan" definition allowing sponsors to average inferior contribution levels or benefit designs for some retirees with superior contribution levels or benefit designs for other retirees and still satisfy the regulatory standard for actuarial equivalence. Requiring such a notice not only will provide retirees with necessary information for deciding among their coverage options, but also influence the coverage sponsors offer to retirees. Because employers likely will not want to send out notices informing retirees that their coverage is inferior even though it satisfies the test of average actuarial equivalence, some employers may improve coverage for affected segments of retirees. We believe this will promote the core objectives of the statute.

- The regulations should require employers that offer a supplemental benefit that combines medical and drug coverage to offer a separate medical benefit that allows retirees to retain those benefits even though they may enroll in a Medicare Part D plan. This is particularly important for retirees who are offered drug benefits that are inferior to the standard Medicare Part D prescription drug benefit (i.e., the benefits do not constitute creditable coverage or the value of the benefit offered is less than the value of the standard Part D benefit). In the event CMS does not impose this requirement on employers, it should require employers to notify retirees that leaving the employer's plan to enroll in a Medicare Part D plan will automatically eliminate their employer-provided supplemental medical coverage, as well.

- Employers should provide a separate notice to individuals that they have creditable coverage, in order to ensure retirees are aware of their options and can make timely decisions necessary to avoid the late enrollment penalty for the Part D benefit. For example, providing notice as part of other disclosures, such as ERISA summary plan descriptions, is not sufficient.

IV. Annual Actuarial Equivalence Application Process

A plan sponsor must complete an annual application process before it can receive the subsidy. Proposed steps for the process include the following. The plan sponsor must submit the Actuarial Attestation no later than 90 days prior to the beginning of the calendar year for which it requests the subsidy. In order to receive the subsidy for 2006, the Actuarial Attestation and accompanying documents must be submitted by September 30, 2005. For plans that begin coverage in the middle of a year, the plan sponsor must submit an Actuarial Attestation no later than 90 days prior to the date coverage begins. For new plans that institute coverage after September 30, 2005, the plan sponsor must submit an Actuarial Attestation no later than 150 days prior to the start of the new plan.

CMS also proposes to require a plan sponsor to submit an Actuarial Attestation no later than 90 days prior to the implementation of a material change to the drug coverage of the plan that impacts the actuarial value of the coverage. (A material change means "any change that potentially causes the plan to no longer meet the actuarial equivalence test.") If the change would result in the benefit no longer being actuarially equivalent, beneficiaries would have to be

informed of the change 90 days prior to it taking effect. We support this recommendation with the following qualifications:

- The 90-day application requirement should be retained in final regulations.
- Extensions from the 90-day application requirement should be permitted only upon application showing justifiable need. However, any extension granted must allow sufficient time for retirees to make decisions about their options and avoid the late enrollment penalty for the Part D benefit.
- The requirements regarding notification of a material change in the plan's determination of actuarial equivalence should be clarified to assure that notice is provided 90 days prior to the effective date of the change.

V. Retiree Protections Against Improper Employer Disclosure

Retirees should not be penalized with respect to the Part D program if they make a choice based on their employer's incorrect representation regarding Part D coverage. Specifically, we support the proposed regulation's position that retirees who are misinformed or not informed about their employer's level of coverage should not incur a penalty for late enrollment in the Part D program. In addition, retirees should not incur a penalty if their employer's Actuarial Attestation was not filed in a timely manner.

VI. Plan Sponsor

Definition. CMS should confirm that the "plan sponsor" of a multiemployer plan is the same as provided for in ERISA Section 3(16)(B).

The proposed regulations (42 CFR § 423.882) repeat the statutory exception for certain jointly administered arrangements maintained by a single employer. In that case, contrary to Section 3(16)(B) of the Employee Retirement Income Security Act of 1974, as amended, the sponsor is deemed to be the employer if "the employer is the primary source of financing."

In many situations, a collective bargaining agreement defines the employer's retiree health obligation as a specified contribution to a trust, qualified as a voluntary employees beneficiary association (VEBA) under Section 501(c)(9) of the Internal Revenue Code, and as a result, the retiree health benefits to be provided are limited to those that may be funded by the employer and retiree contributions (as well as any investment return). There is no reason for these situations to be treated any differently than jointly administered multiemployer plans. It is the trust that finances the benefits and in order to avoid a windfall to the employer, it is the trust that should be entitled to payment of the subsidy. CMS should clarify that in these kinds of arrangements – in which the employer's only obligation is a defined contribution to a trust and the plan in fact is financed by the trust – the VEBA or similar plan setup, not the employer, is the primary source of financing.

Further, CMS should clarify which entity is the plan sponsor in certain public-sector arrangements that are not present in the private sector. For example, in the case of a plan covering the retirees of one or more public employers and maintained by a designated representative or group of designated representatives (typically, a retirement board, board of trustees or office designated as responsible by the public employer(s) for maintaining the benefits) of the parties establishing the plan, the plan sponsor should be that designated representative or group of representatives. Also in the public sector, in the case of a benefit financed by a welfare trust fund established or maintained by an employee organization through reimbursements to retirees, or that provides the prescription drug benefit itself, that trust fund providing reimbursements for the prescription drug benefit should be considered the plan sponsor, even if access to the benefit is offered through a group health plan established by another entity, such as a public employer.

Payments to Plan Sponsors. CMS's proposed regulations do not address how the Part D plan sponsor subsidy is paid if the retiree prescription drug benefits are insured (other than through a MA-PD or PDP arrangement). To ensure further that the subsidy is used to preserve retiree prescription drug benefits, the final regulations should assure that the Medicare Part D plan subsidy is paid to the plan sponsor. In no case should an insurer underwriting or administering the plan be paid the subsidy.

VII. The Treatment of HSAs

Comment was requested as to whether to treat payments from Health Savings Accounts (HSAs), Archer Medical Savings Accounts (MSAs), Flexible Spending Arrangements (FSAs), or Health Reimbursement Arrangements (HRAs) as group health plan payments for purposes of counting against True Out of Pocket ("TROOP") costs. CMS states that its strong preference is not to treat HSAs as group health plans, insurance or otherwise, or third party payment arrangements. Under this interpretation, a Medicare beneficiary could withdraw funds from his or her HSA, pay Part D drug expenses, and allow these expenses to count toward the beneficiary's out-of-pocket payments. Medicare catastrophic coverage would consequently begin sooner than if these payments were not counted as TROOP.

CMS states that it believes HSA funds should count toward the beneficiary's incurred costs since the funds are essentially analogous to a beneficiary's bank account. No position is taken regarding whether payments from an HRA or FSA would count against the beneficiary's TROOP costs.

We strongly oppose creating a special exception for these types of accounts by counting payments from them as TROOP costs. Giving preferential treatment to an account like an HSA would provide a financial advantage to employers that offer these types of accounts and would discriminate against employers that provide a comprehensive retiree medical and drug benefit.

VIII. Waivers for Plan Sponsors to contract with or become a Part D Plan or Medicare Advantage plan

Employers that do not choose to provide coverage that qualifies for the subsidy or provide coverage that supplements or wraps around the Part D benefit can instead contract with or become a PDP or Medicare Advantage (MA) plan. CMS indicates that an MA plan or a PDP plan may request, in writing from CMS, a waiver or modification of the Medicare Advantage or Part D requirements that hinder the design of, the offering of, or the enrollment in Medicare Advantage plans by employees or former employees receiving benefits from plans sponsored by employers, labor organizations, or multiemployer plans. MA and PDP plans that receive a waiver may restrict the enrollment to participants and beneficiaries in an employer-sponsored plan. Waivers might include restricting enrollment to the plan sponsor's retirees and offer a benefit that resembles existing active coverage. A waiver might also include authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group.

A waiver process should be established for employers and other plan sponsors to contract with or otherwise create Medicare Part D PDPs and MA plans that serve employment-based populations. Waivers should be published and made easily available online. Existing waivers that were made available to Medicare+Choice plans should be catalogued and placed online so that plan sponsors can determine what requirements have already been considered for waiver.

CMS recognizes that one option available to employers under the MMA is to provide retiree prescription coverage that supplements coverage offered under PDP or MA-PD plans. For this option to work smoothly for employers and other plan sponsors, particularly those with retirees living across the PDP and MA-PD regions to be established, CMS should take appropriate steps to encourage the development of supplemental plans by PDP and MA-PD providers. If both the Part D plan and the supplemental plan are offered a single provider, it may be easier to coordinate benefits.

CMS should consider extending waiver authority to purchasing coalitions involved with employer-sponsored plans. For example, many unions have developed purchasing coalitions that pool membership in order to arrange for contracts with Pharmacy Benefit Managers. These types of purchasing coalitions may be potential PDP plan sponsors. CMS should not preclude waivers for such entities.

Conclusion

CMS has stated in the proposed regulations that the federal subsidy has the potential to stem the erosion of retire health benefits. We believe this goal is laudable and that incorporating the comments included above into the final regulation is necessary in order to meet this goal. We urge CMS to issue final regulations that integrate our comments.

Thank you for your willingness to consider our views. We would be pleased to meet with you to discuss these comments and any other issues on which you are seeking input.

Sincerely,

Gerald M. Shea
Assistant to the President
Government Affairs
AFL-CIO

Carolyn York

Carolyn York
Manager
Collective Bargaining and Compensation
NEA

Submitter : Dr. Steven Daviss **Date & Time:** 10/04/2004 08:10:01

Organization : Maryland Psychiatric Society

Category : Physician

Issue Areas/Comments

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Research indicates that, in general, the earlier one gets EFFECTIVE treatment, the better the outcome. Delays in getting these treatments may result in worse long-term outcome. Access to a variety of drugs with different mechanisms of action and side effect profiles is critical to these patients and their families.

The classification system used by CMS is based on a disease-linked therapeutic category or indications followed by pharmacologic classes primarily based on mechanism of action with some exceptions, i.e., based on chemical structure. However, the draft "Pharmacologic Classes" fail to adequately recognize mechanism of action. For example, lumped together in one class under the heading "Reuptake Inhibitors" are two different classes of tricyclic antidepressants, all the serotonin reuptake inhibitors, and all the dual serotonin and norepinephrine reuptake inhibitors. This lumping together ? also seen in the lumping together of all the atypical antipsychotics into a single drug class ? when carried through to the Pharmacy Benefit Managers who will craft formularies based on these pharmacologic classes, will:

-fail to pass the discouragement-from-enrollment test, and
-fail to pass the non-discrimination test.

Why?

1- Patients now on medications which are tailored to their SPECIFIC needs ? based on mechanism of action, drug side effects (which relate to receptor binding profile), and potential for drug interactions ? may be required to switch to less effective drugs with more unwanted side effects and greater risks of drug interactions.

2- Many psychotropic drugs are metabolized by the liver's P450 enzymes. Some people have genetic variations in these enzymes, which would cause increased drug levels and more side effects. As it turns out, people of African and Asian ancestry have a much greater risk of some of these genetic variations (3- or 4-fold in some cases). Failure to account for these pharmacogenetic differences in the classification scheme may require some individuals to suffer worse side effects due to their genetic profile, discriminating against these populations.

3- Other populations at risk of unintended discrimination will include seniors and those on multiple medications for other medical illnesses.

We anticipate that CMS will work with the APA and other organizations to correct these deficiencies and to improve the safety of drug use based on these categories.

Submitter : David Hanig **Date & Time:** 10/04/2004 08:10:01

Organization : WA State Medical Assistance Administration

Category : State Government

Issue Areas/Comments

Issues 1-10

BACKGROUND

Part 423.774
In completing re-determinations of eligibility, changes in the client?s circumstances must be addressed. However, they are not addressed in these rules. We suggest that the processes for re-determinations and appeals be the same for whether conducted by the State Medicaid agency or SSA. This would provide uniformity in the re-determinations and appeals process.
CMS envisions a verification process whereby States and SSA will build on the existing verification processes used for other programs, maximizing the use of automated data matches for verification of income and certain liquid resources. A major problem is access to data for the States (i.e. data matches with 1099 files from the IRS) and the timeframe needed for building access to data. We do not believe that the automation envisioned will be available when this program is implemented and recommend that this provision be removed.
The section notes that the Act provides that ?statements from financial institutions shall accompany applications in support of the information provided therein,? can not happen automatically. The financial institution statements must be provided by the individual; this will be problematic with this aged, blind and disabled population. Unless liberalized, this requirement will result in many elderly and disabled individuals losing prescription drug coverage. This is not acceptable.
If, as stated in this section, CMS will permit the use of a ?proxy signature process? to allow applications to be taken over the phone or by an Internet process, does this mean that CMS is relaxing their requirement for signatures on applications?
CMS states that the time and effort for an individual or personal representative to complete the low-income subsidy application, provide financial statements and certify that the information provided is accurate is 10 minutes. This estimate is grossly understated. It also does not include the time it will take the individual or personal representative to select a plan. Depending on the number of plans available, selecting a plan could take 30 minutes to two hours for this population.

Section H
CMS did not include the States costs for conducting eligibility determinations for low-income benefits in the estimate of net State savings. They roughly estimate the State share of costs for these determinations at approximately $100 million a year, beginning in FY 2005. Due to the complexity of the program and the incidence of cognitive impairment in this population, we believe this figure is underestimated and should be reconsidered.

Part 423.904
States will be required to begin accepting application forms for the low-income subsidy no later than July 1, 2005. This is not a reasonable expectation. Once rules are established, States will have to adopt new rules, program their technology systems and train staff. Interfaces between State and SSA systems also must be established. July 1, 2005 does not provide enough time to implement this new program. We recommend that states be allowed to provide applicants with the SSA application, provide assistance to complete the application, and forward the application to SSA for determination.

BENEFITS AND BENEFICIARY PROTECTIONS

Enrollment for the Prescription Drug Plans (PDPs) opens on November 15, 2005. If dual eligibles have not selected a plan, CMS states that they will be randomly assigned a plan by December 1 with an effective date of the benefit of January 1, 2006. These plans will have their own formulary and their own network of pharmacies. It is possible that clients will not be assigned to a plan that covers their specific ongoing medications or uses their preferred pharmacy.
? Impact on Clients. Individuals will have only 2 weeks to examine the choice of plans or face auto enrollment. Considering the incidence of dementia, mental disabilities, and confusion in the dual eligible population, a significant number will require assistance to choose a plan. Once they know their plan, they will have only a few weeks to compare the formulary to their own drug profile, obtain different prescriptions for the necessary changes, pick a new pharmacy, and transfer all their prescriptions to the new pharmacy. This all occurs over the holiday season. We recommend providing additional time for dual eligibles to select and convert to a plan. Dual eligibles should also be able to continue receiving existing medications without interruption until the plan can implement changes without destabilizing the condition of the beneficiary.
? Impact on Facilities. Facilities usually have working relationships with a single, main pharmacy. Their individual residents could be auto-

enrolled randomly in PDPs whose formularies are not a good match for the residents? medication profiles and whose network of pharmacies are not used to providing services to their facility and/or providing them the safeguards currently needed at the facilities. Facilities which currently work with a single, main pharmacy may find they need to develop new relationships with many different pharmacies. It is highly likely that facilities will attempt to get each resident enrolled with a ?house? plan. However, the ?house? plan?s formulary may not be the best choice for all of the clients? medication profiles, resulting in chaos as clients and the facility attempt to change medications to match the applicable formulary. Because the Medicare enrollment information is likely to be mailed directly to the resident or their designee, facilities will not know of the plans selected or auto assigned for all of their residents. Since most residents of nursing home, Assisted Living facilities, etc. have Medicare, this, at best, will be an extremely chaotic time for the facilities. We recommend provisions to assure that pharmacies providing services to long-term care facilities be able to participate with all local PDPs or MAs which serve individuals in those facilities.
? Impact on the State. The State will be unable to obtain federal match for any Part D medications for dual eligibles after January 1, 2006; therefore, any attempts to ease this transition would be very costly for the State. In addition, for the significant number of Medicare/Medicaid eligibles unable to choose their own plan (such as those with developmental disabilities, mental health issues, or dementia), the 2 weeks prior to auto enrollment will create an impossible workload for DSHS and AAA staff and providers who will be assisting clients with their choices. With such a tight timeframe and the holiday season, it will be impossible to hire sufficient staff, even if properly funded. Moreover, it is not yet clear whether the State will have responsibility to auto-enroll dual eligibles. If so, this would create a workload at a time when staff are dealing with end-of-calendar year requirements. We recommend providing additional time for dual eligibles to select and convert to a plan.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Transition Issues

There will be transition issues that adversely affect a very vulnerable population unless adequate provisions are made. Part D enrollment represents incredibly complicated system changes occurring over the holiday season. At best, dual eligibles will have 3 weeks to identify which of their current medications do not match their new plan?s formulary, contact their physician, obtain a new prescription, send that new prescription to their new pharmacy and pick up their medications. In addition, they may need to switch the remaining prescriptions to an in-network pharmacy. When you consider dual eligibles who reside in some sort of congregate care, either nursing facilities or a variety of community-based care settings, this becomes even more difficult. Facilities frequently use one major pharmacy and in this transition there will have to be extensive, timely work with residents to ensure that appropriate plans are chosen, or facilities will have to develop business relationships and communication with numerous, potentially unknown pharmacies. In order to protect the health and welfare of the most vulnerable beneficiaries, CMS should incorporate the following protections:
? Require Part D plans to reimburse current pharmacies for current medications for at least 6 months. This will allow a smooth transition for all parties and allow prescriptions to be switched to formulary medications and allow everyone to switch to in-network pharmacies in a manner that does not endanger health.
? Allow States to obtain federal financial participation for any wrap-around medication until July 1, 2006. It is not likely that auto- enrollment will be a completely smooth process without errors. In addition, many disabled and elderly individuals in the dual eligible population will be confused by change and paperwork. There will be beneficiaries who accidentally opt out of Part D and will lose all drug coverage, placing their health in jeopardy, increasing hospitalizations, and placing the facilities and homes in an untenable position. Licensing requirements (including federal regulations for nursing facilities) require them to meet the health needs of their clients; but there will be no resources to purchase these needed medications. States need the option to provide a matched program to assist dual eligible citizens whose health could be harmed in this transition without coverage.
? CMS must develop the system to notify the facilities of each resident?s plan choice.

GENERAL PROVISIONS

General

The responsibility is given to State Medicaid offices and Social Security for eligibility determinations for the low-income subsidies, increasing the workload substantially in providing information, making eligibility determinations for known and also for all the currently unknown clients, training staff and dealing with appeals. Despite the additional workload, states will receive at most 50% FFP. This represents an unfunded mandate and states require additional federal dollars to perform these new duties.

SPECIAL RULES FOR STATES

Part 423.34
This section states that a process will be established to automatically enroll full benefit dual-eligible individuals who fail to enroll in a PDP or MA-PD plan timely. We recommend that this function be fulfilled by a CMS hired outside contractor. Benefits include:
? Nationally consistent information dissemination
? Nationally consistent implementation
? Nationally consistent oversight of the function
? Reduction of information dissemination between States and CMS regarding this function.
Prior to the automatic enrollment this section mentions a widespread education and information campaign to equip full benefit dual-eligibles to make an informed decision on enrollment. This education and information campaign is not described: how the information will be distributed, especially for the transition of the full benefit dual-eligible people when this law is implemented 1/06. States need more information about how CMS will distribute the information and assist this population in selecting a plan that will work for them.
Part 423.36
There is no definition of ?institutionalized individuals? ? the assumption is that the definition is the same as in Part 423.772 and excludes full benefit dual eligible individuals receiving services under a waiver program or those in ICF/MRs.

Part 423.120
Under the proposed regulations, prescription drug plans are required to cover only two medications in each therapeutic category and class. PDPs are not at risk for down-stream health costs from an inadequate drug formulary and the better bid prices of a limited number of formulary medications create a fiscal incentive to limit formularies. This is acceptable for some categories and classes, but not all. For some clients there will be a significant risk to their health if they are required to switch medications, or the client and their physician will be required to appeal through a potentially cumbersome process. A multi-state consortium has examined several drug classes and concluded that anti-seizure medications and atypical antipsychotics should not be limited for current recipients of these medications. The regulations should be revised to reflect this and similar evidence-based pharmaceutical reviews in order to protect the health and safety of the beneficiaries. In the absence of this change, we anticipate that many individuals with mental disabilities will destabilize and require costly hospitalizations and endure increased symptoms. At a minimum, the regulations should require PDPs to provide current medications to current recipients of antipsychotics and anti-seizure medications indefinitely.

Part 423.772
The proposed regulations is not clear whether individuals in 1915c waivers and 1115 waivers should be treated as fully Medicaid eligible, making them eligible for full dual benefits. We recommend clarifying that individuals in 1915c and 1115 community-based care waivers be treated as full Medicaid dual eligibles.

Part 423.773
While all dual-eligible individuals and SSI beneficiaries will be eligible for the full low-income subsidy without regard to income and resources, co-payment subsidies for these individual will vary depending on their institutional status and income. Institutionalized full-benefit dual eligibles pay no co-payments. The definition of ?institutionalized? in Part 423.772 excludes waiver program individuals, resulting in waiver program clients paying co-payments. Waiver program clients also participate in the cost of their services. Their participation is reduced by the cost of their medical expenses and since the co-payments are considered a medical expense, the client?s participation will have to be adjusted regularly. This will create a significant workload for the Medicaid agencies. We recommend changing the definition of ?institutionalized individual? to include clients receiving waiver program services since they already have to participate in the cost of their care.

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Medicare Modernization Act (MMA)
Comments on Regulations
Washington State Summary

General

The responsibility is given to State Medicaid offices and Social Security for eligibility determinations for the low-income subsidies, increasing the workload substantially in providing information, making eligibility determinations for known and also for all the currently unknown clients, training staff and dealing with appeals. Despite the additional workload, states will receive at most 50% FFP. This represents an unfunded mandate and states require additional federal dollars to perform these new duties.

Transition Issues

There will be transition issues that adversely affect a very vulnerable population unless adequate provisions are made. Part D enrollment represents incredibly complicated system changes occurring over the holiday season. At best, dual eligibles will have 3 weeks to identify which of their current medications do not match their new plan's formulary, contact their physician, obtain a new prescription, send that new prescription to their new pharmacy and pick up their medications. In addition, they may need to switch the remaining prescriptions to an in-network pharmacy. When you consider dual eligibles who reside in some sort of congregate care, either nursing facilities or a variety of community-based care settings, this becomes even more difficult. Facilities frequently use one major pharmacy and in this transition there will have to be extensive, timely work with residents to ensure that appropriate plans are chosen, or facilities will have to develop business relationships and communication with numerous, potentially unknown pharmacies. In order to protect the health and welfare of the most vulnerable beneficiaries, CMS should incorporate the following protections:

- Require Part D plans to reimburse **current pharmacies** for **current medications** for at least 6 months. This will allow a smooth transition for all parties and allow prescriptions to be switched to formulary medications and allow everyone to switch to in-network pharmacies in a manner that does not endanger health.
- Allow States to obtain federal financial participation for any wrap-around medication until July 1, 2006. It is not likely that auto- enrollment will be a completely smooth process without errors. In addition, many disabled and elderly individuals in the dual eligible population will be confused by change and paperwork. There will be beneficiaries who accidentally opt out of Part D and will lose all drug coverage, placing their health in jeopardy, increasing hospitalizations, and placing the facilities and homes in an untenable position. Licensing requirements (including federal regulations for nursing facilities) require them to meet the health needs of their clients; but there will be no resources to purchase these needed medications. States need the option to provide a matched program to assist dual eligible citizens whose health could be harmed in this transition without coverage.
- CMS must develop the system to notify the facilities of each resident's plan choice.

Enrollment for the Prescription Drug Plans (PDPs) opens on November 15, 2005. If dual eligibles have not selected a plan, CMS states that they will be randomly assigned a plan by December 1 with an effective date of the benefit of January 1, 2006. These plans will have their own formulary and their own network of pharmacies. It is possible that clients will not be

assigned to a plan that covers their specific ongoing medications or uses their preferred pharmacy.

- **Impact on Clients.** Individuals will have only 2 weeks to examine the choice of plans or face auto enrollment. Considering the incidence of dementia, mental disabilities, and confusion in the dual eligible population, a significant number will require assistance to choose a plan. Once they know their plan, they will have only a few weeks to compare the formulary to their own drug profile, obtain different prescriptions for the necessary changes, pick a new pharmacy, and transfer all their prescriptions to the new pharmacy. This all occurs over the holiday season. We recommend providing additional time for dual eligibles to select and convert to a plan. Dual eligibles should also be able to continue receiving existing medications without interruption until the plan can implement changes without destabilizing the condition of the beneficiary.
- **Impact on Facilities.** Facilities usually have working relationships with a single, main pharmacy. Their individual residents could be auto-enrolled randomly in PDPs whose formularies are not a good match for the residents' medication profiles and whose network of pharmacies are not used to providing services to their facility and/or providing them the safeguards currently needed at the facilities. Facilities which currently work with a single, main pharmacy may find they need to develop new relationships with many different pharmacies. It is highly likely that facilities will attempt to get each resident enrolled with a "house" plan. However, the "house" plan's formulary may not be the best choice for all of the clients' medication profiles, resulting in chaos as clients and the facility attempt to change medications to match the applicable formulary. Because the Medicare enrollment information is likely to be mailed directly to the resident or their designee, facilities will not know of the plans selected or auto assigned for all of their residents. Since most residents of nursing home, Assisted Living facilities, etc. have Medicare, this, at best, will be an extremely chaotic time for the facilities. We recommend provisions to assure that pharmacies providing services to long-term care facilities be able to participate with all local PDPs or MAs which serve individuals in those facilities.
- **Impact on the State.** The State will be unable to obtain federal match for any Part D medications for dual eligibles after January 1, 2006; therefore, any attempts to ease this transition would be very costly for the State. In addition, for the significant number of Medicare/Medicaid eligibles unable to choose their own plan (such as those with developmental disabilities, mental health issues, or dementia), the 2 weeks prior to auto enrollment will create an impossible workload for DSHS and AAA staff and providers who will be assisting clients with their choices. With such a tight timeframe and the holiday season, it will be impossible to hire sufficient staff, even if properly funded. Moreover, it is not yet clear whether the State will have responsibility to auto-enroll dual eligibles. If so, this would create a workload at a time when staff are dealing with end-of-calendar year requirements. We recommend providing additional time for dual eligibles to select and convert to a plan.

Part 423.34

This section states that a process will be established to automatically enroll full benefit dual-eligible individuals who fail to enroll in a PDP or MA-PD plan timely. We recommend that this function be fulfilled by a CMS hired outside contractor. Benefits include:

- Nationally consistent information dissemination

- Nationally consistent implementation
- Nationally consistent oversight of the function
- Reduction of information dissemination between States and CMS regarding this function.

Prior to the automatic enrollment this section mentions a widespread education and information campaign to equip full benefit dual-eligibles to make an informed decision on enrollment. This education and information campaign is not described: how the information will be distributed, especially for the transition of the full benefit dual-eligible people when this law is implemented 1/06. States need more information about how CMS will distribute the information and assist this population in selecting a plan that will work for them.

Part 423.36

There is no definition of "institutionalized individuals" – the assumption is that the definition is the same as in Part 423.772 and excludes full benefit dual eligible individuals receiving services under a waiver program or those in ICF/MRs.

Part 423.120

Under the proposed regulations, prescription drug plans are required to cover only two medications in each therapeutic category and class. PDPs are not at risk for down-stream health costs from an inadequate drug formulary and the better bid prices of a limited number of formulary medications create a fiscal incentive to limit formularies. This is acceptable for some categories and classes, but not all. For some clients there will be a significant risk to their health if they are required to switch medications, or the client and their physician will be required to appeal through a potentially cumbersome process. A multi-state consortium has examined several drug classes and concluded that anti-seizure medications and atypical antipsychotics should not be limited for current recipients of these medications. The regulations should be revised to reflect this and similar evidence-based pharmaceutical reviews in order to protect the health and safety of the beneficiaries. In the absence of this change, we anticipate that many individuals with mental disabilities will destabilize and require costly hospitalizations and endure increased symptoms. <u>At a minimum, the regulations should require PDPs to provide current medications to current recipients of antipsychotics and anti-seizure medications indefinitely.</u>

Part 423.772

The proposed regulations is not clear whether individuals in 1915c waivers and 1115 waivers should be treated as fully Medicaid eligible, making them eligible for full dual benefits. <u>We recommend clarifying that individuals in 1915c and 1115 community-based care waivers be treated as full Medicaid dual eligibles.</u>

Part 423.773

While all dual-eligible individuals and SSI beneficiaries will be eligible for the full low-income subsidy without regard to income and resources, co-payment subsidies for these individual will vary depending on their institutional status and income. Institutionalized full-benefit dual eligibles pay no co-payments. The definition of "institutionalized" in Part 423.772 excludes waiver program individuals, resulting in waiver program clients paying co-payments. Waiver

program clients also participate in the cost of their services. Their participation is reduced by the cost of their medical expenses and since the co-payments are considered a medical expense, the client's participation will have to be adjusted regularly. This will create a significant workload for the Medicaid agencies. We recommend changing the definition of "institutionalized individual" to include clients receiving waiver program services since they already have to participate in the cost of their care and they are full-benefit dual eligible individuals.

According to this section states would:

- Use the rules of the SSI program in making income determinations for the low-income subsidy, rather than using more liberal methodologies under 1902(r) (2). This means the States will have to adopt new rules for this program.
- **Not** use the rules of the SSI program in making resource determinations. Countable resources and the resource standard would be different than SSI resource rules, again, requiring States to adopt new rules for this program.

CMS does not believe that this policy will have a significant impact on program costs because the administrative savings resulting from a more simplified program would offset the program costs associated with not counting non-liquid resource other than countable real estate.

We do not agree. The inconsistency between programs will result in new rules being adopted requiring staff training and additional programming for technology systems, and will be error prone in delivery of eligibility determinations.

Part 423.774

In completing re-determinations of eligibility, changes in the client's circumstances must be addressed. However, they are not addressed in these rules. We suggest that the processes for re-determinations and appeals be the same for whether conducted by the State Medicaid agency or SSA. This would provide uniformity in the re-determinations and appeals process.

CMS envisions a verification process whereby States and SSA will build on the existing verification processes used for other programs, maximizing the use of automated data matches for verification of income and certain liquid resources. A major problem is access to data for the States (i.e. data matches with 1099 files from the IRS) and the timeframe needed for building access to data. We do not believe that the automation envisioned will be available when this program is implemented and recommend that this provision be removed.

The section notes that the Act provides that "statements from financial institutions shall accompany applications in support of the information provided therein," can not happen automatically. The financial institution statements must be provided by the individual; this will be problematic with this aged, blind and disabled population. Unless liberalized, this requirement will result in many elderly and disabled individuals losing prescription drug coverage. This is not acceptable.

If, as stated in this section, CMS will permit the use of a "proxy signature process" to allow applications to be taken over the phone or by an Internet process, does this mean that CMS is relaxing their requirement for signatures on applications?

CMS states that the time and effort for an individual or personal representative to complete the low-income subsidy application, provide financial statements and certify that the information provided is accurate is 10 minutes. This estimate is grossly understated. It also does not include the time it will take the individual or personal representative to select a plan. Depending

on the number of plans available, selecting a plan could take 30 minutes to two hours for this population.

Section H

CMS did not include the States costs for conducting eligibility determinations for low-income benefits in the estimate of net State savings. They roughly estimate the State share of costs for these determinations at approximately $100 million a year, beginning in FY 2005. Due to the complexity of the program and the incidence of cognitive impairment in this population, we believe this figure is underestimated and should be reconsidered.

Part 423.904

States will be required to begin accepting application forms for the low-income subsidy no later than July 1, 2005. This is not a reasonable expectation. Once rules are established, States will have to adopt new rules, program their technology systems and train staff. Interfaces between State and SSA systems also must be established. July 1, 2005 does not provide enough time to implement this new program. We recommend that states be allowed to provide applicants with the SSA application, provide assistance to complete the application, and forward the application to SSA for determination.

CMS-4068-P-1271

Submitter : Mrs. Mary Ninos **Date & Time:** 10/04/2004 08:10:51

Organization : Coventry Health Care

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached Word document

CMS-4068-P-1271-Attach-1.doc

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4069–P
P.O. Box 814
Baltimore, Maryland 21244

Subject: Medicare Program: Establishment of the Medicare Advantage Program [File Code CMS-4069-P]

Coventry Health Care, Inc. (Coventry) is pleased to provide comments to the proposed rules published Tuesday, August 3, 2004, Part III Department of Health and Human Services, Centers for Medicare and Medicaid Services, 42CFR Parts 417 and 422 Medicare Program; Establishment of the Medicare Advantage Program; Proposed Rule.

Coventry Health Care is a managed health care company established in 1986 and based in Bethesda, Maryland operating health plans and insurance companies under the names Coventry Health Care, Coventry Health and Life, Altius Health Plans, Carelink Health Plans, Group Health Plan, HealthAmerica, HealthAssurance, HealthCare USA, OmniCare, PersonalCare, SouthCare, Southern Health and WellPath.

The Company provides a full range of managed care products and services, including HMO, PPO, POS, Medicare Advantage (MA), Medicaid, and Network Rental to 3.1 million members in a broad cross section of employer and government-funded groups in 14 markets throughout the Midwest, Mid-Atlantic and Southeast United States.

Coventry Health Care serves approximately 70,000 MA members through contracts with CMS in four of its subsidiary plans: Health America of Pennsylvania/ Health Assurance, Carelink Health Plans, Group Health Plan, Coventry Health Care of Kansas and PPO Demonstration contracts through Coventry Health and Life and Health Assurance.

Coventry supports the Medicare Modernization Act of 2003 (MMA) and applauds Congress for increasing benefits and coverage opportunities for Medicare Beneficiaries through this legislation. Coventry is committed to work with CMS to continue to provide high quality, affordable health care to our members. We appreciate CMS' providing this opportunity to comment and express our concerns on the proposed rule for Title I and II.

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General Comments on Competitive Bid

Although not specific to sections of the proposed rule, Coventry would like to convey some of our concerns regarding the competitive bid and its potential impact.

Pre-MMA, local plans received a pre-determined amount from CMS, subject to risk adjustment, to cover traditional Part A and Part B services and supplemental benefits, which in many cases included prescription drug benefits. Health Plans had the flexibility to designate supplemental benefits as optional or mandatory to best meet the needs of beneficiaries and respond to market demand. Efficient plans with strong provider networks and effective utilization, care and disease management programs had additional funds for supplemental benefits and could offer more competitive products than their less efficient counterparts.

Separating the bid into three distinct components and prohibiting subsidization of one component with another penalizes the more efficient plans and may ultimately result in increased medical costs. For example, for years the health care industry has struggled with increased prescription drug costs, inadequate information systems and data limitations on plans' abilities to identify, group and analyze episodes of care. With the advent of systems that identify episodes of care, it is now possible to determine the efficacy of specific prescription drugs. Research has shown that although a specific drug may cost more, the total episode of care may cost less than total episode costs associated with lower cost alternative drugs. Requiring plans to prepare separate Parts A & B and Part D bids, may ultimately result in higher total medical cost because the emphasis is placed on the individual components and not the cost of care in its entirety.

Additionally, the current structure of the bid process that requires multiple bid components based on estimated benchmarks that are actuarially normalized for average (not actual) populations will by design, require resubmission (possibly multiple times) once benchmarks are determined. This process is overly complex and burdensome to the private sector. CMS should consider a more straightforward bid process similar to the FEHBP.

Under the current ACR process, MA-plans file their basic employer group package. Employer groups then "buy-up" additional benefits to best meet the needs of their retirees. Coventry would like CMS to clarify the impact of competitive bid on the employer group waiver and whether employer groups can continue to offer limited drug benefits under part C if they forgo the Rx subsidy and Part D coverage is not purchased by or on behalf of the eligible retirees. Likewise please clarify whether MA plans offer a non- actuarially equivalent prescription drug benefit for Medicare beneficiaries who choose not to purchase Part D.

Availability of 2002 and 2003 5% sample data.
Because many of the plans who will apply to be a regional MA plan will not have experience in all areas, it is important that CMS work to make available the 2002 5% sample data (with a denominator file where the members can be tied to the claims) as well as the 2003 5% sample data as soon as possible.

Part 422 Medicare Advantage Program: File Code CMS 4069-P

Subpart A - General Provisions

Section 422.2 Definitions: Special Needs Individual (SNI): Coventry supports the establishment of special needs plans for dual eligibles, the institutionalized, and subgroups such as ESRD and AIDS. CMS should allow MA plans the flexibility to develop disease-focused innovations in health care delivery that use the appropriate mix of services to meet the individual's care needs, both acute and long-term. We encourage CMS to use demonstration authority to support the development of such plans. Special Needs Plans should be permitted to bid the Cost of Care against a Benchmark that recognizes the significantly more complex needs of these individuals and have the flexibility to disenroll members who no longer meet the criteria for membership

Subpart B - Eligibility, Election, and Enrollment.

The lock-in provision will decrease choices available to Medicare beneficiaries under the MMA. This provision will discourage Medicare beneficiaries from enrolling in private plans for fear of becoming trapped in a plan that may not meet their expectations or meet their future needs should their circumstances change. Currently beneficiaries understand that they can "opt out" of an individual MA Plan at any time, so there is no penalty for trying something new. This knowledge helps to overcome natural reluctance to change. Medicare Supplements are not bound by a "lock-in" and many potential members will prefer the fact that they can change to being legally unable to change insurers; in effect the proposed lock-in may discriminate against MA plans and will have a negative consumer effect. CMS' projections of tripling enrollment in private plans over the next 5 years will be seriously jeopardized if the lock-in provision is enacted. Operationally, the lock-in makes it difficult to maintain dedicated sales staff so critical to assisting Medicare Beneficiaries in making an informed choice. Rather CMS should allow Plans to develop incentives for members to stay with a Plan through quality improvement activities or more tangible benefit variations or value added services. Likewise Medicare Beneficiaries who are aging into Medicare should make positive selection of the insurer or health plan they prefer based on informed choice and should not default to either system.

CMS will need to clarify operational issues on the status of Part D members who fail to pay the Part D premium; will they be locked into the MA-PD Plan? Does the member default to a non-drug plan? Can members default to a zero premium plan if available in case of non-payment? Does that become an election under lock-in?

Subpart C - Benefits and Beneficiary Protections.

Coventry Health Care, Inc. supports the Centers for Medicare and Medicaid Services efforts to reduce overly burdensome administrative requirements. These include relaxing the 90-Day Notice Period for Non-payment of Premium to 30 days with notices, establishing a web site with functionality to include: document lookup, electronic enrollments on a secure site. CMS should consider the use of e-mail or web site as adequate distribution of certain required member notices, including EOC, SOB, ANOC. In this on-going process Coventry recommends that File and Use requirements should be clarified and reviewers should apply them consistently. Since CMS has indicated that many of the administrative and marketing requirements are under ongoing review, a degree of flexibility to allow for various 'gray area' situations should be built into the criteria. The File and Use program has not had much participation throughout its history in the M+C program and we would hope that CMS would review the limited participation as an indication that the program is not designed to encourage Plan participation. We would recommend an overhaul to the program to include a broader range of materials that can be approved under the File and Use umbrella, a more specific and precise list of what constitutes "materially accurate" or "materially inaccurate materials". We would also suggest that the File and Use be a designation that is perpetual and not granted on a calendar quarter basis.

Similarly the Internet is a relatively new and evolving Media, we would encourage less regulation to allow for creativity and innovation.

Coventry supports a re-definition of the ER Cost Sharing to indicate that it applies to use of Emergency Department. Ability to vary the ER Co Pay enables Plans to encourage members to contact their Primary Care Physician so that members health care needs are identified and coordinated without deterring patients who must have emergency care. CMS should consider raising the maximum copay of $50 on emergency services to $200, which is much more in line with copay requirements on commercial health plans.

Subpart D - Quality Improvement Program

We encourage CMS to consider the issue of parity between competing plans and Fee for Service (FFS) It is important that all Plans serving Medicare Beneficiaries focus on the needs of the members, from preventive care to palliative care. CMS should apply requirements for quality standards and health outcomes' improvements equally and avoid the imposition of strict criteria on certain MA Plans. The degree of flexibility CMS has

recently supported will allow plans to focus on member needs, encourage innovation and result in competition on quality outcomes.

Providing consumers with timely and appropriate information on measurable quality indicators is of vital importance. In a quality improvement environment this information must be timely to be relevant to the decision-maker. The current proposed Performance Assessments inputs are dated and don't accurately reflect the current status of the health plan. This outdated information should not be put forward to the public to use for decision making particularly given the market dynamics of the past several years. This is even more important if comparable data is not published for regional MA PPOs or traditional Fee for Service providers.

The use of HOS Survey data to stack-rank Health Plans when there is no benchmark should be discouraged. This survey should be paid for from savings.

Subpart F-Submission of Bids, Premiums, and Related Information and Plan Approval.

ESRD

Coventry encourages CMS to exclude the ESRD members from the 2006 competitive bid process because of the absence of data related to disease staging and lack of credibility of current plan data. The inclusion of ESRD with incomplete or unreliable data may jeopardize the competitiveness of the Plan bid for traditional Parts A and B services and compromise plans' abilities to assess savings available to fund supplemental benefits. This could lead to fewer benefits for Beneficiaries since MA Plans will be unable to assess true savings. In addition, the inclusion of ESRD increases the complexity of the initial first year bid.

Maximum Cost Sharing Calculation

In calculating the maximum cost sharing for the basic A/B bid the cost share should reflect the MA Plan-specific proportional amounts based on the MA organization's pricing and utilization estimates. MA Plan members have traditionally used a different mix of services than Fee for Service beneficiaries. Plans seek to use the most appropriate level of care. Negotiated provider and physician arrangements are also a factor. This results in higher rates of home care and sub-acute services and lower inpatient stays. This efficiency should be reflected in the actuarially equivalent cost share. This meets the goal to increase benefits to the Medicare beneficiary through improved efficiency and effectiveness within the health care delivery system.

Application of Risk Adjuster in Calculation of the Saving

Further analyses are needed to determine whether CMS should adopt a Plan specific or state-wide/region specific methodology for the calculation of savings. Given variations in cost and utilization, a state-wide/regional approach may inadvertently penalize some

Plans and create windfalls for others if cost, utilization, and population risk scores underlying the bid differ widely from benchmarks.

Plan specific risk adjusters increase the administrative burden of calculating savings. Depending upon the statistical/actuarial validity of a plan's population, plan specific risk scores may prove unreliable and result in under/over calculation of savings. Plan specific scores are also more likely to be subject to fluctuation caused by enrollments/disenrollments, changes in member demographics as well as the progression of disease states. If plan specific risk scores differ markedly from their peers, they may be placed at a competitive disadvantage because, "on paper", they cannot support the same level of supplemental benefits as other plans within the region.

County specific risk scores may mitigate problems associated with both approaches and would be consistent with CMS reimbursement prior to Competitive Bid.

Induced Utilization

Under competitive bid, plans must bid for FFS Part A & Part B services and supplemental benefits separately. CMS has indicated that the induced utilization related to reductions in copays should be recorded in the supplemental benefit bid. Coventry believes that the current FFS utilization already includes utilization increases related to copay reductions because a large proportion of the Medicare FFS beneficiaries purchase Medicare supplement policies. The inclusion of induced utilization under supplemental benefits penalizes health plans and decreases funds available to fund supplemental benefits because CMS retains 25% of the calculated savings. From a financial perspective, Coventry believes that the induced utilization component relative to MA plan copay reductions as they relate to actual FFS utilization is negligible and should not be included in the calculation of the supplemental bid. The impact of induced utilization is a legitimate concern for Part D.

Actuarial Certification

In the preamble on Federal register page 46891, the proposed rule states that CMS would verify the reasonableness of the actuarial utilization and pricing projections for optional and mandatory supplemental benefits in the same way they would verify the enrollment numbers and enrollment mix for an optional supplemental product. Coventry requests that CMS clarify and further explain this process.

Coventry would like clarification from CMS on how to develop the 1.0 bid for 2006.

Will CMS require an actuarial certification for each bid component or for each bid or at the H number level? Providing the certification at the H number gives the health plan the maximum flexibility in designing plans to meet market needs.

Subpart G-Payments to Medicare Advantage Organizations

HOSPICE

MA Beneficiaries who choose to enroll in a Medicare Hospice program should also assign their Medicare Rx benefits to the Hospice. Prescription drugs are usually an integral component of hospice care and should be managed by the Provider. Once the member enrolls in a hospice the Health Plan no longer is involved in care management and should not be responsible for prescription drug management.

Additionally, CMS should consider a demonstration allowing beneficiaries to elect hospice while still receiving life saving treatment as a means to overcoming the fear and perceived finality of electing hospice. The well publicized extremely low rate of hospice elections and the short duration of services should trigger some innovative approaches to identifying how to better transition beneficiaries with terminal or advanced illness into a care environment that provides needed and appropriate care, while improving quality of life.

Information in section 422.320. CMS should clarify the requirements to "inform each Medicare enrollee eligible to select Hospice care under 418.24 of this chapter about the availability of Hospice care…". Should this information be provided routinely to certain members based on criteria to be developed or at the request of Physician, Beneficiary, or family?

MSAs

Coventry supports most of the measures CMS is implementing to increase the attractiveness of Medical Savings Accounts (MSA) plans. We are however concerned about CMS' ability to risk adjust premiums and contributions for these members. Given the complexities of risk adjustment, unavailability of mechanisms for member claim/encounter submissions and absence of member incentives to submit claims/encounter data, Coventry is concerned that risk scores for many of these members will be artificially low. In the absence of systems and incentives that encourage members to submit medical expenses that are applied against the deductible, MSA contributions may not be commensurate with the health status and thus risk associated with these members. As a result, members will exceed the deductibles "prematurely" and the plan will be responsible for all medical payments without the benefit of the risk-adjusted revenue. Coventry encourages CMS to explore mechanisms that will increase the likelihood that the risk scores associated with MSA participants will be captured or allow MSAs to elect payment based on demographic tables only. Additionally, CMS should consider allowing MSA Plans to structure non-uniform contributions to MSAs. Since CMS' payment rates to Plans are not uniform, CMS should consider allowing Plans to propose a prospective schedule that determines the amount of the CMS contribution based on the age/sex band of the individual, determined annually as of the first of the year.

Please clarify whether the Proposed Provider rules will now require a Provider accepting Medicare assignment to limit their fee to 100% of Medicare Allowable for members of a Medicare MSA.

Subpart J - Special Rules for MA Regional Plans

Coventry strongly supports the availability of affordable Medicare options to all Medicare beneficiaries that the MMA provides. To this end it is important that regulations meant to encourage these options not disadvantage local Plans or compromise the ability of local plans to compete with regional plans or traditional fee for service options.

CMS should provide similar financial and administrative incentives that will encourage local health Plans to continue to grow and to provide services to Medicare Beneficiaries in uncovered counties. Flexibility in network adequacy standards is as critical to local plans as to regional plans in areas with limited provider competition. The same alternatives for meeting access requirements should be available to both regional and local Plans. This would include funding to contract with essential hospitals. Additionally, CMS should revisit the moratorium on local MA plans for 2006, permitting local as well as regional plans to file expansion or new markets by 6/05 for entry in 1/06.

Inter-Area Adjustment

Coventry would like to understand what potential inter area adjustments CMS is considering in order to comment on the viability of a methodology for adjustment to the revenue. For example is CMS considering a FFS payment relativity adjustment and if so how would this work?

Medicare Program: Medicare Prescription Drug Program [file code:CMS-4068-P]

Although Coventry supports the MMA legislation, we wish to express concerns related to the implementation of the Title I regulation. The administrative burden and costs associated with implementing the grievance and appeals process and ensuring compliance with quality and POS notification requirements may deter sponsors from entering the market. Health Plans may need to re-contract networks to ensure compliance at the point of sale. This will result in additional administrative costs and burden and hinder market entry. CMS should work with the plan sponsors to determine which standards must be implemented immediately and which components can be phased into the program over time.

The aggressive time frames for a June 2005 bid, the unavailability of risk adjusters until April 2005 and the absence of reliable Medicare pharmacy utilization data impedes sponsor's abilities to generate actuarially sound Part D bids and may further limit sponsor participation. Given the ambiguities and the uncertainties surrounding the process would a delayed implementation be possible?

Subpart D-Quality Assurance

423.153(b) Quality Assurance: The current health care delivery system, especially pharmacy is heavily fragmented. Patients may utilize multiple pharmacies including suppliers in Canada and Mexico, receive scripts from multiple providers, receive free-samples form physicians and use different sources of payment depending upon drug coverage - MA plan, discount drug card as well as purchase over-the-counter (OTC) medications. The ability to capture all medications taken by an individual patient including OTC medications is a formidable task and virtually impossible in the absence of a universal electronic prescribing system. The ability to accurately report on medication errors is severely compromised by this fragmentation and is not a reliable quality measure. Coventry supports all efforts to help minimize medication errors but does not believe that health plans should be evaluated based on this statistic given that they have limited abilities to impact the physician or pharmacists prior to filling the prescription. Coventry recommends that CMS work with potential plans to determine which standards can be readily implemented and which should be phased in over time or perhaps eliminated in their entirety.

423.153(c) Medication Therapy Management Programs (MTMP)
The goals of this program is to, (1) enhance the enrollee's understanding through education and counseling on the use of medications, (2) Increase adherence to prescription medications, (3) Detection of adverse drug events and patterns of prescription under-use, (4) performing health assessments, formulation of treatment plans and managing high cost medications, (5) offering a component of coordinated disease management. Currently there is not consensus within the industry on how this program is defined or administered. To date we do not have national accepted payment standards nor do we have the monitoring standard in place for pharmacists.

Many health plans do various forms of MTMP. Coventry recommends that CMS collaborate with health plans and National Pharmacy Organization to evaluate options for MTMP.

Subpart F – Submission of Bids and Monthly Beneficiary Premiums

Coventry strongly encourages CMS to collect the Part D premium as a reduction to the Social Security payment for all Medicare Beneficiaries enrolled in Part D. This clarifies to the beneficiary the nature of the benefit and ensures against members dropping in and out of Part D. There should not be an additional fee charged by the SSA if premium rebates are required.

Can CMS establish safe have rules of qualifying plan designs? Can MA plans offer a non-qualifying plan for members who choose not to enroll in Part D or for employer groups?
Can supplemental benefits be offered to low income members if a portion of the supplemental benefit covers cost share or premium on Part D (which is part of the low-income subsidy)?

Impact Analysis

There is concern that CMS has not developed its pricing estimates using a robust enough experience base; instead relying heavily on self-reported data obtained through the Medicare Current Beneficiary Survey (MCBS) and through high level estimates of projected growth in pharmacy costs derived from the National Health Expenditure projections. It is recommended that CMS seek to obtain program level pharmacy experience from the FEHBP retiree program and other public programs that reflect a large number of geographically diverse Medicare beneficiaries so as to not rely fully on self-reported data, which tends to be biased and incomplete.

There is concern that CMS has not adequately reflected the potential for selection bias in its initial cost estimates. Instead, CMS has relied on the extraordinarily high participation in Part B as indicative of the participation it will see in Part D. There are striking differences in the structure of the benefit, and of the availability of other options that will lead healthier beneficiaries to forego participation.

Because of the proposed structure of the benefit and the doughnut hole, it is easier for Medicare beneficiaries to determine the point at which they would break-even financially if they were to participate. Given a $35 monthly premium and relying on CMS cost estimates, that break-even point occurs at between $800 and $900 of annual pharmacy expense for a beneficiary that does not qualify for low income subsidies. There is a large percentage of beneficiaries (estimated in the 50% range according to the Society of Actuaries: Projected Cost Analysis of Potential Medicare Pharmacy Plan Designs, July 9, 2003) that fit into the segment of beneficiaries with <$1000 of annual pharmacy cost. There will be a large number of other programs including Manufacturer discount programs, limited pharmacy benefits available under MA plans (for those not electing Part D) and other discount programs that will provide attractive alternatives to the healthier segment of beneficiaries.

CMS has proposed a late enrollment penalty as a deterrent for beneficiaries not to forego participation. However, as currently structured, where the penalty is 1% of member premium per month not enrolled, the monthly penalty at a $35 monthly premium amounts to $.35 per month and is inadequate to meet assumed participation levels. At a minimum, we would recommend that CMS consider a more substantial penalty, i.e. 1% of the full program premium per month. Based on the above, CMS' estimate that 99% of "non low income": and non-actively working beneficiaries participate in Part D in 2006 is unrealistic.

In its pricing estimates, CMS assumes a sliding scale of savings estimated to result from the Part D Program. These savings are assumed to result from discounts and cost containment programs. In 2006, the estimate is 15%, growing to 23% in 2010. These savings are estimated to apply to all segments of the program. Because there are severe limitations to cost sharing provisions for the low income population, it is not realistic to expect the same level of savings for this population, where there is little ability to incentivize use of cost effective drugs.

Because of the significant risk of anti-selection under the Program as currently structured for individual Medicare beneficiaries, CMS should consider permitting PDPs to elect to serve employer group sponsored programs only (as a risk segment), where the anti-selection risk is much smaller. There will be a need for employer-sponsored options; allowing PDPs to elect to serve only a group segment will result in more choices and higher potential for employer groups to maintain retiree pharmacy coverage.

Because risk-adjustment for Part D is new, organizations preparing bids will not have the benefit of being able to estimate the impact of risk-adjustment until very late in the bid process, which may not allow sufficient time for full evaluation.

Coventry appreciates the opportunity to submit these comments on the Medicare Advantage program and the Prescription Drug Benefit proposed rules. If you have any questions regarding our comments or require any additional information, please do not hesitate to contact me at (301) 581-5519 or mninos@cvty.com.

Sincerely,

Mary Ninos
Vice President Government Programs
Coventry Health Care, Inc.
6705 Rockledge Drive
Suite 9000
Bethesda, MD 20817

CMS-4068-P-1272

Submitter : Ms. Julie Ward **Date & Time:** 10/04/2004 08:10:22

Organization : United Cerebral Palsy

Category : Consumer Group

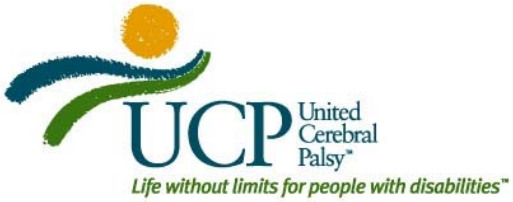
Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter from United Cerebral Palsy regarding the Medicare Prescription Drug Benefit regulations.

CMS-4068-P-1272-Attach-1.doc



October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS – 4068 – P
P.O. Box 8014
Baltimore, MD 21244-8014

To Whom It May Concern:

United Cerebral Palsy (UCP) appreciates the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632, CMS File Code CMS-4068-P. UCP is gravely concerned that the proposed regulations fall short of protecting the health and safety of individuals with disabilities. In order to ensure that Medicare beneficiaries with disabilities have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must be protected from tiered cost-sharing. Furthermore, the inadequate outreach provisions and the cumbersome exceptions and appeals process create nearly insurmountable access barriers for these individuals, their families and providers that serve them. UCP urges the Center for Medicare and Medicaid Services (CMS) to significantly revise the proposed rules to meet the needs of the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

United Cerebral Palsy has been committed to progress for people with disabilities for the last 50 years. The national office and its nationwide network of approximately 100 affiliates strive to ensure the inclusion of people with disabilities in every facet of society. UCP affiliates serve more than 30,000 children and adults with disabilities and their families every day through a variety of programs including therapy, assistive technology training, individual and family support, community living, employment assistance and advocacy. Over 65% of the people served by UCP have disabilities other than cerebral palsy. Individuals served by UCP may have developmental disabilities, mobility impairments, learning disabilities and speech impairments and frequently rely on Medicaid and Medicare for access to health care services.

Every person with a disability is a unique individual, with different medical problems, which mirror the range of health problems that occur in the general population. However, research is showing that older persons with disabilities are more likely to develop secondary conditions or have them worsen over time. Secondary conditions occur because of the presence of the primary disability and may include continuous pain, excessive fatigue, changes in skills or physical conditions fractures from fall or pressure sores from continuous use of a wheelchair.

As they age, adults with cerebral palsy experience multiple physical stresses such as joint and muscle pain, bone and muscle mass losses, changes in gait, arthritic changes, increased respiratory problems causing heart and lung complications and spine and joint changes affecting join and weight bearing. It is estimated that 10% of adults with cerebral palsy have cardiovascular problems and there appears to be excess mortality as compared to the general population. Cerebral palsy is also often associated with neurological conditions that require medication treatment, for example about 33% of adults with cerebral palsy have seizures. Many individuals with cerebral palsy also use medications to treat dystonia and muscle spasticity

The medical management of these primary and secondary conditions is complex. Finding the right medications may take time and careful attention must be made to drug interactions and side effects. For these reasons we strongly support open access to medically necessary medications and strong consumer protections in the regulations.

While we fully endorse the comments of the Consortium for Citizens with Disabilities and the Medicare Consumers Working Group, we are using this opportunity to emphasize the concerns of people with cerebral palsy and their families. UCP believes that significant revisions in the proposed rule are needed in order to ensure that people with disabilities have access to a quality prescription drug benefit and to ensure that full benefit dual-eligible beneficiaries (“dual eligibles”) are not disadvantaged further by inadequate access to needed care. We recommend that CMS take the following steps to protect the health of people with disabilities and chronic conditions:

- Delay the implementation of the Part D program for dual-eligibles
- Expand outreach to Medicare beneficiaries with disabilities
- Designate special populations who will receive affordable access to an alternative formulary
- Impose reasonable limits on cost containment tools
- Strengthen and improve the inadequate and unworkable exceptions and appeals processes
- Require plans to dispense a temporary supply of drugs in emergencies

SUBPART B—ELIGIBILITY AND ENROLLMENT

A successful implementation of the MMA will require strong regulatory protections to ensure that people with disabilities are adequately informed that they must enroll in the Part D program and select a private prescription drug plan. In addition, for many people with disabilities, Medicaid prescription drug coverage will end—dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) must be clearly informed of the need to take action to prevent interruptions in access to prescription drugs.

The final rule must ensure that the enrollment process takes into account the unique needs of people with disabilities and recognizes the exceptional challenges of appropriately educating, screening, and enrolling people with disabilities.

423.34(d)(1), Temporarily Extend Medicaid FFP for Full Benefit Dual Eligibles

UCP is deeply troubled by the very real possibility that CMS will not be able to implement the MMA under the current timeframe in a way that adequately responds to the needs of people with disabilities and that ensures that access to prescription drugs will not be interrupted for dual eligibles for whom drug coverage will transfer from Medicaid to a private Medicare Part D plan. Therefore, in the strongest possible terms, we request that CMS immediately indicate its support for legislation that would delay the implementation of the MMA for dual eligibles.

Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006.

CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit starting on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the likelihood that not all 6.4 million dual-eligibles will be identified, educated, and enrolled in six weeks (from November 15, 2005, the beginning of the enrollment period to January 1, 2006), we recommend that the transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months.

The statute requires auto-enrollment on a random basis for all dual eligibles not enrolled on January 1, 2006. UCP has grave concerns regarding how this process might occur for the following reasons:

- It is very likely that many, if not a majority, of dual eligibles will not be able to enroll by January 1, 2006. Existing caseworkers in non-profits, government offices, or SPAPs will not have sufficient time with all 6.4 million dual eligible beneficiaries to educate them on the myriad choices, finding new providers, counseling them on formularies, or shepherding them through a complex enrollment process.

- Assigning dual eligibles on a random basis will—by statute—steer dual eligible beneficiaries into the lowest-cost plan. As a result of being the lowest cost plan, beneficiaries will have significantly restricted access to medications currently being administered to dual eligible beneficiaries.

- Because many dual eligibles will be enrolled in plans not tailored specifically to their unique needs, many beneficiaries will be forced—within a short span of time—to switch critical medications, find a new network pharmacy, and, at worst, go without medications simply because they did not receive enrollment materials in time.

A delay in implementation is critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation.

423.36(c)(4), Special Enrollment Periods and Dual Eligibles

The selection of an appropriate prescription drug plan for people with disabilities will be especially challenging given their extensive and complex needs. Moreover, individuals may find that despite their best efforts to evaluate their private plan options, they have selected a plan that does not meet their needs or, their needs may change. For these reasons, we support granting dual eligibles special enrollment periods.

It is critical that dual eligibles receive notice explaining their right to a special enrollment period when they enroll in a plan, and every time their PDP changes its plan in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

423.44(d)(2), Disenrollment for Disruptive or Threatening Behavior

We are very concerned that the proposed rules would allow prescription drug plans to disenroll beneficiaries if their behavior is “disruptive, unruly, abusive, uncooperative or

threatening." These provisions create great potential for discrimination against individuals with mental illness and cognitive disabilities.

The proposed provisions will be used purposefully to discriminate against persons with mental illness or other disabilities or will result in discrimination as an indirect consequence of plans not making adequate accommodations for individuals with disabilities, e.g., by training plan personnel on the special needs of these individuals and providing simplified processes for them to use to access the medications they need. Therefore, plans must be required to develop mechanisms for accommodating the needs of beneficiaries with these disabilities, and CMS must provide safeguards to ensure that these individuals do not lose access to drug coverage. The provisions to allow involuntary disenrollment for disruptive behavior must not be included in the final rule.

Additionally, we urge CMS to exclude the proposed expedited disenrollment process in the final rule. This process is offensive and unnecessary - and could lead to abuse by private plans that do not have the cultural competence needed to serve some people with disabilities or who wish to avoid potentially high cost individuals who have significant mental health needs or other types of disabilities.

Alternatively, CMS must provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and must waive the late enrollment penalty for these individuals. Individuals most likely to be disenrolled for disruptive behavior do not have the resources to pay for needed medications out of pocket and would suffer great hardship from losing drug coverage for an extended period.

Section 423.46, Late Enrollment Penalty

UCP urges CMS to delay implementation of a late enrollee penalty for all enrollees for two years. The drug benefit is a new and particularly complex program, especially for many people with disabilities. In our view, many beneficiaries with disabilities will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. During the initial implementation process, people should not be penalized because of the complexity of the program.

After the first two years, CMS should require plans to allow individuals with disabilities a waiver or grace period if they miss an enrollment deadline. These individuals face additional challenges and may need additional time to select a plan and enroll. Furthermore, the rationale for imposing late penalties – i.e., to discourage healthier beneficiaries from waiting to enroll until later – is less likely to apply to people with disabilities who are likely to require on-going treatment for one or more conditions or illnesses.

In addition, after the first two years, implementation of the late enrollment penalty should be delayed for individuals eligible for the low-income subsidy. Again, individuals may not understand that they have to apply separately for the subsidy and a drug plan, and may think application for the subsidy is sufficient. UCP also recommends that the final rule allow enrollees to appeal late enrollment penalties.

Section 423.48, Information about Part D

UCP believes that people with disabilities must have access to information in order to make informed judgments about private plan options. The final rule (rather than guidance) should include binding and enforceable standards defining the information plans must provide to beneficiaries and how they must make this information available. CMS has important obligations to ensure that information is accessible to people with various types of disabilities and the proposed rule is inadequate in this regard.

CMS must require plans to make information available in accessible formats for people who are blind or have low-vision. Materials must also be available in "plain English" for individuals with cognitive disabilities or low-literacy. On request, plans must be required to provide information in Braille, large print, audio-tape or computer disc. In addition, CMS should require that PDPs' Internet web sites are accessible for individuals with vision impairments.

Information should also be provided in languages other than English to reflect the languages spoken in a plan's service area. This should include adequate information about drug plan options and should be provided annually, in writing, and include details about the plan benefit structure, cost-sharing and tiers, formulary, pharmacy network, and the appeals and exception processes.

Need for Targeted Outreach to Beneficiaries with Disabilities

Targeted and hands-on outreach to Medicare beneficiaries with disabilities, especially those with low-incomes, is vitally important in the enrollment process. We strongly urge CMS to develop a specific plan for facilitating enrollment of beneficiaries with disabilities in each region that incorporates collaborative partnerships with state and local agencies and disability advocacy organizations.

SUBPART C- BENEFITS AND BENEFICIARY PROTECTIONS

No section of the proposed rule is more important to ensuring that the Part D program provides a prescription drug benefit that will meet the diverse needs of people with disabilities than subpart C. UCP is deeply concerned that the proposed rule fails to

meet even minimal standards for ensuring that people with disabilities will be able to access Part D drug coverage that meets their needs.

Definition of "Long-Term Care Facility" to Explicitly Include ICF/MRs and Assisted Living Facilities

For people with disabilities residing in residential facilities, including intermediate care facilities for persons with mental retardation and related conditions (ICF/MRs) and assisted living facilities, it is necessary that Part D prescription drug coverage is compatible with the manner in which residential facilities deliver prescription drugs. The final rule must ensure that persons with disabilities residing in residential living facilities are not subject to additional cost-sharing, or out-of-network cost-sharing if they access prescription drugs through a long-term care (LTC) pharmacy.

For this reason, we recommend that the final rule include a definition of "long-term care facility" that explicitly includes ICF/MRs and assisted living facilities. We believe that many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

423.104(e)(2)(ii), Establishing Limits on Tiered Copayments

UCP strongly opposes the provision in the proposed rule that permits Part D plans to "apply tiered co-payments without limit."

The final rule must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs. Permitting unlimited cost-sharing tiers could allow a Part D plan to effectively bar access to clinically necessary covered Part D drugs because cost-sharing is unaffordable and the exceptions process does not include adequate safeguards or standards to ensure a fair review of an individual's request for an exception to a Part D plan's non-preferred cost-sharing.

Moreover, allowing plans unlimited flexibility in establishing cost-sharing tiers increases their opportunity to discriminate against people who need costly medications or who need multiple medications. We also believe that permitting multiple cost-sharing tiers will greatly complicate the ability of CMS to determine actuarial equivalence and to determine that the design of a plan does not substantially discourage enrollment by certain eligible Part D individuals under the plan.

Section 423.120, Access to Covered Part D Drugs

Balancing Convenient Access with Appropriate Payment for Long-Term Care Pharmacies

UCP believes that CMS must propose a way to ensure that plan enrollees residing in long-term care facilities must have access to the LTC pharmacy in the facility where they reside. We could support one of two approaches for achieving an appropriate balance of convenient access with appropriate payment.

The first option is for the final rule to require PDPs to contract with all LTC pharmacies. Alternatively, the final rule could require PDPs to make available a standard contract to all LTC pharmacies. However, plan enrollees residing in facilities where the LTC pharmacy has elected not to contract with a prescription drug plan must be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy.

Further, we believe that there are overlapping responsibilities for the delivery of services between LTC facilities and prescription drug plans. To the extent that prescription drug plans are responsible for coordination and medication management, the final rule should encourage plans to contract with LTC pharmacies to provide these services to the plan's enrollees in long-term care facilities.

1860D-11(e)(2)(D) Authority to Review Plan Designs to Ensure that They Do Not Substantially Discourage Enrollment by Certain Part D Eligible Individuals

UCP is very concerned that plans will discourage enrollment of people with complex medical needs who will need access to a wide variety of medications. CMS must take advantage of every opportunity to ensure this does not happen.

We urge CMS to use the authority provided under section 1860D-11(e)(2)(D) to review plan designs, as part of the bid negotiation process, to ensure that they are not likely to substantially discourage enrollment by certain Part D eligible individuals.

CMS needs to analyze formularies, cost-sharing tiers and cost-sharing levels, and how cost-sharing (including both tiers and levels) is applied to assure that people with the most costly prescriptions are not required to pay a greater percentage of the cost of those drugs.

CMS also needs to assure that a variety of drugs are included in a formulary at the preferred cost-sharing tier to treat chronic conditions and conditions that require more costly treatments. Furthermore, as recommended previously, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-

based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through high cost-sharing for out-of-network access.

423.120(b), Formulary Requirements

UCP has many concerns related to formulary requirements and urges CMS to release a final rule that strengthens the consumer protection requirements and requires special treatment for specific populations.

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must be protected from tiered cost-sharing or burdensome prior authorization procedures that could create insurmountable access barriers.

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing bed rest, unnecessary hospitalizations and even death, on the other. Often, people with disabilities need access to the newest medications, because they have fewer side effects and may represent a better treatment option than older less expensive drugs.

Medicare beneficiaries with disabilities also require access to a broad range of medications. For example, people with spinal cord injuries or diseases of the spinal cord must have access to a broad range of antibiotics. Bacterial infection is a leading cause of hospitalization and death for these individuals. Because bacterial resistance to antibiotics is currently a very serious and growing issue CMS must ensure broad and timely access to a wide variety of antibiotic medications. Bacterial resistance coupled with the common problem associated with individual beneficiary allergies make broad antibiotic access a matter of life and death for this population and the elderly.

Many individuals have multiple disabilities and health conditions making drug interactions a common problem. Frequently, extended release versions of medications are needed to effectively manage these serious and complex medical conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects, making it more important for the doctor to be able to prescribe the best medication for the individual. Often that process takes time since many people with significant disabilities must try multiple medications and only after much experimentation find the medication that is most effective for their circumstance.

The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury or debilitating side effects, as well as hospitalization or other types of costly medical interventions. It can also impact a person's decisions about work. The Ticket to Work and Work Incentives Improvement Act (TTWWIIA) expanded options for states to cover working people with disabilities under their Medicaid programs. Many of these individuals would already be Title II/Medicare eligible. Because of the state buy-in they have been able to access prescription drugs through Medicaid. If the Medicare formularies are limited for people with disabilities, an important purpose of TTWWIIA would be thwarted.

UCP recommends that the final rule provide for alternative, flexible formularies for special populations that would include coverage for all FDA-approved covered Part D drugs. Further, because of the clinical importance of providing access to the specific drugs prescribed, drugs prescribed to these defined populations must be made available at the preferred level of cost-sharing for each drug. We recommend that this treatment apply to the following overlapping special populations:

- **Dual Eligibles:** In enacting the MMA, Congress and the Administration both promised that dual eligibles (persons eligible both for Medicare and Medicaid) would be better off when coverage for prescription drugs is transitioned from Medicaid to Medicare Part D coverage. Historically, the Medicaid prescription drug benefit has been closely tailored to the poor and generally sicker population it serves, providing beneficiaries with a range of drugs that they need with little or no co-payment. Under federal law, states that elect to provide prescription drugs in their Medicaid programs must cover all FDA-approved drugs from every manufacturer that has entered into an agreement with the Secretary of Health and Human Services to pay rebates to states for the products they purchase.

  Dual eligibles include people with disabilities and other serious conditions who need a wide variety of prescription drugs. Medicare prescription drug plans, as programs serving dual eligibles, must be able to respond to a range of disabilities and conditions, including physical impairments and limitations like blindness and spinal cord injury, debilitating psychiatric conditions, and other serious and disabling conditions such as cancer, cerebral palsy, cystic fibrosis, Down syndrome, mental retardation, Parkinson's disease, multiple sclerosis, autism, and HIV/AIDS. If dual eligibles are not to be worse off when Part D prescription drug coverage begins, then they must have continued access to an alternative and flexible formulary that permits treating physicians to prescribe the full range of FDA-approved medications.

- **Institutionalized Populations:** Many, but not all, Medicare beneficiaries residing in nursing facilities and other residential facilities are dual eligibles. The same rationale provided for dual eligibles applies to providing institutionalized individuals access to flexible formularies on the basis of their complex and multiple prescription drug needs. Moreover, although we recommend that any alternative formulary include

access to all FDA-approved medications, should the final rule permit a more restrictive alternative formulary, it must ensure that all drugs included on the formulary of participating LTC pharmacies are included on the plan's formulary, and drugs that are preferred by the LTC pharmacies' formularies must be treated by the plan as a preferred drug.

Institutionalized individuals have limited capacity to pay cost-sharing for non-preferred drugs or to purchase drugs for which coverage has been denied. It is imperative that any alternative formulary provides strong protections that prevent individuals from being charged cost-sharing. For dual eligibles residing in institutions, a condition of eligibility requires them to pledge all, but a nominal personal needs allowance, to the cost of their care. For non-dual eligibles, the high cost of nursing home coverage leaves few remaining resources to pay non-preferred cost-sharing or to purchase drugs for which coverage has been denied.

- **Persons with Life-Threatening Conditions**: These are individuals with a diverse range, but limited number of conditions in which the absence of effective treatment would be life-threatening.

  These individuals must have unrestricted and affordable access to the full range of available treatments. We believe that the MMA intended to ensure that beneficiaries will have access to all needed medications, including newly approved medications. Provisions in the proposed rule are inadequate for persons with life-threatening conditions for whom access to life-saving medications cannot be weighed against the financial interests of for-profit Part D plans. The MMA requires Pharmacy and Therapeutics (P&T) Committees to consider scientific evidence when developing formulary policies. This is an inadequate protection for persons with life-threatening conditions because scientific or clinical evidence often does not exist to support or undermine a new indication for an approved drug or when breakthrough drugs receive FDA approval. This is especially problematic for rare conditions. Further, a major criticism of the MMA is that plans appear to be permitted to wait up to one year before even considering whether to include new drugs on their formulary. Therefore, these individuals must have immediate access to all FDA-approved medications.

- **Persons with Pharmacologically Complex Conditions:** Medications to treat many complex conditions are not generally interchangeable, including those with the same mechanism of action, and have fundamental differences that render them pharmacologically unique.

  In these circumstances, it is inappropriate to permit private plan formulary and cost-sharing policies to drive utilization to specific preferred drugs within a class. UCP recommends that the final rule require the Secretary to seek input from affected

groups and the general public and publish annually a list of conditions for which pharmaceutical management is complex and which have access to an affordable and flexible alternative formulary. This category should encompass.

- Persons with conditions that are recognized for their pharmacological complexity must include, at a minimum, conditions such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS;

- People who require multiple medications to treat many conditions—where drug-to-drug interactions are a critical challenge and where certain formulations might be needed to support adherence to treatment; and,

- Persons taking drugs with a narrow therapeutic index. These drugs are clinically effective and safe only at a narrow dosage range, and generally require blood level monitoring and highly individualized dosing requirements. To allow automatic substitution without physician approval can be deadly.

423.120(b)(1), Development and Revision by Pharmacy and Therapeutics (P&T) Committee

UCP strongly recommends that the final rule ensures that P&T committee decisions are binding on plans.

P&T committees can provide important checks on the profit-seeking motives of private drug plans by bringing research findings and clinical experiences to bear on decisions that will restrict access to certain medications. P&T committees must be empowered to make policy decisions regarding formulary tiers and any clinical programs to encourage the use of preferred medications, including formulary tiers and any clinical programs to encourage the use of preferred medications including prior authorization, fail first and step therapy.

In order to fulfill these critical functions the P&T committees must be charged with a strong mission to promote and protect the health of the beneficiaries. In all cases, the P&T committee should be responsible for ensuring that adequate access is provided for the most clinically efficacious drugs in the preferred tier for all classes of covered drugs. The final regulations should require a majority of the members to be independent and free of conflicts.

The final rule must require P&T committees to have formalized contractual relationships to advise the P&T committee in decision making with respect to areas where the P&T committee does not have adequate clinical expertise. At a minimum, this must include current clinical expertise and current experience in the following areas of medicine:

geriatric medicine, oncology, cardiology, neurology, infectious disease, mental illness, and rare disorders.

The final rule should also require P&T committees to do the following:

- Hold public hearings and receive input from the public prior to the adoption of or revision to plan formularies.
- Specify that meetings of the P&T committee should be open to the public and occur at least quarterly.

In addition, plans should be required to seek input in the P&T committee process from affected enrollee populations, including elderly populations, and a diverse range of organizations representing people with disabilities.

Ensuring the Adequacy of the USP Model Guidelines

We do not support the CMS position that the USP model guidelines should not be required to include classes of drugs if there is no FDA approved drug with an on-label indication for each class, even though there are FDA-approved drugs with commonly accepted off-label uses that would fall within a class. Further, we do not believe it is appropriate for physicians to be given the new burden to "document and justify off-label use in their Part D enrollees' clinical records."

We have urged the USP to make significant changes to the model guidelines to ensure that individuals have access to the medication they require. We are very concerned that in many cases two drugs per class will not provide a sufficient level of access to ensure a quality prescription drug benefit for individuals with disabilities. CMS must ensure that the model guidelines do not create access barriers to clinically appropriate off-label drugs or to newer, more effective medications within the classes.

We were also significantly concerned that the model guidelines did not have classes for the medications used to treat serious long term conditions like multiple sclerosis and that the classes for psychiatric medications and the anti-convulsants require significant revisions.

Standards for determining PDP/MA Formulary Discrimination

We strongly believe that any review standards developed by CMS must be published as legally enforceable regulations and not as guidelines. We urge CMS to develop criteria and standards that do not allow plans to discourage enrollment by requiring higher levels of cost sharing on drugs that disproportionately affect specific groups of beneficiaries. CMS needs to develop standards that can assess whether the formulary

is directing utilization away from efficacious treatments and commonly recognized treatment protocols.

Providing a quality drug benefit to individuals with disabilities will require access to a broad range of medications including many of the newer drugs with fewer side effects. For example, a formulary that only included two anti-convulsants would clearly be discriminatory to people with seizures since epilepsy medications are not interchangeable. Different drugs control different types of seizures and the response to the medication is very individualized. No one or two products of currently available anticonvulsants will be successful for all people with seizures. Access to the medication an individual requires to control their seizures can be a matter of life and death for people with epilepsy.

CMS must also ensure that the formularies do not exclude whole classes of drugs such as immunomodulating drug therapies use to treat multiple sclerosis. This is a significant concern with the USP model guidelines and must be addressed in order to avoid discrimination toward the people who rely on these medications.

Notification Requirements for Formulary Change

UCP believes that the proposed rule provides inadequate notification provisions regarding formulary changes. They are inadequate both for effectively notifying and protecting beneficiaries.

We recommend that if the final rule limits the notice requirements to persons directly affected by the change, then plans must be required to provide notice in writing, mailed directly to beneficiary, 90 days prior to the change, and the notice must inform the beneficiary of their right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary.

423.128 (d), Access to Call Centers

We believe that it is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center. The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program. This is a critical requirement that must be included in the final rule.

423.128(e), Required Information in the Explanation of Benefits

We support the inclusion in the final rule of provisions in the proposed rule regarding elements of the explanation of benefits. These elements, however, must be supplemented by the following:

- **Appeals Rights and Processes:** Information about relevant requirements for accessing the exceptions process, the grievance process, and the appeals process.

- **Access for all Beneficiaries to Formulary Information:** Plans should be required to provide information to all Part D eligible individuals, and not just plan enrollees, about the plan formulary. (See our comments in Subpart B, Section 423.48, Information about Part D.)

- **Including Formulary in Explanation of Benefits**: While we are supportive of the provision in the proposed rule that requires plans to make available access to the plan's formulary, in isolation, this is insufficient. Beneficiaries need precise and detailed information about the formulary both to make an informed choice about enrollment and then to minimize their out-of-pocket costs once enrolled in a plan. Simply giving beneficiaries a description of how they can obtain information about the formulary is insufficient to further the goals of the statute. Plan descriptions should include a detailed formulary, listing not only all the drugs but the tier and amount of co-payment upon which each drug is placed, especially if plans will be allowed to require beneficiaries to pay 100% of the cost of certain formulary drugs.

- **Plan terminations:** 423.128(c)(iii) requires plans to tell all Part D eligible individuals that the part D plan has the right to terminate or not renew its contract, but only if the individuals request this information. Information about the potential for contract termination needs to be included in all plan descriptions and in all marketing materials, and not just if requested by an enrollee or Part D eligible individual.

  Based upon experience with the Medicare+Choice market, the drug plan market will experience volatility that results in adverse consequences to many beneficiaries. The Medicare+Choice model summary of benefits requires this information to be in the summary of benefits and in the evidence of coverage; the same rule should apply for Part D.

SUBPART D – COST CONTROL AND QUALITY IMPROVEMENTS REQUIREMENTS FOR PRESCRIPTION DRUG BENEFIT PLANS

Section 423.150, Scope

The need to limit and prohibit unacceptable cost containment strategies—UCP has serious concerns that the proposed rule contains no restrictions on the ability of plans to use cost-containment tools such as dispensing limits, or prior authorization.

Indeed, the preamble to the proposed rule appears to specifically encourage plans to use such cost management tools, without constraint, to limit the scope of the prescription drug benefit. We believe that this is completely inappropriate, and inconsistent with commitments made by CMS to the Congress and the public.

We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration, and scope of coverage for covered Part D drugs. Specifically, the final rule must prohibit plans from limiting access to covered Part D drugs through limits on the number of drugs that can be dispensed within a month, limiting the number of refills an individual can obtain for a specific drug, or by placing dollar limits on the amount of the prescription drug benefit. For example, research in the mental health field has demonstrated that fewer than six mental health medications per month seriously risks patient health.

UCP also strongly recommends that the final rule explicitly prohibit plans from requiring therapeutic substitution. While the MMA authorizes the use of formularies which could lead prescribers' practices to alter their practice in order to comply with standard Part D plan preferences for covered drugs within a class, we believe that the ultimate authority to decide which specific drug a Medicare beneficiary will receive must reside with the treating physician. Therefore, to protect patient safety and health, the final rule must prohibit plans from requiring or encouraging pharmacists to engage in therapeutic substitution without the advance knowledge and written concurrence of the treating physician. We are encouraged that the preamble to the proposed rule indicates that therapeutic substitution will be prohibited without the prescriber's approval, this prohibition must appear in the text of the final rule.

Further, the use of prior authorization has become a common practice in the private sector and Medicaid. For many Medicare beneficiary populations, the manner in which prior authorization and fail first (or step therapy) systems have been implemented in these other contexts has been clearly unworkable both from the perspective of beneficiaries and treating physicians. Prior authorization can delay necessary and appropriate treatment putting at risk the health and safety of individuals who depend on medications for the management of their conditions.

Prior authorization is particularly burdensome to people in group home settings and institutions where often there may not be a well-informed and aggressive advocate or health care professional to ensure that residents with disabilities get the medication they need.

The final rule must establish clear standards and requirements for Part D plans that elect to adopt prior authorization and fail first policies. In particular, the final rule must require plans to ensure that any system of prior authorization is easily accessible to beneficiaries and physicians, and must impose negligible burdens with respect to time needed to complete the prior authorization process, expense, and information documentation.

Most state Medicaid programs exempt certain types of prescription drugs from prior authorization/fail first policies because of the complexity of the underlying condition, the recognized need for physicians to have broad prescribing flexibility, and the grave clinical consequences that could result if necessary access to prescription drugs is denied. Medicaid experience also shows that when certain populations are not exempted from prior authorization, significant problems arise. We propose that the final rule require the Secretary to consult with the public and publish annually a list of conditions which will be exempted from prior authorization/fail first policies, and should include conditions such as mental illness, epilepsy, HIV/AIDS, multiple sclerosis and cancer, that are widely acknowledged for the difficulty and complexity of pharmaceutical management.

Further, UCP strongly recommends that when prior authorization is imposed, whenever the prior authorization process has not been completed within 24 hours of the time that a prescription was first presented at a pharmacy, plans must be required to dispense a temporary supply of the prescribed drug pending the completion of the prior authorization process, including any time needed to receive an exception process and appeal decision. The final rule must also provide for exigent circumstances when an emergency temporary supply of a prescription drug must be dispensed immediately, without allowing for a 24 hour prior authorization period.

Requiring beneficiaries who have been stabilized on a particular psychiatric or anti-convulsant medication to switch to another medication can be very dangerous for the beneficiary and is not fiscally prudent. It is very difficult to determine which medication will work best for an individual and most have to try many different kinds of medications. Moreover some of these medications stay in the system for a long time (e.g., up to six weeks) and modifications of drug therapy must be done very carefully to avoid dangerous drug interactions. Each failed trial results in suffering and possible worsening of a person's condition.

We recommend that the final rule require plans when enrolling new enrollees to continue for at least six month any prescription drug regimen for all individuals who

have been stabilized on a course of treatment. Moreover, the plan must provide an organization determination within the first month of enrollment for all covered Part D drugs that are part of the treatment regimen and notify, in writing, the beneficiary whether each drug in the regimen is covered and the beneficiary's cost-sharing requirement. Should the plan determine that any drugs in the regimen are not covered, all individuals stabilized on a treatment regimen should be automatically eligible for an exception request, and plans should be prohibited from discontinuing access to all drugs in the regimen pending final resolution of the appeals process.

Cost management tools subject to P&T Committees—In response to a question in the preamble of the proposed rule, we strongly recommend that P&T committees should approve and oversee implementation of utilization management activities of health plans offering the Medicare drug benefit. These committees should be empowered to make policy decisions and be charged with a mission to promote and protect the health of beneficiaries. In overseeing utilization management activities, P&T committees must be empowered to ensure that beneficiaries have access to a variety of drugs that reflect current utilization patterns, research and clinical experience and that take into account the efficacy and side effects of medications in each therapeutic class and the complex needs of an ethnically diverse, co-morbid, and medically complex population.

SUBPART M—GRIEVANCES, COVERAGE DETERMINATIONS, AND APPEALS

Many people with disabilities who are dually-eligible for Medicaid and Medicare have cognitive or mental disabilities which make it more difficult for them to navigate a cumbersome and multi-step appeals process. The final rule must ensure that these individuals who currently receive their prescription drugs through Medicaid are not harmed by the enactment of the MMA. Additionally, for many individuals with a variety of physical and mental disabilities, access to appropriate medication is one of the major factors which allow them to live full and more independent lives in their communities. CMS must ensure that the final rule is consistent with the principles and goals of the President's New Freedom Initiative to ensure that all people with disabilities have the opportunity to live in the community where they belong.

The proposed rule fails to meet the requirements of the Due Process Clause of the Fifth Amendment to the Constitution.

UCP believes that the proposed rule fails to meet Constitutional due process requirements and fails to satisfy the requirements of the statute. As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid beneficiaries, whose prescription requests are not being honored, receive a 72-hour supply of medications pending the

initial coverage request. They are entitled to notice and face-to-face hearings, pending an appeal if their request is denied and they file their appeal within a specified time frame. Currently, all state Medicaid appeals processes are completed more expeditiously than Medicare appeals. Based on this fact and on the fact that the majority of people with disabilities who are dually-eligible for Medicaid and Medicare, have major health care needs, UCP believes it is completely inappropriate for the proposed rule to expose these individuals to a weakened due process system.

The appeals process as described in Subpart M does not accord dually-eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights; with an adequate opportunity to a face-to-face hearing; with an adequate opportunity to have access to care/prescription drugs pending resolution of the appeal; or with a timely process for resolving disputes. While UCP recognizes that the most efficient means of protecting enrollees – which would be to amend the MMA to provide for an appeals process similar to Medicaid -- is beyond the authority of CMS, UCP does believe that CMS can take steps in the final regulations to improve notice and the opportunity for speedy review.

Sections 1860D-4(f), (g), and (h) require that sponsors of Part D plans establish grievance, coverage determination and reconsideration, and appeals processes in accordance with Section 1852 (f) & (g) of the Social Security Act. In addition, CMS – in the settlement of *Grijalva v. Shalala* and in the Medicare Plus Choice program – already has established the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review. UCP strongly recommends that CMS incorporate a similar fast-track process for Part D, which would be more in keeping with due process requirements.

Require plans to have an expedited appeals and exceptions process and to dispense a temporary supply of drugs pending the resolution of an exception request or an appeal.

The proposed system does not ensure that beneficiaries' rights are protected and does not guarantee that beneficiaries have access to needed medications. This is a major cause for concern for UCP. For millions of individuals with disabilities such as epilepsy, mental illness, HIV, Multiple Sclerosis, and spinal cord injuries -- treatment interruptions can lead to serious short-term and long-term problems. For this reason, UCP strongly recommends that the final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

Many people with epilepsy depend on specific medication to control their seizures. A disruption in their medication regimen can cause breakthrough seizures, the consequences of which can be very severe and can include loss of driving privileges, absence from work and hospitalization. Access to a temporary supply of drugs is also

critical for people with physical disabilities such as spinal cord injury (SCI). Urinary tract infections, a common secondary condition of SCI, can worsen quickly and result in kidney infections which can lead to autonomic dysreflexia, a life threatening condition.

For many people with mental illness, access to the one specific medication or the critical combination of specific drugs, is what helps them maintain their mental and physical health as well as their independence and the ability to live a full life in the community. Treatment interruptions for these individuals are just as dangerous to them as is a treatment interruption to a person with a physical disability such as epilepsy.

Our concerns related to treatment interruptions are heightened due to the absence of any adequate protections to ensure that individuals can receive a timely resolution of an appeal. We are also extremely concerned about the lengthy period of time that is allowed to pass before an individual has access to a fair and independent review of their appeal by an independent decision maker at the Administrative Law Judge (ALJ) level. We recognize that the expedited time-frames and the general 72-hour standard are a significant improvement over the standard time-frame of 14 days to make a determination and 30 days for a reconsideration. Nonetheless, from the perspective of individuals with serious and complex health conditions and disabilities, 72 hours is an unacceptable delay.

UCP strongly recommends that the final rule clearly specify that all disputes relating to coverage of Part D drugs for people with disabilities automatically qualify for an expedited decision (for all types of requests including a request for an exception, a grievance, and all level of the appeals). Moreover, we strongly recommend that the final rule clearly require plans to dispense a temporary supply of the drug in dispute pending the final outcome of an appeal.

Strengthen and improve the inadequate and unworkable exceptions and appeals processes by establishing clear standards; expediting decisions; minimizing evidence burdens on physicians; and ensuring that drugs provided through the exceptions process are made available at the "preferred drug" level of cost-sharing.

We are also concerned that the appeals processes outlined in the proposed rule are overly complex, drawn-out, and inaccessible to beneficiaries with disabilities. We are specifically concerned about the impact of such a burdensome process on individuals with cognitive and mental disabilities. We strongly recommend that CMS establish a simpler process that places a priority on ensuring ease of access and rapid results for beneficiaries and their doctors. We also strongly recommend that the final rule include a truly expedited exceptions process for individuals with immediate needs. Under the proposed rule, there are too many levels of internal drug plan appeals that a beneficiary must navigate before receiving a truly independent review by an administrative law judge (ALJ) and the timeframes for plan decisions are unreasonably long.

UCP believes that the provisions in the MMA that call for the creation of an exceptions process are a critical consumer protection that -- if properly crafted through enforceable regulations -- could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. However, as structured in the proposed rule, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and appeals process.

UCP is particularly concerned that the proposed rule would require treating physicians to assert that an exceptions request is based on both clinical experience and scientific evidence. This is an inappropriate standard that most doctors could not meet because scientific experience is not always available to support the knowledge which they acquire through clinical experience treating people with a range of disabilities – from HIV to mental illness – to epilepsy – to cerebral palsy – to spinal cord injury – to MS. UCP recommends that this requirement be eliminated from the final rule.

UCP recommends that CMS revamp the exceptions process to:

1. Establish clear standards by which prescription drug plans must evaluate all exceptions requests;
2. Minimize the time and evidence burdens on treating physicians; and
3. Ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

SUBPART P –PREMIUMS AND COST SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

432.772, Definitions

Institutionalized individual: The definition should include those individuals eligible for home and community based services under a Medicaid waiver (see, e.g., definition of "institutionalized spouse" at 42 U.S.C. § 1396r-5(h)(1)(A)), since those individuals must meet the acuity standards for Medicaid coverage in a nursing facility, and should include individuals in ICF/MRs and individuals in any institution in which they are entitled to a personal needs allowance.

423.782(a)(2)(iii), Dual eligible beneficiaries must not be denied medications for failure to pay co-payments.

Dual eligible beneficiaries will be required to pay $1 for generic drugs and $3 for brand-name drugs under Medicare Part D. Currently under Medicaid statute, an individual cannot be denied a medication for failure to pay a co-payment. Many people with disabilities depend on multiple medications including brand name medications. Even minimal co-payments will create a financial burden for individuals who will be left to choose between paying for medications and meeting other needs, like food and housing.

UCP strongly recommends that in the final rule dual eligibles must maintain the protection that they currently have under Medicaid and not be denied a drug for failure to pay cost sharing.

423.782(a)(iv) and §423.782(b)(2), Low-income individuals should not be denied medications for failure to pay co-payments.

Low-income Medicare beneficiaries between 100% and 150% of the FPL face considerable cost-sharing requirements in the proposed regulations that could prevent them from filling necessary prescriptions. Studies have demonstrated that even minimal levels of cost sharing restrict access to necessary medical care for individuals with low incomes. Individuals between 100% and 135% of FPL must pay $2 for generics and $5 for brand-name drugs. Those between 135% and 150% are required to pay a 15% co-insurance for their drugs. For individuals who require expensive treatments or multiple medications, this requirement will impose an enormous financial burden on thousands of individuals who will be unable to pay out-of-pocket for these medications. Beneficiaries eligible for the full or partial low-income subsidy should not be denied a prescription for failure to pay a co-payment or other co-insurance.

UCP appreciates the opportunity to comment on the proposed rules. If you have questions about our comments please contact Julie Ward, jward@ucp.org or (202) 973-7146.

Sincerely,

Leon Triest
UCP Co-Chair
The Arc and UCP Public Policy Collaboration Steering Committee

CMS-4068-P-1273

Submitter : **Date & Time:** 10/04/2004 08:10:11

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Pharmacy Access Standards: Patient autonomy in choosing healthcare services is a defining characteristic that pharmacists ethically respect when it comes to interacting with our patients. Thus, allowing patients to have fair access to the pharmacy and pharmacy services of their choice is crucial to upholding the patient-pharmacist relationship.

Level Playing Field: While mail order pharmacies do provide some advantages at this time for patients in obtaining their prescription medications, it is important to again consider that it is the patient?s choice in determining which services they would prefer, whether this is thru mail order or thru the traditional retail setting. Face-to-face interactions with patients are essential in developing and furthering the patient-pharmacist relationship. This relationship is the key to the patient care focus of the pharmacy profession.

Medication Therapy Management (MTM) Program: While it is feasible that plans inform providers which patients are eligible for MTM, it can be foreseen that eligibility requirements for MTM may not always allow likely targeted beneficiaries to be selected for eligibility. For example, requirements for eligibility should not deny access to any patient desiring participation in a medication therapy management program due to income or access requirements. While it may not be as feasible to allow access to all individuals who have a need for these services, it should be considered that baseline MTM services are likely to be necessary for many patients, and then follow-up MTM services may be required with discretion to meet the providers? goals for patient outcomes. For example, all patients could have access to baseline MTM services, and further services could be made available based on the plan?s coverage criteria and limitations.

E-Prescribing Incentives: As a student pharmacist, I feel that there are several incentives as to why e-prescribing could be considered a positive widespread initiative within the pharmacy profession. First and foremost, the initiative decreases medication errors in the prescribing and dispensing processes. This initiative also allows for greater accuracy in physician verification and increased awareness about generic prescribing opportunities. Also, access to formulary tier information would prove to be very valuable to all healthcare professionals who depend on access to information about formularies. This includes retail pharmacists, who on a day-to-day basis field many questions from patients related to their prescription drug coverage.

CMS-4068-P-1274

Submitter : Mr. David Viele **Date & Time:** 10/04/2004 08:10:58

Organization : First Health Services Corporation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
DEPARTMENT FOR REGULATIONS & DEVELOPMENT

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1. Improper format,
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CMS-4068-P-1275

Submitter : Mr. Charles Fallis **Date & Time:** 10/04/2004 09:10:27

Organization : National Association of Retired Federal Employees

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

BACKGROUND

The nearly 400,000 members of the National Association of Retired Federal Employees (NARFE) have significant concerns regarding a broad range of policies and issues presented in the proposed regulations to implement Medicare Part D, the Medicare prescription drug benefit in 69 Federal Register 46632 (August 3, 2004) (File Code CMS-4068-P). We are writing to highlight several critically important areas, which we feel deserve particular attention.

BENEFITS AND BENEFICIARY PROTECTIONS

Qualified prescription drug coverage: We recommend that the final rule define ?person? so that family members can pay for covered Part D cost sharing.

Treatment of Health Savings Accounts (HSAs) as group health plans: We recommend that the final rule clearly state that health saving accounts (HSAs) meet the definition of employment-based retiree health coverage in Sec. 1860D-22 and the ?insurance or otherwise? provision in Sec. 1860D-24 of the MMA. The law precludes contributions from employer sponsored health plans from being counted as incurred costs and counting toward the deductible or out of pocket limit. We do not believe that contributions from one employer-sponsored benefit should receive differential treatment over contributions from another type of employer-sponsored benefit. Therefore, the final rule must not preferentially treat contributions from HSAs and Health Reimbursement Accounts (HRAs) by counting them as incurred costs when contributions from employer-sponsored group health coverage are not counted as an incurred cost.
Establishing limits on tiered copayments: We strongly oppose the provision in the proposed rule that permits Part D plans to ?apply tiered co-payments without limit?. The final rule must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs.

The MMA permits tiered cost sharing so that Part D plans are permitted to incentivize the use of preferred drugs within a class, when it is clinically appropriate. By placing no limits on the use of tiered cost-sharing, the proposed rule undermines the balance achieved by the Congress between permitting plans to use formularies with numerous provisions (including the Pharmacy and Therapeutics (P&T) committee requirements and the exceptions process) that seek to ensure that individuals receive all of the covered Part D drugs they need when medically necessary.

The absence of reasonable limits on cost-sharing tiers combined with an inadequate and unworkable exceptions process would provide Medicare Part D enrollees with a catch-22. Permitting unlimited cost-sharing tiers could permit a Part D plan to effectively bar access to clinically necessary covered Part D drugs because cost-sharing is unaffordable and the exceptions process does not include adequate safeguards or standards to ensure a fair review of an individual?s request for an exception to a Part D plan?s non-preferred cost-sharing. Moreover, allowing plans unlimited flexibility in establishing cost-sharing tiers increases their opportunity to discriminate against people who need costly medications or who need multiple medications. We also believe that permitting multiple cost-sharing tiers will greatly complicate the ability of CMS to determine actuarial equivalence and to determine that the design of a plan does not substantially discourage enrollment by certain eligible Part D eligible individuals under the plan. We also note that, in 2004, 85 percent of private sector plans that use tiered cost sharing had only two or three tiers, (Employer Health Benefits, 2004, Annual Survey, Kaiser Family Foundation and Health Research and Educational Trust, 2004).

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Employer Retiree Subsidy

Allowable retiree costs: In considering allowable costs for a qualified retiree prescription drug plan, CMS must apply a test that considers only an employer?s financial contribution to retiree prescription drug coverage, net of any payments by the retiree.

In addition, to be consistent with the requirements of the law under Section 1860 D?22 and CMS?s own stated goal (69 Federal Register 46741,

August 3, 2004), CMS must require the employer?s contribution to be at least as generous as the net value of the standard Medicare Part D benefit (i.e., the expected amount of paid claims under Medicare Part D minus beneficiary premiums).

Furthermore, as the Preamble discussion makes clear (p. 46736ff), accounting for retiree costs eligible for the subsidy will be a difficult accounting problem that may be subject to confusion or abuse. We believe one of the best ways to ensure a fair and equitable use of the subsidy amounts is to make the information on employer costs and reimbursements from Medicare public data which employee organizations and advocates can monitor.

Actuarial Attestation: CMS has proposed the use of random audits to ensure qualifying employment-based retiree prescription drug plans meet the actuarial equivalence test. However, we suggest that CMS take additional protections against improper payment of the federal subsidy. In order to help accomplish that, the attestation submitted by employers must include information on the assumptions that are the basis for the valuation of the plan for purposes of determining actuarial equivalence. This information must be available for public inspection.

Late enrollment penalties: The appropriate regulation should make it clear that employees should be held harmless from late enrollment penalties in the event that a retiree plan is discovered to have been in violation of creditable coverage due to an error or misrepresentation of the value of a retiree plan.

Payment methods, including provision of necessary information: The information required to be submitted to ensure accurate subsidy payments should include information on how actual spending compares to projected spending (submitted as basis for actuarial equivalence attestation). Such information should be available for public inspection.

Appeals: To provide further protection against improper payment of the employer subsidy, third parties (such as employee and retiree organizations or other advocates) should be granted the right to appeal a CMS determination regarding the actuarial equivalence of an employer?s retiree prescription drug plan.

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Basic alternative benefit designs that go beyond actuarially equivalent standard coverage: We are strongly opposed to the provisions of Section 423.104(g). We recommend that the final rule exclude provisions for ?enhanced alternative coverage?. The MMA provides for standard prescription drug coverage and alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices.

We believe that the proposed provisions at Section 423.104(g) exceed the authority of the statute and defeat the purpose of the Act, which is to provide meaningful choice of prescription drug plans by eligible Part D beneficiaries. The different options make it virtually impossible to compare plans, and thus make it nearly impossible for older people and people with disabilities to make an informed choice of private plan options. See, for example, Geraldine Dallek, Consumer Protection Issues Raised by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Kaiser Family Foundation, July 2004.

Further, a 2001 study found that ?elderly consumers have much more difficulty accurately using comparative information to inform health plan choice than nonelderly consumers have,? (Judith H. Hibbard and others, ?Is the Informed-Choice Policy Approach Appropriate for Medicare Beneficiaries??, Health Affairs, May/June 2001, Vol. 20, number 3; 199-203). The authors state that, ?given the population-related differences we observed, moving Medicare in the direction of mirroring the market approach used for the under sixty-five population may not be feasible or desirable.? Given that the MMA adopts a consumer choice model, it is imperative that the final rule ensure that elderly beneficiaries and people with disabilities have access to plans with benefit designs that are sufficiently standardized to permit an objective comparison among plan options.

Access to negotiated prices when the beneficiary is responsible for 100 percent cost sharing: We strongly oppose allowing any plan to impose 100 percent cost sharing for any drug. Such cost sharing should be considered as per se discrimination against the group or groups of individuals who require that prescription.

Further, the purpose of the drug benefit is to provide assistance with the high cost of prescription drugs. Therefore, the final rule should require plans to pass along all of their negotiated savings to beneficiaries.

Counting purchases of on-formulary covered Part D drugs as incurred costs: We strongly recommend that the final rule ensure that all beneficiary costs used for the purchase of covered Part D drugs count as incurred costs, including any costs incurred by individuals to purchase a covered Part D drug that is on the plan?s formulary, which has been prescribed by a physician, but which has been denied coverage by the Part D plan.

Requiring PDP sponsors and MA organizations to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call centers: We believe that it is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center. The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program. This is a critical requirement that must be included in the final rule.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Late Enrollment Penalty: We urge CMS to delay implementation of Section 423.46 for all enrollees for two years. The drug benefit is a new program and particularly complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. We see from the Medicare-endorsed prescription drug discount card that, even with significant outreach, the majority of individuals eligible for the low-income subsidy have not yet taken advantage of the $600 subsidy available to them.

We disagree with CMS' observation that healthy beneficiaries will not apply; we believe that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness and cognitive disabilities. The Medicare Part D program is new and confusing. Indeed, people delayed enrollment in the Medicare drug card because they did not understand the program and found the choices overwhelming. Many Medicare beneficiaries will need more than 6 months to understand the program, understand how Part D coordinates with other drug coverage they may have, and then to choose the drug plan that is right for them. During the initial implementation process, people should not be penalized because of the complexity of the program.

Until such time as beneficiaries become familiar with the program, they should not be penalized because of its complications.

Outreach and funding the State Health Insurance Assistance Programs (SHIPs). The preamble references concerns with outreach and enrollment. An extensive network of local, face-to-face counseling services will be needed. The toll free phone number and literature alone will not be adequate.

SHIPs, Area Agencies on Aging (AAA), and other local groups can provide the kind of detailed help needed, but they need additional resources. We believe that the SHIPs and AAAs, and related local counseling services are woefully under-funded. Current funding for SHIPs, even after the much-needed and welcome increases announced this spring, are about 50 to 75 cents per year per beneficiary. This is barely enough for 2 mailings per year, let alone the highly labor intensive one-on-counseling that is needed. The Senate-passed version of the MMA had originally proposed $1 per beneficiary for the SHIPs, but unfortunately that was deleted in the final law. We urge that SHIP/AAA funding be increased further.

Approval of marketing material and enrollment: The marketing rules for the Prescription Drug Plans (PDPs) and Medicare-Advantage (MA)-PDPs should be developed in the historical context of other Medicare programs. From selective marketing to outright fraud, Medicare programs historically have been afflicted with marketing abuses and scams. We urge that CMS be vigilant to identify and prohibit these problematic areas and practices as it develops final regulations.

Procedures to determine and document creditable status of prescription drug coverage: It is absolutely essential that beneficiaries understand whether or not they have creditable coverage. Failure to understand the issue of creditable coverage can lead to a lifetime of higher Part D premiums.

CMS must set forth specific requirements that plans provide information to Medicare beneficiaries enrolled in those plans clearly stating whether or not the coverage they have is creditable.

GENERAL PROVISIONS

We believe that the legislation and regulations should make no Medicare beneficiary worse off than they would have been without this law. The Medicare Moderization Act (MMA) should be a means to improve the quality and quantity of care provided to its constituencies. To ensure that our primary goals are met, we ask the Secretary to institute a second round of comments before promulgating final regulations. The proposed regulations contain many substantive areas about which the Centers for Medicare and Medicaid Services (CMS) seeks broad guidance and for which the agency?s proposal expresses several optional approaches. We find it difficult to imagine that the regulations as proposed will be ready for implementation without a second comment period to follow any CMS revisions that are made.

SUBMISSION OF BIDS, PREMIUMS AND RELATED INFORMATION, AND PLAN APPROVAL

Explanation Of Benefits: We support the inclusion in the final rule of provisions in the proposed rule regarding elements of the explanation of benefits. These elements, however, must be supplemented by:

? Appeals rights and processes: Information about relevant requirements for accessing the exceptions process, the grievance process, and the appeals process.

? Access to formulary information: Plans should be required to provide information to all Part D eligible individuals, and not just plan enrollees, about the plan formulary. Moreover, while we are supportive of the provision in the proposed rule that requires plans to make available access to the plan?s formulary, in isolation, that is insufficient. Beneficiaries need precise and detailed information about the formulary both to make an informed choice about enrollment and then to minimize their out-of-pocket costs once enrolled in a plan. Simply giving beneficiaries a description of how they can obtain information about the formulary is insufficient to further the goals of the statute. Plan descriptions should include a detailed formulary, listing not only all the drugs but the tier and amount of co-payment upon which each drug is placed, especially if plans will be allowed to require beneficiaries to pay 100 percent of the cost of certain formulary drugs.

? Plan terminations: 423.128(c)(iii) requires plans to tell all Part D eligible individuals that the part D plan has the right to terminate or not renew its contract, but only if the individuals request this information. Information about the potential for contract termination needs to be included in all plan descriptions and in all marketing materials, and not just if requested by an enrollee or Part D eligible individual. Based upon experience with the Medicare+Choice (M+C) market, the drug plan market will experience volatility that results in adverse consequences to many beneficiaries. The Medicare+Choice model summary of benefits requires this information to be in the summary of benefits and in the evidence of coverage; the same rule should apply for Part D.

Requiring that an explanation of benefits be provided at least monthly for individuals utilizing their prescription drug benefits in a given month: We recommend that the final rule retain the provision that requires an explanation of benefits be provided at least monthly for individuals utilizing their prescription drug benefits in a given month. The explanation of benefits should include the drugs the plan paid for, the beneficiary cost sharing, whether the deductible has been met, and how much remains to be met in out-of-pocket costs before stop-loss coverage begins. The notice should also tell people how to appeal or to request an exception.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

The grievance and appeals sections need to be simplified and improved. They weaken constitutionally protected rights for all Medicare beneficiaries. As drafted, the time frames for every step of the process is too long. The proposed regulations do not provide adequate and timely, constitutionally required notice, and they do not adequately provide for emergency supplies of medicines while an individual is appealing. Many events (such as a change in formulary) that can harm beneficiaries do not appear to be appealable. CMS should set the criteria plans must use for evaluating requests for exceptions, and not leave the standards to each individual plan. As drafted, the proposed rule sets an impossibly high requirement for receiving an exception to cover non-formulary drug or to provide a formulary drug at a lower tiered cost sharing.

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National Association of Retired Federal Employees
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Alexandria, VA 22314

October 4, 2004

Mark McClellan, MD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-814

Dear Administrator McClellan:

The nearly 400,000 members of the National Association of Retired Federal Employees (NARFE) have significant concerns regarding a broad range of policies and issues presented in the proposed regulations to implement Medicare Part D, the Medicare prescription drug benefit in 69 Federal Register 46632 (August 3, 2004) (File Code CMS-4068-P). We are writing to highlight several critically important areas, which we feel deserve particular attention.

We believe that the legislation and regulations should make no Medicare beneficiary worse off than they would have been without this law. The Medicare Moderization Act (MMA) should be a means to improve the quality and quantity of care provided to its constituencies. To ensure that our primary goals are met, we ask the Secretary to institute a second round of comments before promulgating final regulations. The proposed regulations contain many substantive areas about which the Centers for Medicare and Medicaid Services (CMS) seeks broad guidance and for which the agency's proposal expresses several optional approaches. We find it difficult to imagine that the regulations as proposed will be ready for implementation without a second comment period to follow any CMS revisions that are made.

Employer Retiree Subsidy

Allowable retiree costs: In considering allowable costs for a qualified retiree prescription drug plan, CMS must apply a test that considers only an employer's financial contribution to retiree prescription drug coverage, net of any payments by the retiree.

In addition, to be consistent with the requirements of the law under Section 1860 D—22 and CMS's own stated goal (69 *Federal Register* 46741, August 3, 2004), CMS must require the employer's contribution to be at least as generous as the net value of the standard Medicare Part D benefit (i.e., the expected amount of paid claims under Medicare Part D minus beneficiary premiums).

Furthermore, as the Preamble discussion makes clear (p. 46736ff), accounting for retiree costs eligible for the subsidy will be a difficult accounting problem that may be subject to confusion or

abuse. We believe one of the best ways to ensure a fair and equitable use of the subsidy amounts is to make the information on employer costs and reimbursements from Medicare public data which employee organizations and advocates can monitor.

Actuarial Attestation: CMS has proposed the use of random audits to ensure qualifying employment-based retiree prescription drug plans meet the actuarial equivalence test. However, we suggest that CMS take additional protections against improper payment of the federal subsidy. In order to help accomplish that, the attestation submitted by employers must include information on the assumptions that are the basis for the valuation of the plan for purposes of determining actuarial equivalence. This information must be available for public inspection.

Late enrollment penalties: The appropriate regulation should make it clear that employees should be held harmless from late enrollment penalties in the event that a retiree plan is discovered to have been in violation of creditable coverage due to an error or misrepresentation of the value of a retiree plan.

Payment methods, including provision of necessary information: The information required to be submitted to ensure accurate subsidy payments should include information on how actual spending compares to projected spending (submitted as basis for actuarial equivalence attestation). Such information should be available for public inspection.

Appeals: To provide further protection against improper payment of the employer subsidy, third parties (such as employee and retiree organizations or other advocates) should be granted the right to appeal a CMS determination regarding the actuarial equivalence of an employer's retiree prescription drug plan.

Eligibility And Enrollment

Late Enrollment Penalty: We urge CMS to delay implementation of Section 423.46 for all enrollees for two years. The drug benefit is a new program and particularly complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. We see from the Medicare-endorsed prescription drug discount card that, even with significant outreach, the majority of individuals eligible for the low-income subsidy have not yet taken advantage of the $600 subsidy available to them.

We disagree with CMS' observation that healthy beneficiaries will not apply; we believe that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness and cognitive disabilities. The Medicare Part D program is new and confusing. Indeed, people delayed enrollment in the Medicare drug card because they did not understand the program and found the choices overwhelming. Many Medicare beneficiaries will need more than 6 months to understand the program, understand how Part D coordinates with other drug coverage they may have, and then to choose the drug plan that is right for them. During the initial implementation process, people should not be penalized because of the complexity of the program.

Until such time as beneficiaries become familiar with the program, they should not be penalized because of its complications.

Outreach and funding the State Health Insurance Assistance Programs (SHIPs). The preamble references concerns with outreach and enrollment. An extensive network of local, face-to-face counseling services will be needed. The toll free phone number and literature alone will not be adequate.

SHIPs, Area Agencies on Aging (AAA), and other local groups can provide the kind of detailed help needed, but they need additional resources. We believe that the SHIPs and AAAs, and related local counseling services are woefully under-funded. Current funding for SHIPs, even after the much-needed and welcome increases announced this spring, are about 50 to 75 cents per year per beneficiary. This is barely enough for 2 mailings per year, let alone the highly labor intensive one-on-counseling that is needed. The Senate-passed version of the MMA had originally proposed $1 per beneficiary for the SHIPs, but unfortunately that was deleted in the final law. We urge that SHIP/AAA funding be increased further.

Approval of marketing material and enrollment: The marketing rules for the Prescription Drug Plans (PDPs) and Medicare-Advantage (MA)-PDPs should be developed in the historical context of other Medicare programs. From selective marketing to outright fraud, Medicare programs historically have been afflicted with marketing abuses and scams. We urge that CMS be vigilant to identify and prohibit these problematic areas and practices as it develops final regulations.

Procedures to determine and document creditable status of prescription drug coverage: It is absolutely essential that beneficiaries understand whether or not they have creditable coverage. Failure to understand the issue of creditable coverage can lead to a lifetime of higher Part D premiums.

CMS must set forth specific requirements that plans provide information to Medicare beneficiaries enrolled in those plans clearly stating whether or not the coverage they have is creditable.

Qualified prescription drug coverage: We recommend that the final rule define “person” so that family members can pay for covered Part D cost sharing.

Treatment of Health Savings Accounts (HSAs) as group health plans: We recommend that the final rule clearly state that health saving accounts (HSAs) meet the definition of employment-based retiree health coverage in Sec. 1860D-22 and the “insurance or otherwise” provision in Sec. 1860D-24 of the MMA. The law precludes contributions from employer sponsored health plans from being counted as incurred costs and counting toward the deductible or out of pocket limit. We do not believe that contributions from one employer-sponsored benefit should receive differential treatment over contributions from another type of employer-sponsored benefit. Therefore, the final rule must not preferentially treat contributions from HSAs and Health Reimbursement Accounts (HRAs) by counting them as incurred costs when contributions from employer-sponsored group health coverage are not counted as an incurred cost.

Establishing limits on tiered copayments: We strongly oppose the provision in the proposed rule that permits Part D plans to "apply tiered co-payments without limit". The final rule must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs.

The MMA permits tiered cost sharing so that Part D plans are permitted to incentivize the use of preferred drugs within a class, when it is clinically appropriate. By placing no limits on the use of tiered cost-sharing, the proposed rule undermines the balance achieved by the Congress between permitting plans to use formularies with numerous provisions (including the Pharmacy and Therapeutics (P&T) committee requirements and the exceptions process) that seek to ensure that individuals receive all of the covered Part D drugs they need when medically necessary.

The absence of reasonable limits on cost-sharing tiers combined with an inadequate and unworkable exceptions process would provide Medicare Part D enrollees with a catch-22. Permitting unlimited cost-sharing tiers could permit a Part D plan to effectively bar access to clinically necessary covered Part D drugs because cost-sharing is unaffordable and the exceptions process does not include adequate safeguards or standards to ensure a fair review of an individual's request for an exception to a Part D plan's non-preferred cost-sharing. Moreover, allowing plans unlimited flexibility in establishing cost-sharing tiers increases their opportunity to discriminate against people who need costly medications or who need multiple medications. We also believe that permitting multiple cost-sharing tiers will greatly complicate the ability of CMS to determine actuarial equivalence and to determine that the design of a plan does not substantially discourage enrollment by certain eligible Part D eligible individuals under the plan. We also note that, in 2004, 85 percent of private sector plans that use tiered cost sharing had only two or three tiers, (*Employer Health Benefits, 2004, Annual Survey*, Kaiser Family Foundation and Health Research and Educational Trust, 2004).

Basic alternative benefit designs that go beyond actuarially equivalent standard coverage: We are strongly opposed to the provisions of Section 423.104(g). We recommend that the final rule exclude provisions for "enhanced alternative coverage". The MMA provides for standard prescription drug coverage and alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices.

We believe that the proposed provisions at Section 423.104(g) exceed the authority of the statute and defeat the purpose of the Act, which is to provide meaningful choice of prescription drug plans by eligible Part D beneficiaries. The different options make it virtually impossible to compare plans, and thus make it nearly impossible for older people and people with disabilities to make an informed choice of private plan options. See, for example, Geraldine Dallek, *Consumer Protection Issues Raised by the Medicare Prescription Drug, Improvement and Modernization Act of 2003*, Kaiser Family Foundation, July 2004.

Further, a 2001 study found that "elderly consumers have much more difficulty accurately using comparative information to inform health plan choice than nonelderly consumers have," (Judith H. Hibbard and others, "Is the Informed-Choice Policy Approach Appropriate for Medicare Beneficiaries?", *Health Affairs*, May/June 2001, Vol. 20, number 3; 199-203). The authors state that, "given the population-related differences we observed, moving Medicare in the direction of

mirroring the market approach used for the under sixty-five population may not be feasible or desirable." Given that the MMA adopts a consumer choice model, it is imperative that the final rule ensure that elderly beneficiaries and people with disabilities have access to plans with benefit designs that are sufficiently standardized to permit an objective comparison among plan options.

Access to negotiated prices when the beneficiary is responsible for 100 percent cost sharing: We strongly oppose allowing any plan to impose 100 percent cost sharing for any drug. Such cost sharing should be considered as per se discrimination against the group or groups of individuals who require that prescription.

Further, the purpose of the drug benefit is to provide assistance with the high cost of prescription drugs. Therefore, the final rule should require plans to pass along all of their negotiated savings to beneficiaries.

Counting purchases of on-formulary covered Part D drugs as incurred costs: We strongly recommend that the final rule ensure that all beneficiary costs used for the purchase of covered Part D drugs count as incurred costs, including any costs incurred by individuals to purchase a covered Part D drug that is on the plan's formulary, which has been prescribed by a physician, but which has been denied coverage by the Part D plan.

Requiring PDP sponsors and MA organizations to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call centers: We believe that it is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center. The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program. This is a critical requirement that must be included in the final rule.

Explanation Of Benefits: We support the inclusion in the final rule of provisions in the proposed rule regarding elements of the explanation of benefits. These elements, however, must be supplemented by:

- **Appeals rights and processes:** Information about relevant requirements for accessing the exceptions process, the grievance process, and the appeals process.

- **Access to formulary information:** Plans should be required to provide information to all Part D eligible individuals, and not just plan enrollees, about the plan formulary. Moreover, while we are supportive of the provision in the proposed rule that requires plans to make available access to the plan's formulary, in isolation, that is insufficient. Beneficiaries need precise and detailed information about the formulary both to make an informed choice about enrollment and then to minimize their out-of-pocket costs once enrolled in a plan. Simply giving beneficiaries a description of how they can obtain information about the formulary is insufficient to further the goals of the statute. Plan descriptions should include a detailed

formulary, listing not only all the drugs but the tier and amount of co-payment upon which each drug is placed, especially if plans will be allowed to require beneficiaries to pay 100 percent of the cost of certain formulary drugs.

- **Plan terminations:** 423.128(c)(iii) requires plans to tell all Part D eligible individuals that the part D plan has the right to terminate or not renew its contract, but only if the individuals request this information. Information about the potential for contract termination needs to be included in all plan descriptions and in all marketing materials, and not just if requested by an enrollee or Part D eligible individual. Based upon experience with the Medicare+Choice (M+C) market, the drug plan market will experience volatility that results in adverse consequences to many beneficiaries. The Medicare+Choice model summary of benefits requires this information to be in the summary of benefits and in the evidence of coverage; the same rule should apply for Part D.

Requiring that an explanation of benefits be provided at least monthly for individuals utilizing their prescription drug benefits in a given month: We recommend that the final rule retain the provision that requires an explanation of benefits be provided at least monthly for individuals utilizing their prescription drug benefits in a given month. The explanation of benefits should include the drugs the plan paid for, the beneficiary cost sharing, whether the deductible has been met, and how much remains to be met in out-of-pocket costs before stop-loss coverage begins. The notice should also tell people how to appeal or to request an exception.

Grievances, Coverage Determinations And Appeals

The grievance and appeals sections need to be simplified and improved. They weaken constitutionally protected rights for all Medicare beneficiaries. As drafted, the time frames for every step of the process is too long. The proposed regulations do not provide adequate and timely, constitutionally required notice, and they do not adequately provide for emergency supplies of medicines while an individual is appealing. Many events (such as a change in formulary) that can harm beneficiaries do not appear to be appealable. CMS should set the criteria plans must use for evaluating requests for exceptions, and not leave the standards to each individual plan. As drafted, the proposed rule sets an impossibly high requirement for receiving an exception to cover non-formulary drug or to provide a formulary drug at a lower tiered cost sharing.

Thank you for considering these comments on the proposed regulations to implement Medicare Part D, the Medicare prescription drug benefit in 69 Federal Register 46632 (August 3, 2004).

Sincerely,

Charles L. Fallis
President
National Association of Retired Federal Employees

CMS-4068-P-1276

Submitter : Tim Palmer **Date & Time:** 10/04/2004 08:10:14

Organization : Kings Daughters Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As a pharmacist of Kings Daughters Hospital Home Infusion in Madison Indiana, I am pleased to submit my comments on the proposed rule to implement the new medicare part D prescription drug benefit. Being a small town infusion provider I find myself being both the pharmacist and the billing clerk for our company and therefor have a great appreciation for the daunting task that CMS confronts in implementing this benefit. I applaud CMS for recoginizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system. The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients homes but the essential services, supplies and equipment that are intergral to the provision of home infusion therapy (dispnesing fee option 3 as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans. At that point, Medicare will finally be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

My experience leads me to believe that dispensing fee option 3 is the only proposed option that will enabel Medicare beneficiaries to receive home infuison therapy under the Part D benefit. CMS should follow the well established home infusion per diem model encoded using the national hcpcs S codes. If implemented properly this model will ensure access and avoid duplication of services just as it does in the private payer sector.

Thank you in advance for your consideration
Sincerely,

Tim Palmer R.Ph.
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CMS-4068-P-1277

Submitter : Mr. Paul Tibbits Jr **Date & Time:** 10/04/2004 08:10:52

Organization : American Diabetes Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4068-P-1277-Attach-1.doc

COMMENTS ON THE PROPOSED RULE FOR THE MEDICARE PROGRAM: MEDICARE PRESCRIPTION DRUG BENEFIT

Submitted by the American Diabetes Association
October 04, 2004

Nathaniel Clark, MD
National Vice President, Clinical Affairs

It is the understanding of the American Diabetes Association (ADA) that the proposed rules governing the Medicare Modernization Act (MMA) should promote widespread participation from both drug plans and Medicare beneficiaries. They are also intended to protect consumers from insurer practices that will discourage enrollment. However, ADA is concerned that the proposed rules, as written, will not accomplish these goals. ADA submits the following comments and recommendations regarding the proposed rules for Medicare Part D.

Subpart C - Benefits and Beneficiary Protection.

423.104(e)(2)(ii), Establishing limits on tiered copayments.
ADA opposes the provision that permits Part D plans to "apply tiered co-payments without limit." ADA recommends that the final rule limit the use of tiered cost-sharing by permitting no more than three cost-sharing tiers and by requiring Part D plans to use the same tiers for all classes of drugs.

In allowing tiered cost-sharing, Congress has attempted to balance the need to ensure that beneficiaries have access to all of the covered Part D drugs they need when necessary with the need for cost containment. The MMA permits Part D plans to incentivize the use of preferred drugs within a class when it is clinically appropriate to do so. But by placing no limits on the use of tiered cost-sharing, the proposed rule undermines the balance Congress intended to achieve.

Permitting unlimited co-payment tiers could effectively bar Medicare Part D enrollees from accessing clinically necessary drugs because the cost-sharing might become unaffordable. Moreover, allowing plans unlimited flexibility in establishing cost-sharing tiers increases the potential for discrimination against people who need costly medications or who need multiple medications. ADA also believes that permitting multiple cost-sharing tiers will greatly complicate the ability of CMS to determine actuarial equivalence and to determine whether or not the design of a plan substantially discourages enrollment by certain eligible Part D individuals. ADA also notes that in 2004, 85% of private sector plans that use tiered cost-sharing had only two or three tiers, (*Employer Health Benefits, 2004, Annual Survey*, Kaiser Family Foundation and Health Research and Educational Trust, 2004).

423.120(b) - Formulary requirements.
ADA recommends that the final rule ensures that Pharmaceutical & Therapeutic (P&T) committee decisions are binding on plans. Many Medicare beneficiaries and consumer advocates are gravely concerned by the financial incentives in the MMA for for-profit plans to design formularies and utilize cost management strategies in a way that maximizes profits at the expense of enrollees' interests and in contravention of current standards of clinical practice. The existence of P&T committees, whose purpose is to consider existing scientific knowledge and clinical experience in designing formularies, would be dramatically undermined and would run counter to the statute, unless P&T committee decisions are binding on plans.

ADA also believes that Congress intended for P&T committee decisions to be binding on plans. If P&T committee decisions were intended to be merely advisory, then the provisions requiring independent physician and pharmacist participation would be unnecessary. In other comments, ADA will make clear that it has serious concerns about the independence and integrity of P&T committee decision making. The final rule must take greater steps to shield P&T committee decisions from financial considerations and it must reinforce the independence and broad-based clinical expertise of P&T committees.

423.120 (b)(1) - Development and revision by a pharmacy and therapeutic committee.

The preamble to the proposed rule suggests that P&T members should be "independent and free of conflict with respect to the sponsor and plan" as well as pharmaceutical manufacturers. ADA strongly supports this interpretation and recommends that it be incorporated into the final rule. The essential function of P&T committees is to ensure that formulary- and benefit-design decisions are based on existing scientific knowledge and clinical experience. This function cannot be adequately performed when P&T committees consist of a majority of members who are not independent. As with plan employees, employees of pharmaceutical manufacturers have a conflict and cannot be relied upon to give an impartial and fair view of existing scientific knowledge and clinical evidence.

- **Recommendations for ensuring the independence of P&T committees.** ADA recommends that the final rule include stronger provisions for ensuring the independence and integrity of P&T committees. Critical improvements needed for P&T committees to function effectively are:

    - **P&T Committee Charge:** The final rule should include a charge for P&T committees to "ensure that the interests of enrollees, taking into account the unique needs and co-morbidities commonly associated with aging populations and people with disabilities served by Medicare, are protected by all formulary and benefit design decisions made by the Part D plan." The final rule should also make clear that P&T committees have responsibility for the implementation of the formulary, including the application of a plan's cost-sharing structure (including assigning drugs to specific cost-sharing tiers). In all cases, the P&T committee should be responsible for ensuring that adequate access is provided for the most clinically efficacious drugs in the preferred tier for all classes of covered drugs.

      The final rule should also include provisions for sanctions against P&T committee members when P&T committee decisions are in gross violation of this charge.

    - **P&T Committee Required:** The final rule must clearly state that all prescription drug plans are required to operate a P&T committee, without regard to whether or not they operate a formulary. In cases where plans do not operate formularies, the P&T committee would have responsibility for

implementing the cost-sharing structure and assigning specific drugs to each cost-sharing tier.

- **Expertise:** The final rule should require a numerical majority of P&T committee members to be independent and free of conflict with respect to the sponsor, the plan, and pharmaceutical manufacturers.

  The preamble to the proposed rules encourages plans to "select P&T committee members representing various clinical specialties in order to ensure that all disease states are adequately considered in the development of plan formularies." While ADA recognizes that it will not be possible for any committee to have adequate expertise in all areas, it believes that due to the increasing rates and prevalence of diabetes in the Medicare-eligible population, the final rule should require P&T committees to include at least one member with expertise in endocrinology. At a minimum, the final rule must require P&T committees to have formalized relationships to advise the P&T committee in decision-making in this field if P&T committee members do not have adequate clinical expertise in the area of endocrinology.

- **Transparency and Consumer Involvement:** The final rule must require P&T committees to develop formularies and make benefit-design decisions in a way that is transparent to plan enrollees and the general public. The final rule should require P&T committees to hold public hearings and receive input from the public prior to the adoption or revision of plan formularies. Further, during the P&T committee process, plans should be required to seek input from affected enrollee populations, including a diverse range of disabled populations.

- **Timely Review:** The final rule should require P&T committees to meet at least quarterly, and have processes for making formulary revisions between regularly scheduled meetings based upon new clinical information or FDA approval of medications that could be used for the treatment of life-threatening conditions.

423.120(b)(2) - Inclusion of drugs in all therapeutic categories and classes

The MMA charged the United States Pharmacopeia (USP) with developing "a model set of guidelines that consists of a list of drug categories and classes that may be used by prescription drug plan sponsors and Medicare Advantage organizations to develop formularies for their qualified prescription drug coverage, including their therapeutic categories and classes."[1] The ADA is concerned that the model guidelines set forth by USP will create problems for beneficiaries with diabetes attempting to access their necessary medications in a timely way.

ADA's concerns with the initial draft of USP's guidelines and CMS's proposed rules focus on four (4) areas. These include the following items:

[1] SSA § 1860D-4(b)(3).

1. Drug Classification System for Medications
2. Inclusion of Syringes and Related Insulin Delivery Devices
3. Procedures for Adopting New Therapeutic Categories and Pharmacological Classes
4. Implementation

1. Drug Classification System for Medications

ADA is extremely concerned with the current draft of USP's drug classification system. The Association believes that the pharmacological classes listed under USP's "Blood Glucose Regulating Agents" are not adequate to ensure that Medicare beneficiaries will have proper access to the medications necessary to control and treat their diabetes. The Association is equally concerned that the draft will not provide adequate coverage for insulin needs of people living with diabetes.

The current USP guidelines list "insulins" as one class and "hypoglycemic agents, oral" as another class. In addition, there are then four (4) "recommended subdivisions" of insulin and five (5) "recommended subdivisions" of oral agents.

It is critically important to note that each of the nine (9) aforementioned "recommended subdivisions" is a medically distinct product that functions in a uniquely different way. In order for a person with type 2 diabetes to have access to the best and most medically effective treatment regimen, s/he requires that all nine (9) of the "subdivisions" be available to them. Furthermore, it is equally important for a person with type 1 diabetes to have access to all four (4) recommended subdivisions for insulin. Because each individual responds differently to a particular type of insulin or oral agent, it is imperative that all options be available in order to appropriately respond to each person's specific need.

Because the MMA and Medicare regulations require drug plans to include only two (2) drugs from each pharmacological class, USP's current draft risks severely limiting the options available to Medicare beneficiaries with diabetes. Indeed, under the current draft, an approved formulary could include only two (2) insulin types and two (2) oral agents and remain in full compliance with Medicare regulations. This would be disastrous for older Americans living with diabetes.

Insulin

The goal of insulin therapy for patients with diabetes is to control blood glucose levels. Insulin therapy is always extremely individualized, and the appropriate treatment plan depends strongly on what type of diabetes the patient has, how long the patient has had diabetes, and his/her daily routine, activity level, and food intake. Insulin treatment regimens are designed to mimic the actions of a normal pancreas, which continually releases a small amount of insulin into the bloodstream 24 hours a day, while also releasing a bolus of additional insulin in response to each meal consumed.

Insulin is available in rapid, short, intermediate, and long acting forms that may be injected separately or mixed in the same syringe. Because different patients will respond differently to each of the insulin types, all patients must have access to all types in order to create a treatment plan that most effectively mirrors what their bodies would do if they produced insulin naturally. With the proper insulin treatment, blood glucose levels will be successfully lowered, thus significantly reducing the risk of costly hospitalizations and complications in the future. As such, it is absolutely necessary that Medicare beneficiaries are guaranteed access to the four (4) types of insulin.

Oral Hypoglycemic Agents

ADA is also concerned that the draft guidelines provide insufficient access to oral medications for type 2 diabetes. Type 2 diabetes is a complex disease with several causes, all of which lead to increased blood glucose levels. For example, some people with type 2 diabetes produce insulin, but their blood glucose level remains high because their cells are resistant to the action of the insulin. Others also produce insulin, but too much glucose from the liver is released into the blood, causing their blood glucose levels to increase. Over time, most patients with type 2 diabetes produce level of insulin which is simply insufficient to control their blood glucose level.

The various types of oral medications for diabetes are designed to address each of these issues:

- Alpha-glucosidase inhibitors act by slowing the digestion of starches. This prevents post-prandial (after-meal) blood glucose levels from rising too high and improves long-term blood glucose control.
- Meglitinides stimulate the pancreas to release more insulin. This class of drugs is shorter acting than the traditional sulfonylurea and is designed to be taken immediately before each meal.
- Biguanides keep the liver from releasing too much glucose.
- Sulfonylureas stimulate the pancreas to release more insulin. This class of drugs acts more gradually than the meglitinides and is designed to be taken once or twice a day.
- Thiazolidinediones make the body (particularly muscle cells) more sensitive to insulin, and thus are ideal for patients with insulin resistance.

All Medicare drug plan formularies must include drugs from each of the 'recommended subdivisions' so that beneficiaries with type 2 diabetes are assured of having access to the appropriate type of oral agent. For example, if a person is producing a normal amount of insulin but their cells are insulin resistant, it will only be of limited assistance if the only two (2) approved drugs are sulfonylureas and meglitinides. Yet a drug plan could choose to cover two only these two types of oral agents and still be compliant with Medicare's proposed rules and the USP draft model formulary guidelines. Such scenarios are unacceptable and must be addressed.

Cardiovascular Medications

Additionally, because the treatment of type 2 diabetes now focuses on the treatment of blood pressure and lipids in addition to blood glucose, ADA also feels it is necessary to

address the above classification concerns in the areas of "Cardiovascular Medications" as identified by the proposed USP guidelines. The proposed "Cardiovascular" category currently contains medications to treat several distinct disorders. The classes are then subdivided into separate medications; however, because each of these medications has a distinct mechanism of action, it is critically important that each of them be available to enrollees with diabetes in order to secure the best treatment possible.

For example, "Diuretics" contains 4 subdivisions and "Antilipemic" contains 5 subdivisions. For enrollees with diabetes, any limitation of medications in these classes – such as requiring only 2 drugs per class be allowed –based on the current proposed classification system, would not be in keeping with good clinical practice. Indeed, patients with diabetes often also have hypertension and/or dyslipidemia and are commonly treated with multiple medications which fall within the same class (as identified by USP).

Recommendations

With an aim of protecting the needs of people living with diabetes, ADA recommends the following changes to USP's drug classification system:

A. Reclassify the recommended subdivisions for oral agents as distinct pharmacologic classes to ensure that people with type 2 diabetes have coverage for at least two (2) drugs in each class of drug per the direction provided by Congress in the MMA; and
B. Reclassify the recommended subdivisions for insulin as distinct pharmacologic classes to ensure that people with type 1 and type 2 diabetes have coverage for the four (4) classes of insulin required to manage diabetes.
C. Reclassify the recommended subdivisions for all cardiovascular medications as distinct pharmacologic classes allow for the proper treatment of hypertension and dyslipidemia.

ADA could also support the following approach as an alternative to the above proposal:

A. Require all formularies to cover at least one insulin from each subdivision category identified as rapid, short, intermediate, and long-acting by the USP guidelines; and
B. Require all formularies to cover at least one oral hypoglycemic agent from each subdivision category identified as alpha glucosidase inhibitors, meglitinides, biguanides, sulfonylureas, and thiazolidinediones by the USP guidelines.
C. Require all formularies to cover at least one cardiovascular medication from each subdivision category identified by the USP guidelines.

2. Inclusion of Syringes and Related Insulin Delivery Devices

According to the legislative language in the MMA, as well as the CMS proposed rules for the MMA, medical supplies associated with the injection of insulin –including syringes,

needles, alcohol swabs, and gauze– are considered to be drugs covered under Part D benefits. However, these items are not specifically identified in USP's draft model guidelines as a covered benefit under formularies. ADA is concerned that these items have been overlooked and if not included in the model guidelines will similarly be overlooked by approved Part D plans in the future. ADA recommends that USP clearly indicate in their model guidelines that drug plans must cover these supplies as drugs under the new Medicare drug benefit.

3. Procedure For Adopting New Therapeutic Categories and Pharmacological Classes

ADA supports research in the areas of new treatments for diabetes as well as a cure for diabetes. However, the draft model formulary is unclear on how Medicare drug plans should incorporate new drugs and treatments as they are discovered. Phrases contained in the USP guideline, including those requiring formularies to update covered drug lists "from time to time" and "periodically," are extremely vague. Furthermore, there is no guidance for drug plans –and therefore no guarantees to beneficiaries– to ensure that the most medically effective treatments and/or drugs will receive coverage. ADA urges USP to amend the draft model guidelines to include criteria and a specified process for accommodating new categories, classes, and products (including new indications of existing products).

4. Implementation

Many Medicare beneficiaries currently receive their diabetes supplies under Medicare Part B. Under the current system, all patients with diabetes can receive a blood glucose testing monitor, blood glucose test strips, lancets, and glucose control solutions. The number of test strips and lancets covered by Medicare depends on whether or not the patient uses insulin or not. Patients who use insulin receive up to 100 test strips and lancets per month, while those who do not use insulin receive up to 100 test strips and lancets every three months. Furthermore, under Part B, those individuals who require an insulin pump can receive the pump, related supplies, and the insulin used with the pump.

The new Part D drug benefit is intended to "fill the gaps" and offer coverage for those supplies and medications not available under Part B. According to Proposed Rule 42 CFR 423.100, drug plans under Part D are required to cover insulin, syringes, needles, alcohol swabs, and gauze.

ADA applauds CMS for ensuring that all Medicare beneficiaries with diabetes will have access to these necessary supplies and medications. However, there exists potential for significant confusion in implementing and administering this benefit. For example, a new beneficiary who requires an insulin pump should receive the necessary supplies and medication through Medicare Part B, not Part D.

ADA also believes that coverage for insulin pens should be required under Medicare Part D. Individuals who are elderly and disabled often have visual or motor impairments that make handling syringes and vials of insulin extremely difficult. Insulin pens come equipped with pre-measured cartridges of insulin and/or with a "click" system of dosing,

thus significantly improving and simplifying the process for individuals with impaired vision. Insulin pens will be a cost-effective addition to the formulary, as they will minimize the risk of hypo- or hyperglycemic reactions due to incorrect dosing, and thus limit the potential for expensive hospitalizations.

423.120(b)(4) - Periodic evaluation of protocols.
ADA recommends that the final rule require PDPs to conduct, at minimum, quarterly evaluations and analysis of their protocols and procedures related to their formularies. Advances in the clinical management of diabetes are unpredictable, making it essential that the final rule require regular ongoing and timely review of formulary protocols and procedures.

423.120(b)(5) - Provision of notice regarding formulary changes.
The notification provisions regarding formulary changes are inadequate for effectively notifying and protecting beneficiaries. ADA recommends that if the final rule limits the notice requirements to persons directly affected by the change, then plans must be required to provide notice in writing, mailed directly to beneficiary, 90 days prior to the change. The notice must also inform the beneficiary of their right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary.

423.120(b)(6) - Limitation on formulary changes prior to the beginning of a contract year.
ADA recommends that the final rule place strict limits on mid-year formulary changes, requiring plans to justify a decision to remove drugs from a formulary. Permitted reasons for discontinuing coverage would include the availability of new clinical evidence indicating that a particular covered Part D drug is unsafe or contraindicated for a specific use.

Furthermore, in the event that all manufacturers discontinue supplying a particular covered Part D drug in the United States, ADA strongly recommends that plans be required to continue dispensing such a drug until the end of the plan year for all persons currently taking said drug as part of an ongoing treatment regimen.

Subpart D – Cost Control and Quality Improvements Requirements for Prescription Drug Benefit Plans.

423.150 - Scope.
ADA has significant concerns that there are currently no proposed restrictions on the ability of plans to use cost-containment tools such as dispensing limits or prior authorization. Instead, the preamble to the proposed rule appears to specifically encourage plans to use such cost management tools, without constraint, to limit the scope of the prescription drug benefit. ADA believes that this is completely inappropriate, and inconsistent with commitments made by CMS to the Congress and the public.

In response to a question for the record at the confirmation hearing in the Senate Finance Committee for CMS Administrator Mark McClellan, Dr. McClellan stated in response to

Senator Baucus' question number 27, that, "beneficiaries who elect to enroll in this new open-ended drug benefit will have no limits on the number of prescriptions filled, no limits on the maximum daily dosage, and no limits on the frequency of dispensing of a drug." ADA strongly recommends that the final rule prohibit plans from placing limits on the amount, duration, and scope of coverage for covered Part D drugs. Specifically, the final rule must prohibit plans from limiting access to covered Part D drugs through limits on the number of drugs that can be dispensed within a month, limiting the number of refills an individual can obtain for a specific drug, or by placing dollar limits on the amount of the prescription drug benefit.

ADA also strongly recommends that the final rule prohibit PDPs from requiring therapeutic substitution. While the MMA authorizes the use of formularies which could lead prescribers to alter their drug recommendation in order to comply with standard Part D plan preferences for covered drugs within a class, we believe that the ultimate authority to decide which specific drug a Medicare beneficiary will receive must reside with the treating physician. Therefore, to protect patient safety and health, the final rule must prohibit plans from requiring or encouraging pharmacists to engage in therapeutic substitution without the advance knowledge and written concurrence of the treating physician. While ADA is encouraged that the preamble to the proposed rule indicates that therapeutic substitution will be prohibited without the prescriber's approval, this prohibition must appear in the text of the final rule.

Further, the use of prior authorization has become a common practice in the private sector and Medicaid. For many Medicare beneficiary populations, the manner in which prior authorization and fail-first (or step therapy) systems have been implemented in these other contexts has been clearly unworkable both from the perspective of beneficiaries and treating physicians. While prior authorization/fail-first policies may be used appropriately in some contexts to manage the pharmaceutical benefit, the final rule must establish clear standards and requirements for Part D plans that elect to adopt prior authorization and fail-first policies. In particular, the final rule must require plans to ensure that any system of prior authorization is easily accessible to beneficiaries and physicians, and must impose negligible burdens with respect to time needed to complete the prior authorization process, expense, and information documentation.

ADA recommends that CMS encourage Part D PDPs to implement innovative approaches to controlling costs without restricting access. A number of states have developed pharmacy case management programs that focus more on the volume of prescriptions than the disease (as in disease management programs). Such programs use claims data to identify consumers with a large number of prescribers and/or prescriptions, or physicians who provide a large number of prescriptions to many consumers. Other alternative cost containment approaches include:

- Case management of chronic illness to improve coordination of all medical and mental health care, including medications;

- Disease-specific case management programs;

- Closer data review to identify fraud, deviation from clinical best practice, outlier prescribers, and clinicians that are "under"dosing; and,

- Requiring plans to analyze plan-level claims data to identify prescribing patterns, potential areas for fraud and abuse and consumers who are taking multiple medications for the same condition.

Subpart M - Grievances, Coverage Reconsiderations, and Appeals.

As mentioned earlier in these comments, diabetes therapy is very individualized and requires that patients have access to a wide range of medications in order to properly control their blood glucose levels. ADA is pleased to note that CMS has required PDPs to implement coverage determination and exceptions processes for patients in the event that their plan does not offer coverage for the medication they require. However, ADA believes that the proposed rules are overly burdensome to Medicare beneficiaries.

Having two tracks separate tracks –determined by whether the enrollee (1) pays out of pocket for a drug and files an appeal, or (2) is unable to pay out of pocket for their drug and files an appeal– is far too complicated. The timeframes, paperwork, and processes should be simplified into one expedited course of action that beneficiaries can easily understand.

423.566(b) - Actions that are coverage determinations.

ADA recommends that the presentation of a prescription to the pharmacy constitute a coverage determination. If the pharmacy does not dispense the prescription, then the request for coverage should be deemed denied, and the enrollee should be entitled to notice and to request a re-determination. Without such clarification, enrollees will not be informed of their rights, and the appeals process will become meaningless.

423.568 (b) - Timeframe for requests for payment.

ADA recommends that this subsection be eliminated. There should be no distinction in time frames when an enrollee requests payment.

423.568(c) - Written notice for PDP sponsor denials.

The current proposed rules place the responsibility for providing notice of a coverage determination on the plan sponsor. This presumes that a beneficiary will present a prescription, the pharmacy will contact the PDP sponsor, and the sponsor will then have up to 14 days to make a final coverage determination.

In reality, however, pharmacies will most often simply tell beneficiaries that their PDP will not cover the drug. Without notice provided by the pharmacy, most enrollees will not know to tell the pharmacy to submit the prescription anyway so they can get a notice from which to appeal. Enrollees may also not know or understand their right to seek expedited consideration of the initial coverage determination, or an exception if the drug is not on the formulary or on too high a tier. If enrollees pay out of pocket and then seek

reimbursement from the plan, current rules make them ineligible for expedited consideration.

The regulations should require PDP sponsors to develop a notice clearly explaining the right to seek a re-determination, and to ask for expedited review in any situation. Additionally, the pharmacy should be required to give such a notice to the enrollee. Any potential burden of such a requirement is reduced by the need to maintain electronic communications between the pharmacies and the plans in order to keep up-to-date with formularies, coinsurance, and calculations of an enrollee's out-of-pocket expenses.

423.568(d) - Form and content of the denial notice.
The proposed rules require that approved notice language be "in a readable and understandable form." While the intent is commendable, the regulations need to be more specific regarding the required content of said notices.

CMS should take its guidance in this arena from a recently-settled Florida class action lawsuit filed on behalf of Medicaid recipients. It was determined that the state had not provided proper written notification regarding the right of appeal to people whose prescription coverage was denied. The settlement's provisions require the state to provide:

- Written notification that explains why the coverage request was denied;
- Detailed information on how to resolve the issues that triggered the rejection;
- Specific instructions that explain how consumers can request an appeal; and
- Steps that consumers can take to receive medication coverage pending the outcome of an appeal.

Hernandez et al. v. Medows, U.S. District Court for the Southern District of Florida (May 2003).

ADA urges that the final rules require Medicare Part D denial notices to include the same information.

In addition, all notices need to be available in alternate formats to accommodate people with disabilities, and available in languages other than English where non-native English speakers represent a significant portion of the population. ADA supports the August, 2000 HHS OCR guidance detailing how programs can meet their Title VI obligations to provide written materials in languages other than English. The requirements of plans and the rights of beneficiaries in this area must be spelled out in much more detail. There is also an overarching need to consider literacy problems and encourage simplicity.

423.570(c) - How the PDP sponsor must process requests.
All coverage determinations and appeals concerning drugs, including those where the enrollee has paid for the drug, should be treated as requests for expedited review. A patient would suffer adverse consequences if required to wait for the longer time periods; many people will simply go without prescribed medications pending the outcome of the

review. Doubling the time frames and disallowing expedited review in cases where beneficiaries pay for drugs out-of-pocket could adversely affect the health of those who forego other necessities like food and heat in order to pay for their medicine.

At a minimum, all appeals should be automatically given expedited consideration. When a beneficiary seeks expedited review of a request to continue a drug that is no longer on the formulary, the PDP sponsor should be required to process the request as fast as the beneficiary's condition requires. At a minimum, the enrollee should be given a 72-hour supply of the medicine, which is renewable if the plan decides to take longer than 72 hours to review. In such cases, the medication should be treated as an on-formulary drug.

In the event that the final rules do not automatically assign appeals and coverage determinations as requests for expedited review, the rules then state that any such request made by a doctor on behalf of the enrollee should be given an expedited review.

423.572 (b) - Extensions of timeframe.
The timeframe (of 72 hours) can be extended by the plan up to 14 days on showing that extension is in the interests of enrollee. The regulations should define "interests of the enrollee" to include those situations in which the drug plan seeks additional information to substantiate the enrollee's request, or when the enrollee requests additional time to gather supporting information. The rules should also require PDPs to inform enrollees of such extensions immediately, both orally and in writing, rather than "by the expiration of extension."

There should be no allowable extension of time period for requests in cases where payment of drugs has already been received. This imposes extreme hardship on low-income beneficiaries and those with multiple prescriptions who may choose to unnecessarily spend money on their medications (rather than on other urgent necessities of life) because of the uncertainty and length of the appeals process.

423.578 (a)(2) - Requests for exceptions to a PDP's tiered cost-sharing structure.
This subsection fails to meet the statutory requirement that guidelines for an exception process be established by the Secretary. The MMA statutory language is not permissive; it does not say that PDPs may establish additional criteria if they wish. It states that the Secretary is to establish criteria and the plans are to abide by them. PDPs should have no discretion in this area whatsoever. The fact that PDPs may establish differing tiered structures is not relevant to beneficiaries' statutory right to request an exception to whatever structure PDPs devise.

Furthermore, in the instance where the proposed rules do include guidance for such criteria, the criteria listed are not within the original intent and scope of the statute. Indeed, the statute provides that an exception applies if a physician determines that a preferred drug would not be as effective or would have adverse effects, or both. However, the proposed rules provide for a "limited number of elements that must be included in any sponsor's exception criteria" - elements that are irrelevant and do not

apply in light of the statutory provision. For example:

- The cost of the requested drug compared to the cost of the preferred drug should have no bearing on such a decision given that this comparison is not related to differing drugs' efficacies and/or adverse effects.

- Using similar reasoning, the number of drugs in a PDP's formulary within the same class as the requested drug cannot be considered in judging differing drugs efficacies and/or adverse effects.

423.578(b) - Request for exceptions involving a nonformulary drug.
In the preamble, CMS states that "[r]equiring sponsors to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied" and will help ensure these formularies "are based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs." However, the proposed rules give drug plans complete discretion in determining the criteria they will use to determine exceptions requests. In addition, independent review entities "would not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." By failing to adequately define the criteria plans may use to consider exceptions requests or provide any meaningful oversight over these criteria, these proposed regulations would not ensure that formularies are based on scientific evidence and would not establish a transparent process. The rules, as written, thus subvert CMS's stated goals.

The criteria and process described in 423.578(b)(2) will make it virtually impossible to succeed in obtaining an exception. The process is not transparent, as the preamble suggests, because it is left wholly to the discretion of each PDP. ADA urges CMS –and not each individual PDP sponsor– to establish the criteria for evaluating such requests. Without uniform criteria, enrollees in different plans will be treated differently. The need to tailor supporting certificates to the different requirements of each plan will place a substantial burden upon prescribers/providers who file certificates as part of the process.

§423.578(b)(5) of the proposed rules authorizes PDPs to obtain several different types of information in the prescribing physician's statement certifying that an off-formulary drug is needed. This list is excessively long and repetitive, and encourages PDPs to establish burdensome paperwork requirements as a hurdle to prevent physicians and consumers from following through on an exceptions request. Moreover, this proposed rule also leaves the required information entirely up to the plan's discretion by including a vague descriptive phrase: "any other information reasonably necessary." The requirements for this written certification should be standardized to facilitate use of the exceptions process by providers and consumers. These standards would also help achieve CMS's stated goal of establishing a transparent process.

ADA recommends that the final rules establish fixed criteria for evaluating a prescribing doctor's determination that using all formulary drugs would not be effective or would cause adverse consequences to the enrollee. Requiring the amount of evidence suggested

in the proposed rules makes it virtually impossible to receive an exception. Instead, CMS should allow the weight of clinical evidence or the physician's experience to meet the standard.

- To meet the statutory standard, the burden should be placed on the PDP to show why the doctor's decision is not definitive.

- The amount and type of evidence proposed in the certificate would make it impossible to meet the standard. "Gold standard" clinical trials generally do not include the elderly, people with disabilities, and people with co-morbidities. While some minimal evidence exists of this nature, there may not be such evidence for all drugs and conditions. Again, the regulations should require the certificate meet the statutory standard –that "preferred drugs" are not as effective or have adverse effects– and the criteria should recognize a physician's experience in evaluating whether such a statutory standard is met.

- For dosing exceptions, the rules state that evidence must exist that the number/amount of doses available under a dose restriction has been ineffective, is likely to be ineffective (based on sound clinical evidence and/or medical/scientific evidence), or will adversely affect the drug's effectiveness or patient compliance. The standard should additionally include "or cause an adverse reaction or other harm to the enrollee."

423.578(c)(2) - When a sponsor does not make a timely decision.
The rules provide for a one month's supply of a drug, but only if the plan does not act in a timely manner in an exceptions determination. If the request for an exception is not given expedited treatment, the sponsor can take two weeks to issue a decision, meaning the enrollee would wait two weeks before getting the supply of medicine. Even if the exception is treated as a request for expedited review, the enrollee would still have to wait 72 hours (less if they could show the decision needed to be made more quickly because of their condition.) However, most people wait to the last minute to refill a prescription, often because of drug plan and pharmacy restrictions.

As such, any enrollee requesting a refill (for a drug that has been removed from the formulary between refills) or presenting a new prescription for a non-formulary drug should receive a one month's supply while the exception determination is being made. Furthermore, plans should be required to make exception determinations and notify the enrollee in 24 hours as required under Medicaid for prior authorization determinations. 42 U.S.C. 1386r-8(d)(5)(A).

423.578(c)(3) - When an exceptions request is approved.
The lowest coinsurance amount should apply anytime an enrollee wins an exception through this process because the drug at issue has been determined medically necessary with no on-formulary drug as a suitable alternative. The exception for the non-formulary drug should thus meet the criteria for an exception to the tiered cost-sharing structure as well.

The rules need to clearly set forth the requirement that notice be provided when a decision is made on an exception request. The notice should explain that the decision is a coverage determination and explain appeal rights that are available.

ADA commends CMS for specifying that, once an exception request is granted, a plan sponsor may not require the enrollee to keep requesting exceptions in order to continue receiving the drug. However, ADA remains concerned that the "exception" to this protection –which allows the plan to discontinue a drug if safety considerations arise– is too broad. The final rules should be revised to permit reversal of a previously granted exception only if the FDA determines that the drug is no longer safe for treating the enrollee's disease or medical condition.

ADA is deeply concerned that the timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed provisions raise similar concerns. It is inequitable to require longer time frames if a beneficiary has paid out of pocket for a needed medication when the only alternative would be to wait two to four weeks for a determination or an emergency one-month supply of the needed drug. Beneficiaries' health and safety may well be at risk if they are forced to forego other necessities because of the added, and most likely very significant, expense of paying out of pocket for their medicines. Although the proposed regulations include some provisions for an emergency supply of medications while a plan is considering an exceptions request, it is unreasonable and bad health policy to make beneficiaries wait two to four weeks before the drug plan must provide an emergency supply. In addition, plans should be required to demonstrate that an extension of the standard time frame for exceptions determinations is in the best interest of the enrollee and the final rule must charge independent review entities with exercising oversight over these extensions. Plans should be required to make determinations regarding exceptions requests and notify the enrollee of these determinations in 24 hours as required under Medicaid for determinations regarding prior authorization requests (42 U.S.C. 1396r-8(d)(5)(A)).

423.580 - Right to a redetermination, and 423.584(a) - Expediting certain re-determinations.

These proposed rules only authorize an enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) to request a re-determination (or an expedited re-determination). However, the enrollee's authorized representative must also be allowed to request such re-determinations.

Additionally, because the proposed rules allow an enrollee's authorized representative to file a request for Determinations and Exceptions, it is not appropriate to then disallow such a representative from further pursuing a claim through re-determination, reconsideration, and higher levels of appeal. In fact, the proposed rules define an authorized representative as an individual authorized to act on behalf of an enrollee "in dealing with any of the levels of the appeals process."

423.584 - Expediting certain re-determinations.

The rules need to describe in greater detail the notice responsibilities for both standard and expedited re-determinations, including what must be provided in the notice. Given that the next level of review –to the independent review entity (IRE) – is not automatic (as it is with Medicare Advantage plans), this becomes a critically important step. The notice must be required to explain the reason for the denial (including specific medical and scientific evidence), the right to request review or expedited review to the IRE (including timeframes), and the right to submit evidence in writing and in person.

423.590 - Timeframes.
The rules should be amended so that a PDP can only extend the timeframe for a re-determination if requested to do so by the enrollee, or if the plan can demonstrate that the extension is in the **best interest** of the enrollee, for example, the plan needs to obtain additional information to support the enrollee's request.

ADA renews its earlier comments that all re-determination requests, and particularly those involving exceptions, should be treated as expedited, and that plans should not be given more time to resolve re-determination requests involving payment requests.

423.600 - Reconsideration by the IRE.
CMS needs to clarify in the final rules that the role of the IRE is to provide independent, de novo review, especially in regard to the exceptions process. The preamble states that "…The IRE's review would focus on whether the PDP had properly applied its formulary exceptions criteria for the individual in question…..the IRE will not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." However, if the IRE does not review all of the evidence and issue a reconsideration decision based on its own analysis, then enrollees will be denied a truly independent review.

Further, because CMS is required by the statute to set standards for the exceptions process, as noted above, the IRE must have authority to determine whether PDPs' exceptions criteria comply with the statute. Otherwise, enrollees will have no mechanism for review of arbitrary and improper standards.

Since the Part D process is intended to follow the Medicare Advantage process, the regulations should follow the Medicare Advantage regulations and require that ***denials automatically be sent to the IRE for reconsideration***. The regulations as written create a barrier to the first level of independent review for enrollees who have difficulty following the complicated process. Further, ADA disputes CMS's statement in the preamble (pg. 46722) that many of the drug appeals will involve small monetary amounts. Rather, most will involve medications for chronic conditions that enrollees take on an on-going basis; the yearly sum of which will be quite substantial, especially when compared with the income level of most Medicare beneficiaries.

If the final regulations continue to place the burden of requesting a reconsideration on the enrollee, the must at the very least clarify that an authorized representative can act on the enrollee's behalf. Again, without such clarification, enrollees who lack the capacity to file a reconsideration request will be denied their rights of due process. In addition, the

prescribing doctor should also be permitted to request a reconsideration, especially since the enrollee needs the doctor's statement in order to request IRE review of an unfavorable exception request.

423.600(d) - Timeframe.
In order for the process to be truly transparent, the regulations must additionally establish a specific timeframe in which the IRE must issue its decision. Enrollees will have no knowledge of the contract between CMS and the IRE and thus will not know how long they will have to wait for a reconsideration decision. If contractual, the time frame can change with each new contract, putting enrollees at greater risk of adverse health consequences from being denied needed medicines. The regulation must also state that an enrollee may appeal to an Administrative Law Judge (ALJ) if the IRE fails to act within the regulatory time frame.

423.602 - Notice of reconsideration.
The language concerning the contents of a notice of reconsideration is too ambiguous. As written, the notice must "inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under 423.610." This could be interpreted to mean that the notice informs the enrollee the s/he has the right to an ALJ hearing *only* if her claim is large enough. Or it could be interpreted to mean that the IRE only has to notify the enrollees of their rights to an ALJ hearing if their claims meet the threshold amount. The latter interpretation is problematic for several reasons, including the fact that one can aggregate claims (see our comments on §423.610). The final regulation should instead state that notices must unequivocally inform enrollees of their right to an ALJ hearing, and the procedure for requesting such a hearing, including the dollar amount required to request a hearing.

423.610 - Right to an ALJ Hearing.
Through the legislative language contained in the MMA, Congress recognized the special needs of low income populations and that even small co-pays can force lower-income individuals to forgo filling prescriptions. ADA urges CMS to provide exceptions to the ALJ threshold requirements for those receiving the Medicare subsidy. Because individuals who receive the low-income subsidy have lower out of pocket costs, it is more difficult for them to reach the threshold amount than it is for higher-income individuals not receiving the subsidy. In order to compensate for this inequity, we recommend that the threshold amount for a lower-income individual be calculated as if the individual were not receiving the subsidy.

The intent of 423.610(c) remains unclear: "Two or more appeals may be aggregated by the enrollee… if (i) the appeals have previously been reconsidered by an IRE…" This provision could be interpreted to require an enrollee to file a new appeal each month for a prescription to treat an on-going chronic condition. Such a requirement would be unduly burdensome for enrollees, drug plans, the IRE, and the ALJs. The final regulation needs to clarify that an enrollee should be able to consider the total yearly cost of the medication if the medicine treats an on-going chronic condition –or for the number of

refills authorized if the underlying condition is not chronic– in order to satisfy the jurisdictional amount when the plan denies coverage.

Subsection (ii) states that the request for the hearing must list all of the appeals to be aggregated and must be filed within 60 days after all of the IRE reconsideration determinations appealed have been received. This requirement, too, remains vague: in consolidating appeals, it is unclear if the 60 days apply from the issuance of the first denial or the issuance of the last denial being appealed.

423.634 - Reopening and revisions determinations and decisions & 423.638 - How a PDP sponsor must effectuate expedited re-determinations or reconsidered re-determinations.

Subsection (c) in both of these sections allows the PDP to take up to 60 days to implement a reversal by the IRE, an ALJ, or higher. ADA strongly reiterates the opinion that such an extended timeframe is entirely unacceptable, given that additional delays will likely cause increased health consequences to people who have foregone medication pending the outcome of the appeal process. Favorable decisions should be implemented in the same 72 hour time period as reversals at earlier levels of review.

CMS-4068-P-1278

Submitter : **Ms. Elizabeth Blackston** **Date & Time:** **10/04/2004 08:10:46**

Organization : **Office of the Illinois Attorney General**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Marketing

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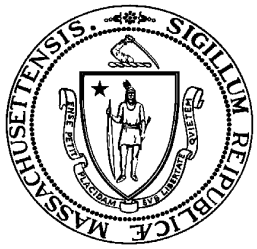

October 4, 2004

Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Re: Docket No. CMS-4068-P

Dear Dr. McClellan:

We write to comment on the Rule 4068-P proposed by CMS. The Offices of the Attorneys General of Illinois and Massachusetts protect our states= consumers from deceptive and unfair acts and practices by enforcing our consumer protection and fraud laws, and a host of other state statutes and federal statutes. Our Offices have conducted many investigations and brought a number of law enforcement actions concerning telemarketing and other types of fraud. We write to share our experience in that area as it pertains to marketing of the Medicare Prescription Drug Benefit provided for by the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

We believe that, in addition to door-to-door solicitations, telemarketing solicitations should be banned. Also, we believe that Prescription Drug Programs should be prohibited from offering additional products or services to Medicare beneficiaries. These positions and the basis for these positions are described in detail below.

I. Telemarketing Should Be Prohibited

Section 423.50 (e) of the proposed rules provide standards for marketing which include a prohibition on door-to-door solicitations. Telemarketing solicitations to Medicare beneficiaries also should be prohibited. The potential for confusion and fraud is high for the population at large, and may be even higher for elder and disabled Medicare beneficiaries. The National Fraud Information Center estimates that telemarketing fraud amounts to $40 billion annually.

Our offices are concerned with abusive telemarketing practices associated with marketing of discount prescription drug plans. We have received complaints about these practices in connection with the current Medicare prescription drug discount card program, and are acting upon them. For example, the Office of the Illinois Attorney General has received consumer complaints regarding unauthorized debits from consumers= checking accounts as a result of telephone solicitations from sellers falsely claiming or implying to be offering discount prescription drug plans authorized by the federal government. On September 17, 2004, Illinois filed a lawsuit in federal court against a company that Illinois alleged had made such fraudulent telemarketing solicitations[1].

In addition to preventing almost unlimited potential for fraud, a prohibition on telemarketing solicitations would allow for a simple message to consumers: ALegitimate Medicare Drug Discount Programs and Part D benefit providers will not solicit you by telephone. If you receive a call from someone claiming to be an authorized Medicare provider, hang up.@

II. Prescription Drug Plans Should Be Prohibited from Offering Additional Products to Medicare Beneficiaries

In the preamble to its Notice of Proposed Rulemaking, CMS seeks comments on the advisability of allowing additional products, such as financial services, to be provided in conjunction with PDP services. Because of the potential for fraud and confusion, as well as for public policy reasons, this should be prohibited.

A. Additional Offerings After Consumer Provides Billing Information

Permitting additional products to be offered could allow Prescription Drug Plans to work a disservice on Medicare beneficiaries. We are concerned that beneficiaries who, having read a direct mail solicitation, seen a television ad, or been solicited by phone (if telemarketing is permitted B we believe it should *not* be), have contacted PDP sponsors to enroll in a PDP and have provided credit card, checking account and/or other billing information will then be subjected to additional sales pitches. In addition, PDPs may later use this billing information for unauthorized sales of additional products and services without the necessity of the consumer providing the information again.

Our Offices have seen this deceptive practice B i.e. the use of preacquired account information B in connection with other merchants. We are troubled that this practice could be permitted by CMS in connection with marketing by Prescription Drug Plans. There are a number of reasons why we are concerned about this. First, often in these situations the consumer does not understand that any positive response to the additional sales pitches is interpreted by the merchant to be a purchasing decision, and that billing information provided

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[1] **People v. Global Benefits Group Corp., Inc., Eileen deOliveira, Leonardo deOliveira, John Doe 1, d/b/a Medications 4 Less, and John Doe 2, d/b/a Euro Banca (U.S. District Court, Central District of Illinois, Springfield Division, 04-CV-3205).**

in conjunction with the initial purchase will be used for these additional purchases. Second, in addition to consumer confusion, there is the potential for fraud on the part of the seller. The billing information the consumer already has provided can be used by an unscrupulous merchant to make a sale even if the consumer declined the additional offer or did not understand he or she was making a purchasing decision.

This area for potential abuse has raised strong concerns in our states. For example, the Office of the Illinois Attorney General has brought three law enforcement actions against companies which we alleged were engaged in such confusing and fraudulent sales pitches[2]. Two of those actions involved both additional sales pitches after consumers had called to order a product advertised on television (inbound calls) as well as direct telemarketing (outbound) calls. The other action involved inbound telemarketing calls only. In all three cases, the consumers did not understand they were making a purchasing decision with respect to the second offer, and in some cases, they were charged for products which they affirmatively declined, which charges the sellers were able to effectuate because of the previously provided billing information.

B. Potential to Create False Impression of Government Endorsement

If additional products are offered in conjunction with government-sponsored benefits, such a combination has the potential to create the impression that such offerings somehow have been endorsed by the government when in fact no such endorsement exists.

The potential for consumer confusion already has been made clear to states during this interim period when prescription drug discount cards are available. States are currently looking into claims that an insurance company that marketed B through direct mail and television advertising B an ordinary prescription drug discount card may have deceptively dressed the card as a Medicare-endorsed, government-issued product, complete with official-looking seals and government-agency-seeming titles. We are concerned that CMS is considering allowing additional products to be offered when such a great potential for confusion and fraud exists.

C. Public Policy

In addition to the potential for fraud and confusion among Medicare recipients, public policy dictates that when a consumer avails himself or herself of a government-sponsored benefit, he or she should not be subjected to sales pitches for products that are not government-sponsored or regulated.

For the reasons stated above, the Offices of the Attorneys General of Illinois and

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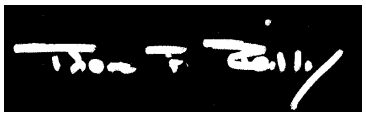
[2] *In Re* MemberWorks, Inc., AVC No. 04-AVC-0008 (Sept. 2004).
People v. Blitz Media, Inc. d/b/a Paradise Value Discount Directory and American Values Discount Directory and Brian MacGregor, No. 01CH592 (7th Judicial Cir. 2001).
People v. Triad Discount Buying, 01CH136 (7th Judicial Cir. 2001).

Massachusetts respectfully request that CMS consider their comments and prohibit telemarketing solicitations and the offering of additional products to Medicare beneficiaries.

Respectfully submitted,



Attorney General Lisa Madigan **Attorney General Tom Reilly**
Attorney General of Illinois **Attorney General of Massachusetts**

CMS-4068-P-1279

Submitter : Ms. Lynne Gross **Date & Time:** 10/04/2004 08:10:05

Organization : Anthem Blue Cross and Blue Shield

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached comment letter

CMS-4068-P-1279-Attach-1.pdf

Lynne Gross
Vice President & General Manager
Government Programs

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October 4, 2004

The Honorable Mark McClellan, MD, Ph.D.
Administrator
The Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 445-G
Washington, D.C. 20201

Attention: CMS-4068-P

Re: Comments on Proposed Rule: Medicare Prescription Drug Benefit (CMS-4068-P), as issued on August 3, 2004.

Dear Dr. McClellan:

Anthem Blue Cross and Blue Shield (Anthem) appreciates the opportunity to comment on the Proposed Rules implementing Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

Developing a new program of this size - arguably the biggest single change to Medicare since the program's inception - is an enormous task. We applaud you and your staff for the outreach you have done to educate stakeholders and to solicit input as you develop these regulations.

Anthem, Inc., through its subsidiary companies, provides health care benefits to more than 12.5 million people. Anthem is the nation's fourth largest publicly traded health benefits company, and an independent licensee of the Blue Cross and Blue Shield Association serving Indiana, Kentucky, Ohio, Connecticut, New Hampshire, Colorado, Nevada, Maine and most of Virginia. Anthem is fairly unique compared to most other health plans in that we have our own pharmacy benefits management (PBM) company, Anthem Prescriptions Management, LLC, which administers the prescription drug benefits for most of our customers.

Anthem also has extensive experience in various roles related to the Medicare program.

- Anthem has been a Medicare contractor since the program's inception.
- Anthem is the leading Medicare supplement insurer in the majority of states where we operate.
- Anthem has participated in the Medicare Advantage program since 1994.

- Anthem is a leading provider of employer sponsored retiree insurance to Medicare beneficiaries in the states where we operate.
- Anthem offers a Medicare Approved Drug Discount card in the states where we operate.

The new prescription drug benefit is an important addition to the Medicare program that will provide financial assistance for Medicare beneficiaries and that has the potential to improve the overall quality of health care. The details of this new program will be critical to ensuring that beneficiaries and the federal government have long-term access to cost effective prescription benefits. In that spirit, Anthem offers comments on five important, overarching issues that we believe are critical to the program's success. In the attachment we provide detailed comments on specific sections of the regulation.

- **Designate 50 state-based Part D regions:** Most health plans, including Blue Cross and Blue Shield Plans, are separately licensed in each state they serve. Anthem is no different. Anthem operates as a Blue Cross and Blue Shield licensee in nine different states under various legal entities. If CMS were to establish multi-state regions this will make it difficult for the majority of health plans, both Blues and non-Blues, to participate as a Prescription Drug Plan (PDP). In addition, establishing multi-state regions could impact the number of plans that are able to participate in 2006 due to the short time period between when regions are named and when applications are due.

  We believe it is in the best interest of the program and beneficiaries to start with 50 state-based regions, with a separate region for Puerto Rico.

- **Provide for effective formulary design:** Balancing access and cost is critical to quality formulary design. Access does not necessarily mean having more choices of prescription drugs. More important is having the right drug classes represented. The formulary requirements need to be carefully developed to ensure that health plans are not faced with situations where a therapeutic class consists of only a few 'copy cat' drugs in a class, with none being clinically superior. If CMS develops requirements for formularies that are too broad health plan will have little ability to negotiate lower prices, particularly if there are only two or three drugs in the class. This inability to effectively negotiate price has the potential to dramatically increase costs for beneficiaries and the federal government.

- **Assure appropriate justification of cost-sharing exceptions:** The proposed regulations reduce the MMA standards applicable to the exceptions process for tiered and closed formularies. While we believe exceptions are appropriate when medically necessary, the need for these exceptions must be adequately justified.

In addition, CMS should clarify the regulation to say that exceptions do not entitle beneficiaries to the lowest copay level that usually is associated with generic drugs. The reason most generic drugs have the lowest co-pay is because they are usually a lower-cost alternative to brand name prescription drugs and have the same efficacy. Allowing brand name drugs to be obtained at the lowest copay through an exceptions process will greatly increase cost.

- **Allow flexibility for use of private sector management tools:** As you are aware, our industry uses a number of management tools such as drug utilization review, prior authorization, therapeutic interchange and lower copayments to help encourage the use of prescription drugs in a safe and cost effective manner. For example, drug utilization review programs look not only for over use of medications, but under use that can cause medical complications. These management tools continue to evolve and overly detailed requirements may inhibit a plan's ability to provide quality, and safe, drug coverage to beneficiaries in the most cost effective manner.

- **Develop accurate risk adjusters:** The payment received by Part D plans under the program is highly dependent upon the accuracy of the risk adjusters which are intended to reflect the beneficiary's prescription drug costs. It is important for CMS to use the best information available to develop both a medical risk adjuster which reflects differences in utilization due to health conditions and a low-income risk adjuster which reflects differences in utilization among this subset of beneficiaries. The low-income risk adjuster is necessary as this population will have an enhanced benefit with lower cost sharing. It is very likely that combination, as well as other factors will result in higher utilization that may not be fully accounted for by the medical risk adjuster.

Anthem appreciates the opportunity to offer these comments for your consideration along with the detailed comments provided in the attachment. We welcome any questions you have regarding our comments or as you develop the final regulation that modernizes Medicare.

Sincerely,

Lynne Gross
Vice President and General Manager
Anthem Blue Cross & Blue Shield
Government Programs

Attachments:
Anthem Blue Cross and Blue Shield Part D Regulations - Detailed Comments
Part §423 – Voluntary Medicare Prescription Drug Benefit

Attachment

Anthem Blue Cross and Blue Shield
Part D Regulations - Detailed Comments

PART §423 – VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

Subpart B – Eligibility and Enrollment

Enrollment periods (§423.36)

Proposed Rule: The Proposed Rule at §423.36 outlines the enrollment periods during which a person can enroll in Part D. In addition to the normal enrollment periods, the proposed regulation also includes circumstances under which a person could qualify for a special enrollment period.

Issue: The special enrollment period (SEP) for an individual who is full-benefit dual eligible is not clearly limited to individuals who have been automatically enrolled in a PDP in §423.36 (c)(4) as it is in §423.36 (d)(3)(ii). The language in §423.36 (d)(3)(ii) appears to indicate that the SEP for full-benefit dual eligibles would be limited to those automatically enrolled in a PDP; however, the proposed regulation as written at §423.36 (c)(4) does not limit the SEP to those individuals who were automatically enrolled in a PDP. As written, full-benefit dual eligibles could switch PDPs at any time. This could lead to adverse selection and increased administrative cost.

Anthem Recommendation: Modify the language in §423.36 (c)(4) to be consistent with the language in §423.36 (d)(3)(ii) that limits the special enrollment period for dual eligibles to persons who have been automatically enrolled in Part D.

Issue: As written, the SEP regulation at §423.36 (c)(1),(3), (5),(6) and (8) does not denote a time within which a beneficiary must exercise their SEP. It appears to be appropriate to apply a timeframe within which a beneficiary must exercise their SEP.

Anthem Recommendation: Provide for a 63 day period in which a person must exercise their SEP to apply to a PDP or MA-PD following the events outlined in §423.36 (c)(1),(3), (5),(6) and (8) in order to be eligible for a special enrollment period.

Disenrollment by the PDP (§423.44)

Proposed Rule: The Proposed Rule at §423.44 provides for the circumstances under which a PDP may disenroll a beneficiary from Part D and the processes to be followed when taking this action.

CMS Request for Comments: CMS has requested comments on limiting the ability of stand-alone PDPs to disenroll individuals for nonpayment of premium and disruptive behavior.

Issue: The regulation contains requirements that a PDP must follow before disenrolling a beneficiary for non-payment of premium or disruptive behavior. These provisions provide the beneficiary with protection to ensure their coverage is not cancelled without proper notice and due process. The potential to lose coverage is the only leverage a PDP has to ensure timely payment of premium or to address disruptive behavior. While a person who is disenrolled for

these reasons could be subject to a late penalty when they re-enroll in Part D, the actual amount of the penalty would be minimal since they could re-enroll at the next annual enrollment period.

Anthem Recommendation: CMS should not require PDPs to re-enroll individuals who were disenrolled for nonpayment of their premiums or who were found to have had disruptive behavior when the PDP followed the proper procedures. In addition, retain the provision in §423.44(d)(3) allowing the PDP to collect any past due premiums.

Procedures to Determine and Document Creditable Status of Prescription Drug Coverage: Disclosure of Non-creditable Coverage (§423.56(c) and (§423.56(e))

Proposed Rule: The Proposed Rule at §423.56(c) and §423.56(e) requires sponsors who provide prescription drug coverage to Medicare beneficiaries (including coverage under Medicaid, Medigap, TRICARE and veterans programs, individual and group insurance, SPAPs and IHS/ITU coverage) to provide disclosure to CMS and to enrollees if their drug coverage is not "creditable," (i.e., that the gross value of the drug coverage provided is *not* actuarially equivalent to the value of the standard Medicare Part D benefit).

CMS Request for Comments: CMS has requested comments on the format, placement, and timing of the creditable coverage notice recognizing that it is important that beneficiaries have this information as they evaluate Part D and that providing this notice could be an administrative burden if the requirements are too cumbersome. CMS has also asked whether it would be a significant burden to include information in the notice regarding the value of the drug benefit, the total amount of annual premium for the drug benefit and the amount of the annual premium that a beneficiary will be required to pay.

Anthem Recommendation: CMS outlines several approaches for the creditable coverage notice in the preamble, including allowing plans to incorporate these notices into materials routinely disseminated by the plan. We believe that allowing notices to be incorporated into other plan materials is a desirable option. Regarding the format, we believe that employers and health plans need the flexibility to adjust the message as appropriate for the given audience's particular circumstances. Given this, a suggested model seems more appropriate than a standard.

If the requirement to provide individualized information regarding the value and premiums of a retiree drug benefit is implemented, dissemination in routine plan documents becomes very difficult. Employers often vary retiree contribution by years of service. Also, it is not uncommon to have numerous plan designs as companies often have acquired other companies with different retiree health plans and commitments. Additionally, since retirees are almost always enrolled in a health plan that includes both medical and drug benefits, and not a stand alone drug plan, this information would be of little value since they could not purchase the medical and drug benefit separately.

Subpart C – Benefits and Beneficiary Protections

Definitions: Dispensing Fees (§423.100)

Proposed Rule: The Proposed Rule at §423.100 does not include a definition of "dispensing fees."

CMS Request for Comments: CMS requests comments on two issues related to dispensing fees:

1) CMS asks for comments on how to best define dispensing fees, offering three potential options.
2) CMS also invites comments on whether dispensing fees should vary for specific types of drugs, such as vaccines or injectibles.

Issue: The three options currently proposed for defining dispensing fees seem to be absolute, either requiring that the dispensing fee only include activities related to the transfer of possession (Option 1); or requiring that the dispensing include all activities associated with dispensing, supplies/equipment and monitoring (Option 3). While typically dispensing fees for prescription drugs are for the services that are outlined in the CMS Option 1, plans should be given the flexibility to include reimbursement for services beyond that. This type of discretion allows drug plans the flexibility required to effectively manage costs and respond to changes in drug therapies. In addition, this affords plans the ability to vary dispensing fees for specific drugs and other reasons that may be appropriate.

Anthem Recommendation: Allow drug plans to define "dispensing fee". Option 1 should define the minimum requirements for a dispensing fee, but drug plans should have discretion to include other costs within the dispensing fee as they deem appropriate.

Definitions: Treatment of HSA Contributions as Incurred Costs (§423.100)

Proposed Rule: The proposed rule in section 423.100 defines a variety of types of coverage whose payments would not count towards a beneficiary's annual out-of-pocket threshold.

CMS Request for Comments: CMS, in the proposed rule's Preamble C(2)(a) requests comments regarding the treatment of health savings accounts (HSAs) vis-à-vis CMS' definition of "group health plan," insurance or otherwise," and "third party payment arrangements." CMS states that it is their strong preference to not treat HSAs as group health plans, insurance or otherwise, or third party payment arrangements and therefore allow HSA contributions to count toward incurred costs as they see HSA funds as analogous to a beneficiary's bank account.

Issue: While HSAs funds could have been contributed to the HSA by the employer, once the funds are contributed they are controlled by the individual. In addition, we believe that the majority of HSA contributions will be by the individual and not the employer. Given this, we agree with CMS' rationale that HSA funds are analogous to a beneficiary's bank account and should be treated as such.

Anthem Recommendation: Anthem agrees with CMS' rationale and recommends that HSAs should not be treated as group health plans, insurance or otherwise, or third party arrangements. This will allow any payments made with HSA funds to be counted towards the annual out-of-pocket threshold.

Establishment of Prescription Drug Plan Service Areas (§423.112)

Proposed Rule: CMS proposes to establish PDP regions under §423.112 of the Proposed Rule and to publish a list of such regions by January 1, 2005.

Issue: CMS is required to establish no fewer than 10 regions and no more than 50, not including Puerto Rico and territories. The majority of Blue Cross and Blue Shield plans and health plans are state based. Establishing multi-state regions will make it difficult for the majority of plans to participate, particularly in 2006.

Anthem Recommendation: As stated in our letter, Anthem recommends that CMS adopt 50 state-based regions for PDPs and a separate region for Puerto Rico. This approach will maximize the number of heath plans able to participate as PDPs and increase competition and beneficiary choice.

Access to Covered Part D Drugs: Assuring Pharmacy Access (§423.120(a))

Proposed Rule: The Proposed Rule at §423.120(a) provides the requirements for network access for Part D plans.

CMS Request for Comments: CMS has requested comments on whether to impose requirements on drug plans regarding long-term care pharmacies. This ranges from requiring plans to approach some or all long-term care pharmacies in their service area with at least the same terms available under their plans' standard pharmacy contract to requiring all long-term care pharmacies to be included in their network.

Issue: Since long-term care pharmacies are typically the single provider of prescription drugs for beneficiaries residing in long-term care facilities, it is important that they be included in the pharmacy network. However, absent some reasonable limits on what they can charge, a mandate requiring plans to have long-term care pharmacies in the network will inhibit a plan's ability to contract at reasonable rates. A basic premise of the Part D bill is that competition in a variety of different ways will reduce costs. In the case of long-term care pharmacies, we envision this competitive force being the fact that long-term care pharmacies that participate with Part D plans will use this to attract long-term care facilities whose pharmacy does not contract.

Anthem Recommendation: Part D plans should not be required to contract with a particular type of pharmacy, including long-term care pharmacies. It is acceptable to have a requirement for Part D plans to offer long-term care pharmacies their standard pharmacy contract.

Access to Covered Part D Drugs: Formulary Requirements: Limitation on formulary changes prior to the beginning of a contract year: (§423.120(b)(5))

Proposed Rule: The Proposed Rule at §423.120(b)(5) limits formulary changes between the beginning of the annual open enrollment period and 30 days after the beginning of the contract year.

Issue: We understand that CMS has proposed this provision in order to make it easier for a person to compare plans. One issue with this approach is that all formulary changes would then be made during the contract year when a beneficiary usually does not have the ability to change plans. An approach that would appear to be more advantageous to beneficiaries is to allow the

PDP to announce the formulary change for the beginning of the new plan year prior to open enrollment and then market the new formulary during open enrollment..

Anthem Recommendation: CMS should modify the language restricting changes during the period around the beginning of the contract year to allow changes at the beginning of the benefit period. If upcoming changes are announced to current beneficiaries prior to the beginning of an open enrollment period a beneficiary can make an informed decision. In addition, the Part D plan is able to market the new formulary for the upcoming year allowing potential enrollees to also make a more informed decision.

Dissemination of Plan Information: Provision of Specific Information (§423.128(d))

Proposed Rule: The Proposed Rule at §423.128(d) contains provisions related to access to information for current and prospective enrollees including a toll-free customer call center that is open during normal business hours.

CMS Request for Comments: CMS requests comments on whether they should require a more stringent 24/7 standard for customer service in their final regulation.

Issue: Anthem currently manages the drug benefit for more than 7 million people and provides customer service during normal business hours. We have not seen a need for, nor has the market dictated, a 24/7 customer service standard. A portion of our customers are Medicare beneficiaries and their service needs do not require us to offer 24/7 customer service access.

Anthem Recommendation: Anthem supports the current proposed regulation's standard for customer service access during normal business hours.

Subpart D – Cost Control and Quality Improvement Requirements for Prescription Drug Benefits

Dissemination of Plan Information: Claims Information (§423.128(e))

Proposed Rule: The Proposed Rule at §423.128(e) contains provisions related to providing an explanation of benefits (EOB) during any month when prescription drug benefits are provided under this plan. This EOB will list the item or service covered and cumulative, year-to-date total amount of benefits as related to the deductible, initial coverage limit, annual out-of-pocket maximum and the cumulative incurred benefits. In addition, any formulary changes that affect the beneficiary must be contained in this notice.

Issue: EOBs are not typically provided for prescription drug benefits since the transaction is handled at the point of sale. Providing EOBs will add additional administrative cost to the program. In addition, the information about deductibles and cumulative spending that would appear on EOBs is not applicable to full dual-eligibles and some low income beneficiaries.

Anthem Recommendation: Allow the Part D plan to provide information related to the items or services covered and cumulative benefits upon request, including making the information available through electronic means such as an IVR. If CMS does decide to require EOBs in the final regulation, the information required on the EOB should be modified so that it is applicable

to the particular beneficiary's benefit (i.e. accounting for the differences in low-income benefits)..

Issue: The regulation currently states that the EOB should be provided during the month any benefits are provided.

Anthem Recommendation: If CMS decides to require EOBs in the final regulation, the language should be modified to reflect that an EOB is provided following a month in which any benefits are provided. Also CMS should consider a quarterly requirement as opposed to a monthly requirement in order to effectively manage administrative costs.

Issue: The regulation would require the notice of any formulary changes for a particular beneficiary to be contained in the EOB. This may be difficult and costly to accomplish from an administrative perspective.

Anthem Recommendation: Allow plans the flexibility to provide the notice of formulary change in other ways, if a plan desires. For example, allow plans to send individual letters to beneficiaries who will be adversely impacted by the formulary change.

Cost-Effective Drug Utilization Management (§423.153(b))

Proposed Rule: The Proposed Rule at §423.153(b) requires each PDP sponsor or MA organization offering a MA-PD plan to establish a cost effective utilization management program (UM).

CMS Requests for Comments: CMS requests input regarding whether they should look to industry standards for setting UM standards for Part D plans.

Issue: UM techniques continue to evolve and different plans are utilizing different methods to obtain the same result. Establishing standards could inhibit innovation in this rapidly evolving area.

Anthem Recommendation: CMS should retain the current requirement for drug plans to establish cost-effective UM programs without prescribing specific "industry" standards.

Quality Assurance Program (§423.153(c))

Proposed Rule: The Proposed Rule at §423.153(b) requires Part D plans to establish a quality assurance program that includes measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

CMS Requests for Comments: CMS requests input with respect to how error rates be used to compare and evaluate plans.

Issue: Error rates do not seem to be an accurate or appropriate measure for comparing Part D plans. A drug plan's utilization review program will identify certain errors, but this error does not reflect the performance of the drug plan. Rather, it reflects the performance of those prescribing the medications. A drug plan cannot control what a physician prescribes, but it can identify

through its utilization review those prescriptions that appear to be inappropriate based upon FDA approved indications or the manufacturer recommended use.

Anthem Recommendation: An error reporting requirement should not be included in the final regulation.

Medication Therapy Management Program (§423.153(d))

Proposed Rule: The Proposed Rule at §423.153(d) requires Part D plans to establish Medication Therapy Management Programs (MTMP) to assure that drugs prescribed to targeted beneficiaries are appropriately used to optimize clinical outcomes through improved medication use.

CMS Request for Comments: CMS requests input with respect to best practices by MTMPs, essential elements of MTMPs, and appropriate quality assurance requirements for MTMPs.

Issue: MTMP programs are relatively new and are evolving. For this reason, CMS should allow drug plans flexibility to develop programs that address the needs of their specific populations. For instance, a drug plan located in one area of the country may have a high concentration of enrollees with diabetes, while a drug plan in another area may have a concentration of enrollees with HIV/AIDs.

Anthem Recommendation: CMS should allow drug plans the flexibility to develop and refine their MTMP programs to meet the needs of their specific enrolled beneficiaries.

Subpart F -- Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

Submission of bids and related information (§423.265(c))

Proposed Rule: The Proposed Rule at §423.265(c) describes the requirements for the Part D bid. Each bid must reflect the applicant's estimate of its average monthly revenue requirements to provide the qualified prescription drug coverage for a Part D eligible individual with a national average risk profile.

Issue: MMA provides for supplemental coverage for low income beneficiaries and Medicaid dual eligible individuals. The proposed regulation appears to contemplate reimbursement for this supplemental coverage as being a separate reimbursement for the additional benefits in addition to the plan's risk adjusted bid amount. We view the additional benefits being provided under the low-income subsidy (LIS) as being different products that will have cost due to:

- additional benefits
- different utilization due the difference in cost sharing
- additional differences in utilization that are not captured by the medical risk adjuster.

We believe this latter factor will have a material impact on the expected claims cost based on our experience in Medicaid managed care and a review of the limited literature available on this subject.

In the preamble, CMS is seeking comment on a risk adjuster for LIS which we believe is appropriate. However, it is likely that companies will want to adjust their bid to reflect their estimate for the difference in cost for LIS beneficiaries not accounted for by the LIS risk adjuster. While this can be accomplished by including a factor in the claims estimate for a beneficiary with a national average risk profile, the bid becomes very sensitive to the mix of LIS versus non-LIS individuals a plan attracts. We believe a better approach is to allow a plan to submit bids for the various categories of enrollees.

Anthem Recommendation: CMS should modify the final regulation to allow plans to submit bids for the various categories of enrollees reflecting the differences in benefits and utilization not accounted for by the medical risk adjuster.

Rules regarding premiums: Late enrollment penalty amount (§423.286(d)(3))

Proposed Rule: The Proposed Rule at §423. 286(d)(3) describes parameters regarding the determination of the late enrollment penalty amount. In the preamble, CMS has asked for comments regarding the 1% penalty.

Issue: The Part D drug benefit is a voluntary benefit and thus subject to adverse selection. For most people on Medicare, prescription drug expenses are much more predictable than medical expenses. A lot of prescription drugs taken by persons on Medicare are for the treatment of chronic conditions and once a person starts taking the medication they will take it the rest of their life, and these drugs often cost close to $100 a month. This makes it easy for a person to evaluate when Part D becomes a good value to them. The 1% per month penalty, which is close to the amount of the Part B penalty, will likely not be adequate to account for this adverse selection, but given there is no other information on which to base a penalty it appears to be reasonable.

Anthem Recommendation: The 1% per month late penalty should be retained.

Subpart G – Payments to PDP Sponsors and MA Organizations Offering MA-PD Plans for All Medicare Beneficiaries For Qualified Prescription Drug Coverage

Determination of Payment: Health Status Risk Adjustment (§423.329(b))

Proposed Rule: Section 423.329(b) of the Proposed Rule states that CMS will publish an appropriate methodology for adjusting the standard bid amount to take into account variation in costs for basic prescription drug coverage among prescription drug plans and MA-PDs based on differences in the actuarial risk of the enrollees being served. CMS will develop the prescription drug risk adjustment methodology taking into account similar methodologies to risk adjust payments to MA organizations. CMS proposes to develop and publish this risk adjustment methodology in the 45-day notice for the announcement of 2006 MA rates.

Issue: Presently CMS only has medical diagnoses on which to base the risk adjuster. A number of models exist that use prescription drug information to identify medical issues. To our knowledge, little work has been done to do the opposite. Accuracy of the risk adjuster is a critical component of the reimbursement a plan will receive under the program. CMS should use the medical and prescription drug data that it has available under FEHBP, Tricare for Life,

Medicaid and other publicly funded programs to test the validity of the proposed risk adjuster. For 2006, this analysis should be published as far in advance of the official 45 day notice of 2006 MA rates in order to seek comments and refine the methodology before officially publishing it for comment.

Anthem Recommendation: CMS should use data from publicly funded programs or from actuarial consulting firms to develop and test the validity of the risk adjusters. This analysis should be shared for comment prior to the 45 day notice for the announcement of 2006 MA rates to facilitate refinement and the development of 2006 Part D bids.

CMS Request for Comment: CMS asks for comment on the risk adjustment methodology for low-income subsidy (LIS) for individuals. They are concerned that a risk adjustment methodology, coupled with the statutory limitation restricting LIS payments for premiums to amounts at or below the average, could systematically underpay plans with many LIS enrollees.

Anthem Recommendation: Risk adjustment should be implemented in a manner that does not disadvantage plans that enroll a disproportionate number of LIS or any other type of high risk, high cost enrollees. Any risk adjuster for LIS enrollees should account for increased utilization because of less cost sharing as well as potential pent-up demand associated with LIS individuals once they become covered under Part D. In addition, we believe there are additional differences in utilization not captured by medical risk adjusters based on our experience with Medicaid managed care and a review of the limited literature on this subject. The accuracy of this risk adjuster is critical as plans that enter the program in 2006 will likely have a much higher concentration of LIS enrollees in later years of the program. In 2006, dual eligibles that have not enrolled will be randomly assigned to a plan and these people are likely to remain in the assigned plan. If the risk adjuster is not appropriate, these plans will be disadvantaged because they entered the program at the outset. The LIS risk adjustment methodology should be disclosed well in advance of the 45 day notice since it is a critical component of preparing the bid. In addition, CMS should obtain claims data from state Medicaid programs for dual eligible individuals and provide this to potential bidders to assist them in preparing their bid.

Subpart J – Coordination Under Part D Plans with Other Prescription Drug Coverage

General Rule (§423.464(a))

Tracking TrOOP Costs

Proposed Rule: The Proposed Rule at §423.464(a) requires Part D plans to coordinate drug benefits with group health plans, FEHBP, Tricare, State Pharmaceutical Assistance Programs as well as other plans providing prescription drug coverage to Medicare beneficiaries. This coordination is necessary for Part D plans to account for true out-of-pocket (TrOOP) costs as required under the MMA and also to comply with Medicare secondary payer provisions in situations where an employer plan is primary.

CMS Request for Comments: CMS is considering two options for data exchange related to the Part D coordination of benefits and accounting for TrOOP costs. Under the first option, Part D plans would have sole responsibility for tracking TrOOP costs. Under the second option, CMS would contract with a TrOOP facilitation coordinator to establish a single point of contact

between payers. This entity would receive enrollment and claims payment information from all primary and secondary payers, match claims and enrollment data, and send claims files to the appropriate Part D plans.

Issue: Part D plans need an effective and efficient means for collecting the data they need to accurately process claims including payment from other sources. Given the multitude of payers which would need to exchange data, a system where each drug plan facilitates their own data exchange would be extremely inefficient. For instance, a Part D plan would need to build links with any employer whose retiree is enrolled in their plan regardless of where the employer is located. Conversely, a national employer who decides to supplement the Medicare benefit could conceivably have to provide information to every PDP in the country.

Anthem Recommendation: CMS should adopt the second option of contracting with an outside entity that serves as some type of intermediary as this will be more efficient than potentially thousands of independent arrangements.

Subpart L – Effect of Change of Ownership or Leasing of Facilities During Term of Contract (423.551 through §423.553)

Proposed rule: The Proposed Rule at §423.551 through §423.553 addresses a PDP sponsor organizations "change of ownership" (CHOW) or leasing of facilities during a PDP contract term and the steps they must follow if they intend to assign (i.e. novate) their PDP contract or business governing a PDP contract to another entity.

CMS Request for Comments: CMS ask for input of whether they should consider modifications of existing CHOW provisions in order to reduce the administrative burden and to increase the effectiveness of the provisions.

Issue: The proposed novation and lease requirements are very similar to current Medicare Advantage requirements and these requirements are not overly burdensome. One area of possible refinement would be to stipulate in the final regulation that financial and solvency information required by state departments of insurance or similar entities is sufficient documentation for purposes of documents that a plan meets financial and solvency requirements.

Anthem Recommendation: Anthem recommends that the final regulation allow for plans to provide the financial and solvency information submitted to state departments of insurance or similar entities as documentation that a plan meets financial and solvency requirements.

CMS Request for Comments: CMS ask for input on how the CHOW and leasing provisions should be applied to large companies with multiple business units.

Issue: Inter-company arrangements should not be considered a CHOW or a leasing arrangement. Multi-state companies are typically made up of various entities and may be licensed in different states, but certain functions may be centralized in one entity to maximize efficiencies and avoid duplication across the entire organization. In order to make Part D and MA programs successful, multi-state companies need to know that such inter-company arrangement do not constitute CHOW or leasing arrangements. Further, multi-state companies need to be able to delegate such functions to a common subsidiary or related entity as efficiently as possible. Currently, most such inter-company arrangement must be submitted to the applicable state regulatory bodies for

review and approval. This process results in differing agreements and additional administrative cost.

Anthem Recommendations: CMS should explicitly note in the regulation that delegation of PDP functions, in whole or in part, to a commonly owned or affiliated company does not constitute a CHOW or leasing and does not require CMS review unless the applicable legal entity truly intends to novate the agreement or lease its facility to an affiliated company as evidenced by written notice to CMS. In addition, CMS should explicitly preempt state inter-company filing requirements as they relate to PDP, Part D and MA functions and services.

Issue: Under most state laws, HMOs are required to be domiciled in the applicable state in order to obtain an HMO license. This means that when CMS contracts with a multi-state entity, they must execute a contract with each licensed entity that makes up that company. This may also cause consumer confusion in those instances where the HMO or the contracted entity must use the licensed name as compared to the dba or common company name.

Anthem Recommendations: CMS should allow one entity to contract for multi-state regions, provided the entity has affiliated entities in such regions that are compliant with applicable state licensure laws. This requirement should apply to both PDP plans and MA plans.

Subpart M – Grievances, Coverage Determinations, and Appeals

Exceptions Process:Requests for Exceptions to a PDP's Tiered Cost-Sharing Structure (§423.578(a))

Proposed Rule: The Proposed Rule at §423.578(a) requires drug plan sponsors to allow enrollees to request exceptions to tiered cost-sharing requirements under certain circumstances. The Proposed Rule does permit drug plans to request certification from the enrollee's prescribing physician documenting the necessity for the exception. If the exception is granted, enrollees would have access to a covered drug at a lower tier of cost-sharing than normally required by the plan. Denials of exceptions requests are subject to appeal.

Issue: Health plans and PBMs developed 3 tier formularies (and now those with more tiers) to provide an alternative to closed formularies. A basic premise of these formularies is that the person has the alternative to purchase the non-preferred drug if they are willing to participate in additional cost sharing. This provides the consumer with choice, while providing the plan with better leverage when negotiating with drug companies. Anthem recognizes that CMS is limited by the statutory language related to this matter and believes that CMS has taken the right approach in requiring the physician to document the medical need for the exception. It is important that these exceptions only be granted when there is a clinically significant medical need.

While the statutory language does allow for this exception, it is important to note that the language references "preferred" and "non-preferred" drugs. In a three tier formulary the lowest tier is usually for generics, along with some multi-source brand drugs. The industry, drug companies and providers refer to the next tier as the "preferred tier" and tier 3 is referred to as "non-preferred". We do not believe it was the intent of Congress for beneficiaries to obtain non-preferred drugs at the lowest "generic" co-pay tier. If this was the intent Congress would have used language such as the lowest copay or the co-pay applicable to generic drugs.

Anthem Recommendation: Retain the language in the Proposed Rule that permit drug plans to require written certification from the enrollee's prescribing physician documenting why such an exception is needed. Drug plans should be expressly permitted to require physicians, as part of the physician certification process, to provide the following information:

1) A copy of the physician's notes from the patient's medical record that demonstrate based upon previous treatment why the preferred drug(s) or generic drug(s), and all similar drugs on the formulary, are clinically inappropriate for the enrollee or the previous adverse impact such a drug(s) has had for the enrollee; and
2) For cases in which an exception is being requested because of an adverse effect of a preferred drug on the enrollee, a copy of the FDA Medwatch form on which the physician reported the adverse drug event on behalf of the enrollee. This will ensure that the FDA is aware of issues that impact quality.

We further recommend that the Final Rule clarify that the granting of an exception will only result in the application of the preferred "brand" cost-sharing amount and not the generic/lowest cost-sharing amount.

Submitter : Mr. Steven Hitov **Date & Time:** 10/04/2004 08:10:40

Organization : National Health Law Program Inc

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See comments on Subpart M attached.

Submitter : Mr. Amar Vyas **Date & Time:** 10/04/2004 08:10:38

Organization : Mr. Amar Vyas

Category : Academic

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plana??s overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy.

I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. This will adversely affect a pharmacista??s ability to continue to serve patients. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congressa?? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Congress wanted to ensure that patients could continue to use the pharmacy and pharmacist of their choice. Requiring plans to provide patients fair access to their pharmacy was a promise made by Congress that CMS should honor. That will help patients access a local pharmacy for their full benefit. a??Accessa?? isna??t a??accessa?? if patients are forced to use other pharmacies.

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

The Medication Therapy Management MTM) services may prove to be the most significant provision. It has the potential to improve the quality, and to reduce the cost of drug therapy for Medicare.
The current pharmacy education system is preparing pharmacists who capable of performing this role. Additionally, Continuing Education programs have been available to pharmacists to update and prepare them to perform this role. Since this provision has the potential to set the standards for MTM services for other plans, it is important that the program is carried out correctly. It is my concern that leaving the decision of who can provide MTM to the plans may allow plans to choose less qualified
providers to provide MTM services. There are several models, such as the NC Polypharmacy Project in nursing homes which reveal that pharmacists do MTM well, so I urge you to encourage plans to use pharmacists unless they have documented evidence that their alternative approach works as well as having that service provided by a pharmacist.
Many North Carolina pharmacists are providing MTM services in their practice that meet the MTM Services Definition and Program Criteria approved July 27, 2004 by eleven supporting organization in pharmacy. Based on our experience in the Asheville Project, face-to-face interaction between the patient and the provider So we urge CMS to require face-to-face interaction for MTM Services, at least for the initial visit.

Some other concerns to help make this program work appropriately:
Plans must be required to inform beneficiaries when they are eligible for MTMS and inform them about their choices (including their local pharmacy) for obtaining MTMS.
Once a beneficiary becomes eligible for MTMS, the beneficiary should remain eligible for MTMS for the entire year.
CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries.
Pharmacists should be allowed to provide MTMS to non-targeted beneficiaries. Since MTMS is not a covered benefit for nontargeted beneficiaries, pharmacists should be able to bill patients directly for the services.
Plans must be required to pay the same fee for MTMS to all providers. For example, plans should be prohibited from paying pharmacists at non-preferred pharmacies less than pharmacists at preferred pharmacies for the same service.
CMS must carefully evaluate each plana??s application to provide an MTM benefit. CMS must examine whether the fee the plan proposes to pay for the MTM services is high enough to entice pharmacists to provide MTMS.

In conclusion, I urge CMS to revise the regulation: to require plans to meet the TRICARE requirements at the local level; to not allow a plan to have both preferred and non-preferred providers; to only allow price differentials for providing an extended drug supply based on cost of service and not on the differentials in drug costs; require MTMS to be performed by pharmacists unless a plan has evidence their approach works as well as a pharmacist providing MTMS; make sure the proposed payment for MTMS is adequate to encourage pharmacistsa?? participation.

Submitter : Melanie Bella **Date & Time:** 10/04/2004 09:10:53

Organization : Indiana - Medicaid Policy and Planning

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Indiana Medicaid and the State Children?s Health Insurance Program (SCHIP) combined provide comprehensive drug coverage to approximately 784,000 individuals. Of those 784,000 enrollees, approximately 93,000 are full benefit dual eligibles as of June 1, 2004.

In addition to Medicaid and CHIP, Indiana also operates a State Pharmaceutical Assistance Program (SPAP), called HoosierRx. HoosierRx provides financial assistance to seniors up to 135% of the federal poverty level. Current enrollment in HoosierRx is approximately 22,800 individuals. Unlike the new Medicare Part D benefit, HoosierRx has no asset test. We support the requirement that the new Medicare Prescription Drug Plans (PDPs) and Medicare Advantage drug plans (MA-PDPs) coordinate with SPAPs but are concerned about CMS? interpretation of the antidiscrimination language in the law at Sec. 1860D-23(b)(2), which would preclude the use of a preferred PDP.

A significant area of concern to us is the transition of dual eligibles to a PDP or MA-PDP and the potential for a gap in coverage between the effective date of Medicare Part D (January 1, 2006) and the time it takes for a dual eligible individual to either choose a plan or to be auto-enrolled (which will not occur until May 2006). This is a vulnerable population and extra care must be taken to ensure they experience no gap in coverage once Medicaid pharmacy benefits end on January 1, 2006.

We recommend that CMS allow for temporary Medicaid coverage via a continuation of federal financial participation until an individual has either voluntarily chosen a plan or has been auto-enrolled into a plan. We realize CMS may be constrained by the law in this area and would urge CMS to seek modification of the law in this area for the dual eligibles. The negative clinical and financial ramifications of a gap in coverage provide ample rationale for seeking statutory change in this area.

Another major area of concern is the cost of the Medicare Modernization Act (MMA) to states. We are particularly concerned that the ?phasedown state contribution? may not fully recognize the aggressive cost containment measures enacted by states in recent years. While congressional intent was to phase down state contributions, by using a growth factor that overstates cost increases and a rebate number that may not reflect current rebate collection levels, states will likely pay more rather than less for prescription drug coverage for dual eligibles under Medicare Part D. In addition, states, such as Indiana, who receive supplemental rebates, will see a substantial part of their leverage taken away when the dual benefit covered lives leave the Medicaid program (even though the majority of their costs remain through the phasedown), which will result in lower rebates for the states. We urge CMS to exercise the flexibility in the statute to use the most appropriate growth factor that actually is representative of Medicaid program prescription drug cost increases.

States will also incur costs through the administrative functions they are required to assume. And, those costs may increase if CMS requires states to develop a completely separate process for determining eligibility for the low-income subsidy, an issue we will address in greater detail in the comments that follow. Additionally, while we support enrolling those individuals eligible for Medicare cost sharing, it will result in an increase in dual eligible individuals, which will result in additional increased expenditures for states. Lastly, we are concerned that CMS/HHS will not be directly negotiating prescription drug prices for Part D. This, combined with the fact that prices will not be subject to Medicaid best price, leaves states exposed to higher costs that otherwise might be reduced.

Medicare Part D leaves states in the undesirable position of having no control over the spending or management of the benefit yet responsible for the costs.

CMS-4068-P-1282-Attach-1.pdf

CMS-4068-P-1283

Submitter : Ruchi Twiari **Date & Time:** 10/04/2004 08:10:45

Organization : UNC- Chapel Hill

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

RE: CMS-4068-P

Dear Sir or Madam:

I would like thank you for accepting comments in behalf of the MTMS regulations and ask you to consider a perspective on behalf of a future pharmacist and my concerns with the proper implementation of this regulation.

Subpart C: Benefits and Beneficiary Protections

The TRICARE retail pharmacy access standards should be amended to propose that only pharmacies that are on the preferred plan should meet the access requirements.
The current access regulations include preferred pharmacy and non-preferred pharmacies; this presents a burden on beneficiaries and compromises effective therapeutic management.
Beneficiaries should be allowed fair access to all pharmacies. This coerced method of providing care takes away the patient's choice of receiving care from a pharmacist they have previously built a personal and confidential relationship with. Patients should have the option to choose a convenient pharmacy.
Forcing patients to travel distances to receive MTMS will affect patient?s behavior by resulting in an increased disregard of their own therapeutic care as a result of frustrations of traveling inconvenience. Patients will arrive to pharmacies irritated and reluctant to spend adequate time engaged in an active MTMS session with the pharmacist.
The current access requirements also place less incentive for proper contracts with pharmacies. I am afraid many pharmacies will be left out of the plan?s pharmacy network. This compromises and excludes the level of service many pharmacists can provide to this patient population.

Subpart D: Cost Control & Quality Improvement Requirements for
Prescription Drug Plans

Medication Management Services

After four years of graduate training for a Doctor of Pharmacy degree, I will become a drug expert on therapeutic medication management. Four years of training in multiple chronic and acute disease states has prepared pharmacists to make effective therapeutic decisions. With extensive preparation we are competent in providing the following services:

? Patient health assessment
? Creating medication treatment plans
? Managing high-cost ?specialty? medications
? Monitoring response to drug therapy
? Monitoring and adjusting for drug interactions
? Educating and training patients on disease states
? Educating patients on medications related concerns such as proper administration, side-effects, contraindications, precautions, monitoring parameters, etc.
? Managing special patient populations ie. children, pregnant females, geriatric

The great thing about implementing pharmacists as primary providers of MTMS is they have the knowledge to manage a great array of chronic conditions which present in one patient. The average Medicaid/Medicare patient is on 8 prescription drugs. We have the ability to decrease duplications/poly-therapy, thus decreasing costs and providing MTMS in one step. Pharmacists along with therapeutic knowledge have the insight of the remarkably increasing drug costs and the specifics of optimizing the use of an agent that is cost effective yet does not sacrifice efficacy.

If pharmacists were not permitted to be the primary providers of MTMS our education would be a waste of time. Please do not take this opportunity away from us. Medication therapy management is the prime focus of our education and this is the first hope for a shift in our role in the current health-care system to one that is more representative of our training/abilities.

In the hospital system, pharmacists continue to prove their effectiveness and value to America?s current health care system. Clinical trials and studies continue to prove that the approach of integrating a pharmacist on a team of health care professionals, to provide patient care has and continues to reduce costs, reduce adverse

CMS-4068-P-1284

Submitter : Mr. Timothy Schuerch **Date & Time:** 10/04/2004 08:10:07

Organization : Alaska Native Tribal Health Consortium

Category : Hospital

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

Please see attached comments in MS Word

CMS-4068-P-1284-Attach-1.doc

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM
Administrative Offices 4141 Ambassador Drive
Anchorage, Alaska 99508
Telephone: 907-729-1900
Facsimile: 907-729-1901

FILE CODE: CMS-4068-P

Comments To Proposed Medicare Part D Regulations

I. INTRODUCTION: The Alaska Native Tribal Health Consortium

The Alaska Native Tribal Health Consortium (ANTHC) is the largest privately operated Indian health program in America, managing over $125 million annually in IHS program and project funds, and with total revenues in excess of $300 million per year, all of which is devoted exclusively to providing health services to Alaska's 100,000+ Alaska Natives.

We are organized under the Alaska Non-profit Code, and enjoy tax-exempt status under Section 501(c)(3) of the Internal Revenue Code. Our three primary sources of revenue are (1) compacted IHS funds; (2) third party reimbursements, including private insurance, Medicare and Medicaid; and (3) federal grant funds. Our vision is *"a unified Native health system, working with our people, achieving the highest health status in the world."*

Pursuant to our charitable public health mission, we employ over 1,600 staff, including over 600 Indian Health Service (IHS) employees assigned to us under the Intergovernmental Personnel Act (IPA), and over 100 Commissioned Officers of the Public Health Service assigned to us under 42 USC 2004b in accord with 42 USC 215(d).

Our services encompass the Alaska Native Medical Center (ANMC), a JCAHO-accredited 150-bed acute care hospital in Anchorage, which we operate in cooperation with the Southcentral Foundation under the authority of Section 325 of P.L 105-83.

The ANMC Pharmacy is a large I/T/U pharmacy providing an array of services to our customer-owners, including Medicaid covered services, Medicare Part A covered services, Medicare Part B covered services, and Medicare Part D covered services. The ANMC Pharmacy serves many thousands of Medicare Part D eligible AI/AN, a significant percentage of which are subsidy eligible AI/AN.

Thus the treatment of AI/AN under the Medicare Part D regulations, especially AI/AN receiving services from I/T/U pharmacies, will have a significant impact on our third party reimbursements, which we heavily rely upon to support the provision of services to our AI/AN customer-owners.

II. KEY POLICY CONSIDERATIONS

(1) Aligning Part D regulations, as permitted by statute, with the Departmental AI/AN policy goal of narrowing the American Indian/Alaska Native health disparities gap, e.g., by lowering AI/AN barriers to access to pharmacy services.

(2) Consistent with Departmental AI/AN policy goals, and as permitted by statute, maximizing participation of Part D eligible AI/AN in the Part D program by ensuring that AI/AN, and the I/T/U pharmacies serving AI/AN, are consistently and uniformly treated in a manner that reflects Departmental AI/AN policy goals.

(3) Consistent with Departmental AI/AN policy goals, and as permitted by statute, maximizing participation of Part D eligible AI/AN by tailoring the regulations to prospectively avoid Secretarial findings for AI/AN under 42 USC 1860D-11(e)(2)(D)(i), with regard to any PDP, that "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan."

(4) Consistent with Departmental AI/AN policy goals, and as permitted by statute, mitigating the financial burden on I/T/U pharmacies and States resulting from transition of payment for Part D covered services for subsidy eligible AI/AN from 100% FMAP-paid State agencies to the Medicare Part D system, which allocates costs for subsidy eligible AI/AN between I/T/U pharmacies, CMS and States.

(5) Consistent with Departmental AI/AN policy goals, and as permitted by statute, avoiding penalization of I/T/U pharmacies for providing services to AI/AN on an IHS-prepaid basis, without charge to the patient (per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)).

III. COMMENTS

SUBPART A—GENERAL PROVISIONS

(NO COMMENTS)

SUBPART B—ELIGIBILITY AND ENROLLMENT

COMMENT WITH REGARD TO THE SUBPART AS A WHOLE: In order to ensure maximum participation of AI/AN in Part D; in order to ensure that the Part D regulations treat AI/AN and the national network of I/T/U pharmacies serving AI/AN in a uniform manner that is consistent with Departmental AI/AN policy goals; and in order to minimize the likelihood of Secretarial findings for AI/AN under 42 USC 1860D-11(e)(2)(D)(i), with regard to any PDP or MA-PD, that, "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan," **ANTHC feels the Secretary should consider amending the provisions of Subpart B of the proposed regulations to reflect the following comprehensive statutory approach to access and enrollment of AI/AN in PDPs and MA-PDs:**

(1) The Secretary should exercise his statutory discretion under 42 USC §1860D-1(b) and 42 USC §1395w-21(b)(1)(A) to waive, in the case of AI/AN, the requirement that Part D eligible individuals may only enroll in a plan that encompasses that PDP's or MA-PD's geographic region;

(2) Through the bidding and approval processes of 42 USC §1860D-11 (PDPs) and §1854(a) (MA-PDs), the Secretary should establish a small number of PDPs and/or MA-PDs that, in addition to providing coverage for all Part D eligible individuals in their respective PDP or MA-PD area(s) who choose to enroll in that plan, would also provides coverage for AI/AN on a national basis for all Part D eligible AI/AN who choose to enroll in each such plan, as permitted by 42 USC §1860D-11(a)(3).

(3) In preparation for PDP and MA-PD bidding processes, the Secretary should develop and publicize, in close consultation with the CMS Tribal Technical Advisory Group (CMS TTAG), an **AI/AN supplemental information packet**. The packet would solicit PDP sponsors and MA-PD organizations to consider including in their bids one or more plans that would provide coverage for Part D eligible AI/AN on a national basis. It would contain information on Part D eligible AI/AN and the national network of I/T/U pharmacies serving AI/AN, in sufficient detail to allow bidders to fairly assess whether they should include in their bids the information required under 42 USC §1860D-11(b)(2), with regard to any plan(s) in the bid proposing to provide coverage for Part D eligible AI/AN on a national basis. The packet would also set forth any "additional information" that the Secretary (in close consultation with the CMS TTAG) would require to be included in bids containing one or more plans to provide national coverage to Part D eligible AI/AN, as permitted under 42 USC §1860D-11(b)(2)(F). Specific types

of information that the Secretary might consider including in the **AI/AN supplemental information packet** might include general information on AI/AN and AI/AN health issues, as carefully and compellingly set forth in **the National Indian Health Board comments to these regulations.** Consideration should also be given to describing in detail the national network of I/T/U pharmacies serving AI/AN, including:

- who they serve (AI/AN, per 25 USC §1680c);
- the basis on which services are provided (IHS-prepaid without charge to the AI/AN);
- where they are located (in I/T/U facilities near the AI/AN served);
- the way they buy drugs (FSS or 340B programs);
- the way they dispense drugs (with much more patient consultation than in the private sector due to the high risk of culture and/or language barriers impeding instructions);
- the information system used track drug and reimbursement information (RPMS);
- the charitable mission served (providing pharmacy services to a population group and in geographic areas characterized by failure of competitive market dynamics); and
- the way Medicare reimbursements are processed (via a nationally centralized system).

(4) In reviewing and negotiating bids (under 42 USC §1860D-11(d)) that contain one or more plans proposing to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such review and negotiation is conducted in a manner consistent with Departmental AI/AN policy goals.

(5) In approving or disapproving any plan (under 42 USC §1860D-11(e)) that proposes to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such approval or disapproval is made in a manner consistent with Departmental AI/AN policy goals, especially with regard to the requirement of 42 USC §1860D-11(e)(2)(D) that the Secretary approve a plan only if he "does not find that the design of the plan and its benefits (including any formulary or tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan."

(6) The Secretary has already successfully adopted a centralized national model similar to that proposed above for processing Medicare Part A and Part B payments to I/T/U facilities, through the use of a single Carrier for I/T/U providers nationwide. With I/T/U facilities already possessing the capacity to be reimbursed for Part A-covered drugs, and on the verge of gaining the capacity to be reimbursed for Medicare Part B-covered drugs and biologicals under §630 of the MMA, the Secretary may wish to consider the efficiencies and improved coordination of benefits in the administration of the various Medicare drug programs as they apply to I/T/U providers that would likely result from adopting a similarly centralized, national system for processing Part D drug benefit payments to I/T/U facilities. For example, Trailblazer LLC has done a fair job of coordinating Part A and Part B payments to I/T/U facilities since the passage of the BIPA. Organizations like Trailblazer might prove to be efficient and effective sponsors of

PDP or MA-PD plans providing Part D coverage to Part D eligible AI/AN on a national basis.

(Additional Comments to SUBPART B, ELIGIBILITY AND ENROLLMENT):

42 CFR 423.44 DISENROLLMENT BY THE PDP

COMMENT: Because I/T/U pharmacies provide services to AI/AN on an IHS-prepaid basis without charge to the AI/AN, per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)), the financial burden of disenrollment of a Part D eligible AI/AN receiving services from an I/T/U pharmacy will fall squarely on the I/T/U pharmacy, rather than the AI/AN. Moreover, the cost and expense of reenrollment of the Part D eligible, including payment of some or all of the premiums that may be owing, will also fall on the I/T/U pharmacy. Thus ANTHC feels the Secretary should consider adding a new subsection to 42 CFR 423.44 to clarify that in the case AI/AN, the Secretary reserves the discretion to waive or amend the disenrollment and reenrollment provisions of the section.

42 CFR 423.48 INFORMATION ABOUT PART D

COMMENT: This section requires each PDP and MA-PD plan to provide to CMS on an annual basis "the information necessary to enable CMS to provide current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage." For PDP or MA-PD plans providing coverage for Part D eligible AI/AN on a national basis, the Secretary should require this information to also be provided to the CMS TTAG and the IHS for distribution to AI/AN through the national network of I/T/U pharmacies.

42 CFR 423.50 APPROVAL OF MARKETING MATERIALS AND ENROLLMENT FORMS

COMMENT: CMS should consult closely with the CMS TTAG and the IHS in carrying out its review and approval of the marketing materials and enrollment forms of PDP and MA-PD plans providing coverage for Part D eligible AI/AN on a national basis.

42 CFR 423.56 PROCEDURES TO DETERMINE AND DOCUMENT CREDITABLE STATUS OF PRESCRIPTION DRUG COVERAGE

COMMENT: Subsection (a)(9) properly includes as creditable prescription drug coverage "coverage provided by the medical care program of the IHS, Tribe or tribal organization, or urban Indian organization (I/T/U)." However, we feel there are significant administrative burdens and inefficiencies with the approach of the proposed regulations to require, before coverage provided by I/T/U providers may be considered creditable prescription drug coverage, that coverage provided by I/T/U providers must meet the general requirement of subsection (a) that "the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles…." Because I/T/U pharmacies uniformly provide services to AI/AN on an IHS-

prepaid basis, without charge to the AI/AN, and uniformly only scale back services as a last resort when funding falls short, it is highly likely that coverage provided by I/T/U providers will nearly always equal or exceed the actuarial value of standard Medicare Part D prescription drug coverage. And, in those few instances when it may not, it will likely nearly always be because program funding was inadequate, in which case the I/T/U provider providing coverage would especially not be in no position to divert scarce resources away from direct services in order to pay for expensive actuarial analyses. Thus we believe significant public health policy interests weigh in favor of amending this section to waive the actuarial equivalence requirements in the case of coverage provided by I/T/U providers.

SUBPART C—BENEFITS AND BENEFICIARY PROTECTIONS

42 CFR 423.100 DEFINITIONS

Definitions of "INCURRED COSTS" and "INSURANCE OR OTHERWISE:

COMMENT: A bona fide question of statutory interpretation exists with regard to whether (1) amounts up to the annual deductible limit paid by an I/T/U pharmacy on behalf of non-subsidy eligible AI/AN, (2) cost-sharing expenses above the annual deductible limit up to the initial coverage limit waived or absorbed an I/T/U pharmacy on behalf of a non-subsidy eligible AI/AN, and (3) amounts exceeding the initial coverage limit paid by an I/T/U pharmacy on behalf of a non-subsidy eligible AI/AN, should be treated as *"incurred costs"* under 42 USC §1860D-2(b)(4)(C)(ii), and thus be counted by CMS towards the non-subsidy eligible AI/AN Part D enrollee's annual out-of-pocket threshold, which in 2006 will be $3,600.

It is fairly clear that under the preceding subsection at 42 USC §1860D-2(b)(4)(C)(i), all three of these cost categories must be treated consistently, i.e., either all three are "incurred costs" in cases where an I/T/U pharmacy pays or waives them on behalf of a non-subsidy eligible Part D AI/AN enrollee, and thus counted towards the AI/AN's annual out-of-pocket threshold, or all three are "insurance or otherwise," and not counted towards the AI/AN's out-of-pocket threshold.

Given his statutory discretion in this matter, the Secretary may wish to consider the likely, reasonably foreseeable outcomes of the latter, more restrictive of the two interpretations, and determine whether those outcomes are consistent with Departmental AI/AN policy goals.

If in 2006, an I/T/U pharmacy were to provide services to a non-subsidy eligible AI/AN Part D enrollee on an IHS-prepaid basis, without charge to the AI/AN, per its charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)), it would likely want to calculate the costs vs. benefits of paying the $250 deductible on behalf of the AI/AN.

If the AI/AN were to use up $1,250 worth of covered drug benefit in the year, then the I/T/U pharmacy might well decide to pay the $250 deductible, because after it was paid, the PDP or MA-PD would pay 75% of the remaining $1,000 ($750) with the I/T/U pharmacy paying the

remaining 25% ($250). In other words, between the deductible payment and its 25% cost-sharing obligation, the I/T/U pharmacy would pay or waive a total of $500 on behalf of the AI/AN, in return for which it would receive $750 from the PDP or MA-PD, or 60% of the AI/AN's total covered drug costs for the year.

If the AI/AN were to use up $2,250 worth of covered drug benefit in the year, topping out but not exceeding the initial coverage limit for the AI/AN in the year, then the I/T/U pharmacy would get a slightly better deal: it would pay $250 for the deductible, plus waive 25% of the remaining $2,000, for a total cost of $750. In return, it would receive from the PDP or MA-PD 75% of the $2,000 of drug costs in excess of the deductible, or $1,500, or 66.67% of the AI/AN/s total covered Part D drug costs for the year.

If the AI/AN were to use up $3,250 worth of covered drug benefit in the year, then the I/T/U pharmacy's benefit received from the PDP or MA-PD, as a percentage of payment for the AI/AN's total costs for covered Part D drugs for the year, would fall significantly: The I/T/U pharmacy would pay $250 for the deductible ($250), plus bear the cost of waiving the 25% cost-share for next $2,000 worth of covered drug benefit usage ($500), plus bear 100% of the cost of the remaining $1,000, because that is the amount by which the AI/AN's covered drug benefit costs for the year exceed his/her initial coverage limit ($1,000), for a total cost to the I/T/U pharmacy of $1,750, in return for which it would receive from the PDP or MA-PD 75% of the $2,000 ($1,500) of covered drug costs exceeding the deductible amount but less than the initial coverage limit, or 46.15%.

And, to the degree the AI/AN were to use up ever higher amounts of covered drug benefit in the year, the I/T/U pharmacy's benefit received from the PDP or MA-PD, expressed as a percentage of payment for the AI/AN's total costs for covered Part D drugs for the year, would continue to decline ad infinitum, since neither the deductible amounts paid by the I/T/U pharmacy, nor the cost-sharing amounts waived by the I/T/U pharmacy, nor the payment by the I/T/U pharmacy on behalf of the AI/AN of costs in excess of the initial coverage limit would be counted as "incurred costs" for purposes of calculating when that AI/AN's out-of-pocket threshold for that year. In other words, the out-of-pocket threshold amount for that year for that AI/AN would never be reached, nor could the out-of-pocket threshold ever be reached in any year for non-subsidy eligible AI/AN Part D enrollees.

Thus the reasonably foreseeable net effect of treating I/T/U pharmacy payment and waiver amounts as "insurance or otherwise," and not as "incurred costs," is a modest benefit if the AI/AN uses up no more than a few thousand dollars per year in covered Part D drug benefit, but a complete absence of any additional benefit for amounts exceeding the initial coverage limit, which in 2006 will be $2,250. The stop-gap benefits that would normally come into play for amounts of the covered Part D drug benefits in excess of the annual out-of-pocket limit, $3,600 in 2006, would be completely eliminated. In other words, with regard to the significant stop-gap benefits that would otherwise be available to non-AI/AN non-subsidy eligible Part D enrollees, AI/AN non-subsidy eligible Part D enrollees, and the I/T/U pharmacies that serve them, are severely penalized precisely because the I/T/U pharmacy providing services to that AI/AN does

so on an IHS-prepaid basis, without charge to the patient (per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)). **In other words, the proposed regulations, as written, subject AI/AN and the I/T/U pharmacies that serve AI/AN to severe financial penalties in comparison to non-AI/AN and non-I/T/U pharmacies precisely for doing nothing more than fulfilling their public health mission and carrying out the Departmental policy objective of narrowing the AI/AN health disparities gap via, e.g., lowering AI/AN barriers to access to pharmacy services.**

We also agree with and incorporate by reference into these comments the excellent, well-thought-out public health policy discussion regarding these definitions in **the National Indian Health Board comments** to the definitions of "incurred costs" and "insurance or otherwise" in 42 CFR 423.100 of the proposed regulations.

42 CFR 423.100 DEFINITIONS (continued)

Definition of "Network Pharmacy:"

COMMENT: ANTHC feels consideration should be given to amending this definition, or otherwise clarifying in regulation, policy, PDP or MA-PD contract, and/or in "additional information" the Secretary might require of certain plans in their bid documents, that PDP or MA-PD plans that provide coverage for Part D eligible AI/AN on a national basis be required to include as "network pharmacies" all pharmacies in the national I/T/U pharmacy network.

Definition of "Person:"

COMMENT: ANTHC strongly urges the Secretary to amend this definition by adding an additional sentence that affirmatively assures the inclusion of all I/T/U pharmacies, regardless of whether operated by the IHS, a Tribe or tribal organization, or an urban Indian organization. The significance of this definition is that it would clarify that costs paid or waived by I/T/U pharmacies on behalf of AI/AN are "incurred costs" for purposes of calculating the annual out-of-pocket limit for all AI/AN Part D enrollees under 42 USC §1860D-2(b)(4)(B)(ii), including non-subsidy eligible AI/AN.

Definition of "Preferred Pharmacy:"

COMMENT: ANTHC feels consideration should be given to amending this definition, or otherwise clarifying in regulation, policy, PDP or MA-PD contract, and/or in "additional information" the Secretary might require of certain plans in their bid documents, that PDP or MA-PD plans that provide coverage for Part D eligible AI/AN on a national basis be required to treat all I/T/U pharmacies as "preferred pharmacies."

42 CFR 423.112 ESTABLISHMENT OF PRESCRIPTION DRUG PLAN SERVICE AREAS

(NO COMMENTS)

42 CFR 423.120 ACCESS TO COVERED PART D DRUGS

Subsections (a)(1) and (3):

COMMENT: We feel consideration should be given to creating an additional waiver under subsection (a)(3) of the pharmacy access requirements of subsection (a)(1) in the case of the national I/T/U pharmacy network. The national I/T/U pharmacy network has been established by the IHS, Tribes and tribal organizations, and urban Indian organizations for the express purpose of maximizing AI/AN pharmacy access within the constraints of the limited resources available to I/T/U pharmacies. To impose the generally applicable access requirements of (a)(1) on I/T/U pharmacies would be inequitable, costly, and have the effect of penalizing the more remote and underfunded I/T/U pharmacies by creating incentives for PDP and MA-PD plans to de-select them and otherwise attempt to exclude them from their respective networks. In other words, it is precisely because I/T/U pharmacies tend to serve populations and geographic areas characterized by failure that what would normally be generally applicable market assumptions implicit in subsection (a)(1) would not hold true. Again, without such a waiver, PDPs and MA-PDs will in many cases avoid dealing with I/T/U pharmacies, which in turn will result in sub-optimized participation of AI/AN, particularly those in remote or impoverished areas, in the Medicare Part D benefit, contrary to Departmental AI/AN policy goals.

Subsection (a)(5), Discounts for Preferred Pharmacies:

COMMENT: We feel consideration should be given to amending this subsection to clarify that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis must treat all I/T/U pharmacies as "preferred pharmacies," to ensure that in all cases, I/T/U pharmacies will receive the best negotiated PDP or MA-PD reimbursement available, assuring that IHS-funded I/T/U pharmacies, and thus taxpayers, will in all cases be able to take advantage of the financial benefits of the MMA's competition-assurance provisions, as well as assuring that the Department policy goal of narrowing the AI/AN health disparities via lowering AI/AN barriers to access to pharmacy services is well-served.

Subsection (b)(1), Formulary Requirements—Development and Revision By a Pharmacy and Therapeutic Committee:

COMMENT: This provision requires that a PDP sponsor's or MA organization's formulary "must be reviewed by a pharmacy and therapeutic committee" that meets certain requirements. We feel consideration should be given to amending this subsection to require that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis must include on their respective pharmacy and therapeutic committees at least one pharmacist or physician selected by the IHS; at least one pharmacist or

physician selected by Tribes and tribal health organizations; and at least one pharmacist or physician selected by urban Indian organizations.

Subsections (b)(4), (5), and (7), Periodic Evaluation of Protocols; Provisions of Notice Regarding Formulary Changes; Provider and Patient Education:

COMMENT: We feel consideration should be given to clarifying in the regulatory language or in Secretarial policy that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis be required to engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies in the protocol evaluation requirement of subsection (b)(4); the provisions of notice regarding formulary changes requirement of subsection (b)(5); and the provider and patient education requirement of (b)(7).

Subsection (c) Use of Standardized Technology:

COMMENT: We feel consideration should be given to clarifying in the regulatory language or in Secretarial policy that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis be required to engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies in the technology standardization requirements of this subsection.

42 CFR 423.128 DISSEMINATION OF PLAN INFORMATION

COMMENT: We feel consideration should be given to clarifying in the regulatory language or in Secretarial policy that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis be required to engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies regarding the plan information dissemination requirements of this section.

42 CFR 423.132. PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS

COMMENT: We strongly urge the Secretary to consider amending this section to provide an exception from this requirement in the case of I/T/U pharmacies. I/T/U pharmacies provide services to AI/AN on an IHS-prepaid basis, without charge to the patient, per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)). Thus it is the I/T/U pharmacies, and not the AI/AN receiving services, that bear the cost of PDP or MA-PD formulary choices, obviating the need for AI/AN receiving services from I/T/U pharmacies to have such price-comparison information.

SUBPART D: …

(NO COMMENTS)

SUBPART F: SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL

COMMENT: COMMENT WITH REGARD TO THE SUBPART AS A WHOLE: In order to ensure maximum participation of AI/AN in Part D; in order to ensure that the Part D regulations treat AI/AN and the national network of I/T/U pharmacies serving AI/AN in a uniform manner that is consistent with Departmental AI/AN policy goals; and in order to minimize the likelihood of Secretarial findings for AI/AN under 42 USC 1860D-11(e)(2)(D)(i), with regard to any PDP or MA-PD, that, "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan," **ANTHC feels the Secretary should consider amending the provisions of Subpart F of the proposed regulations to reflect the following comprehensive statutory approach to access and enrollment of AI/AN in PDPs and MA-PDs:**

(7) The Secretary should exercise his statutory discretion under 42 USC §1860D-1(b) and 42 USC §1395w-21(b)(1)(A) to waive, in the case of AI/AN, the requirement that Part D eligible individuals may only enroll in a plan that encompasses that PDP's or MA-PD's geographic region;

(8) Through the bidding and approval processes of 42 USC §1860D-11 (PDPs) and §1854(a) (MA-PDs), the Secretary should establish a small number of PDPs and/or MA-PDs that, in addition to providing coverage for all Part D eligible individuals in their respective PDP or MA-PD area(s) who choose to enroll in that plan, would also provides coverage for AI/AN on a national basis for all Part D eligible AI/AN who choose to enroll in each such plan, as permitted by 42 USC §1860D-11(a)(3).

(9) In preparation for PDP and MA-PD bidding processes, the Secretary should develop and publicize, in close consultation with the CMS Tribal Technical Advisory Group (CMS TTAG), an **AI/AN supplemental information packet**. The packet would solicit PDP sponsors and MA-PD organizations to consider including in their bids one or more plans that would provide coverage for Part D eligible AI/AN on a national basis. It would contain information on Part D eligible AI/AN and the national network of I/T/U pharmacies serving AI/AN, in sufficient detail to allow bidders to fairly assess whether they should include in their bids the information required under 42 USC §1860D-11(b)(2), with regard to any plan(s) in the bid proposing to provide coverage for Part D eligible AI/AN on a national basis. The packet would also set forth any "additional information" that the Secretary (in close consultation with the CMS TTAG) would require to be included in bids containing one or more plans to provide national coverage to Part D eligible AI/AN, as permitted under 42 USC §1860D-11(b)(2)(F). Specific types of information that the Secretary might consider including in the **AI/AN supplemental information packet** might include general information on AI/AN and AI/AN health issues, as carefully and compellingly set forth in **the National Indian Health Board comments to these regulations.** Consideration should also be given to describing in detail the national network of I/T/U pharmacies serving AI/AN, including:

- who they serve (AI/AN, per 25 USC §1680c);
- the basis on which services are provided (IHS-prepaid without charge to the AI/AN);
- where they are located (in I/T/U facilities near the AI/AN served);
- the way they buy drugs (FSS or 340B programs);
- the way they dispense drugs (with much more patient consultation than in the private sector due to the high risk of culture and/or language barriers impeding instructions);
- the information system used track drug and reimbursement information (RPMS);
- the charitable mission served (providing pharmacy services to a population group and in geographic areas characterized by failure of competitive market dynamics); and
- the way Medicare reimbursements are processed (via a nationally centralized system).

(10) In reviewing and negotiating bids (under 42 USC §1860D-11(d)) that contain one or more plans proposing to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such review and negotiation is conducted in a manner consistent with Departmental AI/AN policy goals.

(11) In approving or disapproving any plan (under 42 USC §1860D-11(e)) that proposes to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such approval or disapproval is made in a manner consistent with Departmental AI/AN policy goals, especially with regard to the requirement of 42 USC §1860D-11(e)(2)(D) that the Secretary approve a plan only if he "does not find that the design of the plan and its benefits (including any formulary or tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan."

The Secretary has already successfully adopted a centralized national model similar to that proposed above for processing Medicare Part A and Part B payments to I/T/U facilities, through the use of a single Carrier for I/T/U providers nationwide. With I/T/U facilities already possessing the capacity to be reimbursed for Part A-covered drugs, and on the verge of gaining the capacity to be reimbursed for Medicare Part B-covered drugs and biologicals under §630 of the MMA, the Secretary may wish to consider the efficiencies and improved coordination of benefits in the administration of the various Medicare drug programs as they apply to I/T/U providers that would likely result from adopting a similarly centralized, national system for processing Part D drug benefit payments to I/T/U facilities. For example, Trailblazer LLC has done a fair job of coordinating Part A and Part B payments to I/T/U facilities since the passage of the BIPA.

SUBPART G: PAYMENT TO PDP SPONSOR AND MA ORGANIZATIONS OFFERING MA-PD PLANS FOR ALL MEDICARE BENEFICIARIES FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

42 CFR §423.329 DETERMINATION OF PAYMENT

Subsection (b), Health Status Risk Adjustment:

COMMENT: We feel that for PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis, the Secretary should engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies in the establishment of risk adjustment factors, data collection of risk adjustment factors, development of methodologies to measure risk adjustment factors, and publication of risk adjustment factors as required under this section.

…

SUBPART P: PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

42 CFR 423.772 DEFINITIONS

Definition of "Resources:"

COMMENT: Many AI/AN hold interests in real property that is held in one or more types of trust status by the U.S. Government. Given the statutory restrictions that these real property interests are subject to by definition, we feel consideration should be given to amending this definition to make clear that real property interests of AI/AN individuals held in some form of trust status by the U.S. Government are excluded from this term. **We incorporate by reference the excellent, well-researched National Indian Health Board comments on this definition**.

Definition of "Income:"

COMMENT: Under the MMA, the Secretary has the option to permit a State to make subsidy eligibility determinations using the methodology set out at section 1905(p) of the Act if the Secretary determines that this would not result in any significant difference in the number of individuals who are made eligible for the subsidy. This in turn would permit a State to use the same resource methodologies that it uses to determine Medicaid eligibility for QMBs, SLMBs, and QIs if the Secretary determines that the use of those methodologies would not result in any significant differences in the number of individuals who are made eligible for a subsidy. This includes the less restrictive methodologies a State may use under section 1902(r)(2) of the Act to determine eligibility for QMBs, SLMBs and QIs.

The Secretary has proposed not to exercise this option at all under the proposed regulations, for two reasons: First, allowing States this greater flexibility to establish their own income determination standards would detract from the policy objective of achieving uniformity in the low-income subsidy determination process. Second, allowing States this flexibility would result in significant administrative burdens and complexity in administering the Medicare Part D low-income subsidy eligibility determination process.

Given the Departmental policy goal lowering barriers to access to services to narrow the AN/AI health disparities gap, and given the well-documented barriers of poverty, distance, high incidence of disease experienced by many Medicare-eligible AN/AI, and given the scarce resources and escalating costs experienced by all I/T/U pharmacies, we feel significant public health policy considerations weigh heavily in favor of the Secretary exercising his statutory discretion granted to him at under 42 USC §1860D-14(a)(3)(C)(iv) of the Act to amend this proposed regulatory definition of "income" in a way that would allow States to employ the less restrictive methodologies of 1902(r)(2) in making subsidy eligibility determinations for AI/AN.

The policy interest of maintaining uniformity would still be well-served, because the exception to the rule that would be created would be miniscule in comparison to the entire Part D program; the exception would only apply to a very defined population group; and in creating their own income determination standards under 1902(r)(2), States would still be constrained by the limits inherent in 1902(r)(2) and related statutes.

The policy interests of assuring economy and efficiency and avoiding unnecessary complexity and administrative burdens in carrying out the Part D program would also be well-served because State programs are already quite familiar with AI/AN populations; the I/T/U pharmacies that serve them; and are quite capable of working closely with I/T/U pharmacies to identify AI/AN beneficiaries and appropriately calculate their income for purposes of subsidy eligibility determination in a way that balances the need to control health care costs with the Departmental policy objective of lowering barriers to health services for AI/AN.

It should also be noted that should the Secretary choose to exercise his statutory discretion under the MMA to allow States 1902(r)(2) flexibility with regard to calculation of AI/AN income for purposes of subsidy eligibility determination, that approach would be consistent with the Secretary's exercise of statutory discretion in similar situations, e.g., such as in 2002, when the Secretary exercised his discretion to not subject I/T/U providers to the Medicaid 100% upper payment limit requirements of 42 CFR 447.272.

42 CFR 423.773 REQUIREMENTS FOR ELIGIBILITY

Under Subsection (c)(3), a State agency must notify individuals treated as full benefit dual eligible individuals that they are eligible for a full subsidy of Part D premiums and deductibles. Individuals to receive such notification would include QMBs, SLMBs, and QIs. We feel consideration should be given to providing such notification to the I/T/U pharmacy serving such subsidy-eligible individuals as well.

AI/AN receiving services at an I/T/U pharmacy are likely to include many individuals who are to be treated as full subsidy eligible individuals, all of whom would be receiving care from such

I/T/U pharmacies on an IHS-prepaid basis, with no charges to the individual, pursuant to the public health mission of I/T/U pharmacies.

In these cases, it is the I/T/U pharmacy, rather than the full-subsidy AI/AN that would bear financial responsibility for the payments and waivers that would apply if there were no subsidy. Therefore, we feel consideration should be given to amending subsection (c)(3) to require that in the case of AI/AN served by an I/T/U pharmacy, notice also be given to the I/T/U pharmacy.

42 CFR 423.780 PREMIUM SUBSIDY

Subsections (a) and (b):

I/T/U pharmacies provide services to AI/AN on an IHS-prepaid basis, at no charge to the AI/AN, pursuant to the Departmental public health policy goal of lowering barriers to health services for AI/AN. For this reason, we feel consideration should be given to amending these subsections to expressly clarify that I/T/U pharmacies may pay Part D premium amounts on behalf of the AI/AN that might not be fully covered by the premium subsidy available to full subsidy eligible AI/AN or other low-income subsidy eligible AI/AN. In addition to this, we feel consideration should be given to amending these subsections to make clear that for AI/AN receiving services from I/T/U pharmacies, the I/T/U pharmacies may pay any other unsubsidized premium amounts on behalf of other low-income subsidy eligible AI/AN, as well as on behalf of unsubsidized AI/AN Part D beneficiaries.

We feel this approach would have a significant positive impact on the participation of AI/AN in the Medicare Part D drug benefit.

It should be noted, however, that we feel strongly that such charitable, public health-oriented premium payment amounts (as well as cost-sharing amounts) by I/T/U pharmacies on behalf of AI/AN MUST be counted as "incurred costs," as defined in the proposed regulations at 42 CFR 423.100, as noted at length above in our comments addressed to that section.

42 CFR 423.800 COST-SHARING SUBSIDY:

Subsections (a) and (e):

I/T/U pharmacies provide covered services to low-income subsidy eligible individuals on a IHS-funded, pre-paid basis, with no out-of-pocket charges to the low-income subsidy eligible AI/AN, pursuant to the public health mission of I/T/U pharmacies of reducing barriers to health services for AI/AN, in furtherance of the Departmental AI/AN policy goals.

The Congress has expressly approved this practice in the MMA itself, at Section 101, Part D, Subpart 5, by amending 42 USC 1320a-7b(b)(3) to permit, in the form of a statutory exception to the federal anti-kickback statute,

> "…(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under Part D of Title XVIII, if the conditions described in clauses (i) through (iii) of section 1128A(i)(6)(A) are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1860D-14(a)(3), section 1128A(i)(6)(A) shall be applied without regard to clauses (ii) and (iii) of that section)."

In light of this very recent, unmistakeably clear statutory expression of the Congress, and in light of the compelling public health mission served by I/T/U pharmacies in lowering barriers to access for AI/AN by providing covered Part D drugs to AI/AN on an IHS-funded, pre-paid basis, we believe consideration should be given to amending subsections (a) and (e) to require that in all cases in which an I/T/U pharmacy waives or reduces cost-sharing amounts that would otherwise have been paid as out-of-pocket costs by a low-income subsidy eligible individual, the reimbursement that would otherwise be paid by the individual shall be paid to the I/T/U pharmacy.

42 CFR 423.800 ADMINISTRATION OF SUBSIDY PROGRAM:

Subsections (c) and (d):

Payment to a PDP sponsor or MA organization for cost-sharing subsidies made on a capitated basis may be inappropriate with regard to payments made on behalf of AI/AN to PDP sponsors or MA organizations for PDPs or MA-PDs primarily serving I/T/U pharmacy beneficiaries. Although such a capitated payment system may work well for the private sector, we believe such a payment system inappropriately creates incentives for PDP sponsors or MA organizations to attempt to maximize profits at the expense of reducing the scarce resources necessary for I/T/U pharmacies to carry out the Secretary's stated goal of narrowing the AI/AN health disparities gap.

We would ask that consideration be given to amending these subsections to reflect that PDP sponsors or MA organizations with PDPs or MA-PDs that serve a significant number of AI/AN would not have available to them the option of having the cost-sharing subsidies reimbursed to them on a capitated basis.

SUBPART P: SPECIAL RULES FOR STATES IN MAKING ELIGIBILITY DETERMINATIONS FOR SUBSIDIES

423.902 DEFINITIONS

Definitions of "STATE MEDICAL ASSISTANCE PERCENTAGE," and "PHASED-DOWN STATE CONTRIBUTION PAYMENT"

The proposed regulatory definition of State medical assistance percentage is identical to the statutory definition at section 1935 of the Act: "The proportion equal to 100% minus the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs."

This definition requires the Secretary, in determining each State's medical assistance percentage to first determine "the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs."

Unfortunately, under the Act's FMAP provisions at 42 USC 1396d(b), a State's FMAP can vary.

On the one hand, a State's FMAP for a given fiscal year could be calculated using the default FMAP formula set out in the first paragraph of subsection (b).

On the other hand, the plain language of the 1935 reference to 1396d(b), under well-established principles of statutory interpretation, ould be read more broadly to include ALL of subsection (b), including (b)(1), (b)(2), (b)(3) and (b)(4).

We feel that the correct reading of §1935 should follow well-established principles of statutory interpretation, and in a manner that weighs in favor of achieving the Departmental AI/AN policy goal of narrowing the AI/AN health disparities gap by lowering AI/AN barriers to access to covered Part D drugs, by allowing States to calculate their SMAP for purposes of §1935 by factoring in the 100% FMAP reimbursement amounts received for the applicable year, weighted in proportion equal to that State's overall proportion of 100% FMAP-paid reimbursement in comparison to the overall reimbursement amounts received in that year at otherwise-applicable FMAP percentages.

For example, if New Mexico's established FMAP percentage for a given year were 50%, but 20% of the total value of Medicaid reimbursements paid by the Secretary to New Mexico for that year were paid at 100% FMAP (due to those reimbursements being made for services provided to AI/AN), then 80% of the total value of paid Medicaid claims for that year were reimbursed at 50% FMAP, and 20% of the total value of paid Medicaid claims for that year were reimbursed at 100% FMAP.

So if New Mexico's total value of paid Medicaid claims in a given year were $1 billion, the actual FMAP experienced by New Mexico would be ($800 million x 50% FMAP) = **$400 million + $200 million** ($200 million x 100% FMAP) = $600 million, or 60%, rather than the published FMAP rate of 50%.

This difference, in turn, significantly impacts the amount of New Mexico's phased-down State contribution payment to the Secretary under the statutory formula.

Under the formula, New Mexico's monthly contribution amount is equal to 1/12 of the product of the base year (2003) Medicaid per capital expenditures for covered Part D prescription drugs

for full-benefit dual eligible individuals, multiplied by the State medical assistance percentage (which is the inverse percentage amount of the FMAP percentage), the applicable growth factor, the number of the State's full-benefit dual eligible individuals that month, and the phased-down state contribution factor.

We feel consideration should be given to accepting the plain language of section 1935 on its face, and to assign an FMAP value to each State for each fiscal year using State's FMAP value

As is pointed out in the General Provisions accompanying the proposed regulations at 69 FR 46638, 3rd column:

> "General principles of statutory interpretation require us to reconcile two seemingly conflicting statutory provisions whenever possible, rather than allowing one provision to effectively nullify the other provision. Consequently, when a statutory provision may reasonably interpreted in two ways, we have an obligation to adopt the interpretation that harmonizes and gives full effect to competing provisions of the statute."

****

(END OF ANTHC COMMENTS TO PROPOSED PART D REGULATIONS)

Submitter : Mr. Russ McDaid **Date & Time:** 10/04/2004 09:10:36

Organization : PANPHA

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

The following comments on the Centers for Medicare and Medicaid Services proposed rule, ?Medicare Program; Medicare Prescription Drug Benefit?, file code CMS-4068-P, are provided by PANPHA, an association of more than 300 Pennsylvania non-profit senior service providers. PANPHA?s members provide nursing homes, personal care homes (also known as ?assisted living?), continuing care retirement communities, and housing.

Section 423.124(a)(2) Of primary concern is the implementation of the prescription benefit for residents of nursing facilities. We recommend allowing several models to be tested prior to implementing the regulation, including allowing LTC pharmacies to function as ?out-of-network? pharmacies, encouraging PDPs and MA-PDs to contract with LTC pharmacies, as discussed in the regulation summary, as well as other models that may be proposed by other commentors.

As regulations are implemented and our members work through them, we will provide additional comments. Thank you for this opportunity to comment.

Sincerely,

W. Russell McDaid
VP/Chief Public Policy Officer
russ@panpha.org

CMS-4068-P-1286

Submitter : Mr. Leonard S. Holman, Jr., R.Ph. **Date & Time:** 10/04/2004 08:10:25

Organization : Option Care of Northeast Ohio

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see comments in attached word document.

CMS-4068-P-1286-Attach-1.doc

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October 4, 2004

JCAHO *Accredited with Commendation*

Dear Sirs:

Option Care of Northeast Ohio is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P, implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Option Care of Northeast Ohio is a home infusion therapy and specialty injectable pharmaceutical company located in Canfield and North Canton, Ohio. Option Care of Northeast Ohio was founded in 1986 and is part of an Option Care, Inc.'s national franchise. We service patients in 40 counties in Northeastern Ohio, Western Pennsylvania, and Northern West Virginia. We are accredited by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) with full standards compliance, the highest level awarded by JCAHO.

Option Care of Northeast Ohio appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home Infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration includes intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune

Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

- **Dispensing fee option 3** is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit.

The dispensing fee paid to the Home Infusion Pharmacy under option 3 must be split into two parts as follows for this to work for the effective provision of Home Infusion Drug Therapy for Medicare beneficiaries:

A. Payment of daily "per diem" fee specific to the type of therapy and frequency of administration of the drugs employed in the therapy[y for each day or portion there of that the patient receives I.V. therapy.
B. Payment for each intermittent skilled nursing visit that occurs during the course of I.V. Therapy.

CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm http://www.nhianet.org/perdiemfinal.htm> .

* CMS should establish **specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies** to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require **specific standards for home infusion pharmacies** under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the **X12N 837 P billing format** for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should **mandate that prescription drug plans maintain open formularies for infusion drugs** to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

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CMS-4068-P-1287

Submitter : Mrs. Ann Berkey **Date & Time:** 10/04/2004 09:10:11

Organization : McKesson Corporation

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

On behalf of McKesson Corporation, I am pleased to submit comments regarding the proposed rule to create the new Medicare Prescription Drug Benefit.

CMS-4068-P-1287-Attach-1.doc

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Ann Richardson Berkey
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Public Affairs

McKESSON
Empowering Healthcare

October 4, 2004

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: The new Medicare Prescription Drug Benefit as authorized by the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 [CMS-4068-P and CMS-4069-P].

Dear Sir or Madam:

On behalf of McKesson Corporation, I am pleased to submit comments regarding the proposed rule to create the new Medicare Prescription Drug Benefit. We commend CMS for seeking industry input as it begins to implement this landmark legislation to make prescription drugs more affordable to our nation's senior population.

Due to the breadth of our businesses and experiences, we offer a broad and credible perspective on the implementation of this legislation. For the past 170 years, McKesson has led the industry in the delivery of medicines and health care products to drug stores. Today, a Fortune 16 corporation, we deliver vital medicines, medical supplies, and health information technology solutions that touch the lives of more than 100 million patients each day in health care settings that include over 5,000 hospitals, 150,000 physician practices, 10,000 extended care facilities, 700 home care agencies, and 25,000 retail pharmacies. As the world's largest health information technology company, providing technology solutions to 65% of U.S. health systems, McKesson supports the transformation of healthcare from a paper based system to one with electronic solutions that will improve patient safety, reduce cost and variability of care, improve healthcare efficiency, and better manage resources.

McKesson also supplies pharmaceuticals to the entire Department of Veterans' Affairs system, as well as to a significant number of Department of Defense and other government facilities. In addition, we repackage over 1.5 billion doses of drugs annually and provide analytical testing services in support of these operations.

As the largest pharmaceutical supply management company in the world, we leverage our leadership in the distribution business to provide specialty pharmaceutical services for providers and patients with chronic conditions. These high-cost, often injectable bio-pharmaceutical drugs call for special handling, storage, and complex shipping requirements. The services associated with such complex distribution processes expand access to necessary medication treatments, increase cost-effectiveness, and improve the convenience and quality of patient care by enabling the administration of these drugs in a lower cost, outpatient setting.

McKesson has actively supported the use of drug savings cards to help lower the costs of pharmaceuticals through our administration of the successful Together-Rx card and our CMS-endorsed Rx Savings Access card. The Together-Rx card has delivered over $492 million in savings to more than 1.4 million low-income seniors in only two years. McKesson's Rx Savings Access card is providing Medicare beneficiaries with an average savings of 15-25% on the most commonly prescribed medicines and is accepted by over 95% of pharmacies. To date, more than 129,000 Medicare eligible seniors are enrolled in this card and have realized $13 million in savings on their prescription drugs.

McKesson is also an industry leader in providing disease management programs for commercial, Medicaid and Medicare populations where we leverage our experience with patient services, pharmacy management and health care quality improvement activities. In seven states where we provide disease management services to Medicaid patients, physician and patient satisfaction as well as health outcomes have improved. Those states are also saving approximately two dollars for every dollar spent with McKesson. Based on our experiences, we know the benefits that can be achieved through disease management programs and strongly advocate their rapid adoption for the eligible Medicare population.

We welcome the opportunity to share our unique insights into the effective implementation and utilization of the Medicare Prescription Drug Benefit. Our specific comments are detailed by section; however, we want to emphasize and highlight the following provisions as critically important to the success of this benefit across the Medicare population:

- Broad access to and participation of retail pharmacy;
- Medication therapy management programs (MTMPs) that adequately compensate health care professionals and provide needed services to beneficiaries with chronic conditions;
- Optimal integration of MTMPs and chronic care programs;
- Inclusion of drugs acquired through manufacturer-sponsored patient assistance and similar charitable programs as incurred costs;
- Medication error prevention through the promotion of technologies and improved processes, including electronic prescribing; and,

- Ultimately, a "user-friendly" program that is easily understood by Medicare beneficiaries and maximizes access to needed health care services.

Comments on CMS-4068-P

Part II – Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule

II. Provisions of the Proposed Rule

A - General Provisions

A.2.b.iii - Prescription Drug Plan Regions

In order to minimize confusion and provide continuity with existing programs, we encourage CMS to align prescription drug plans (PDP) and MA-PD (Medicare Advantage prescription drug plans) regions with existing Medicare Advantage (MA) regions. Lack of alignment is likely to confuse those beneficiaries currently in MA programs as they try to understand their options during the initial enrollment period for this Medicare Part D benefit.

A.2.d – Financial Relationships between PDP Sponsors, Health Care Professionals and Pharmaceutical Manufacturers

McKesson believes any decisions on formularies and covered pharmaceuticals should be driven by clinical evidence and pharmacoeconomic analysis and should not be influenced by payments made by manufacturers to plan administrators. We urge CMS to provide oversight and auditing to ensure appropriate financial relationships.

B – Eligibility and Enrollment

B.2 – Part D Enrollment Process

As CMS has proposed, McKesson supports an auto-enrollment process for Part D plans, particularly for low-income beneficiaries who will qualify for assistance and will incur no sign up costs. When no MA-PDs are available that meet the premium thresholds, we believe that CMS should allow auto-enrollment of low-income MA members into stand-alone PDPs.

Under auto-enrollment, proper safeguards will have to be established to ensure continuity of pharmaceutical care as beneficiaries are transitioned to new plans with potentially different formulary or other coverage provisions. Further, we recommend that the auto-enrollment process be managed by a single entity rather than by individual states to

simplify the coordination of benefits and minimize any additional administrative burden and associated costs.

To protect the reputation and longevity of the program, we recommend that CMS establish a process to re-evaluate, at periodic time intervals, the ability of a plan sponsor to meet the minimum standard levels within the constraints of the low-income premium subsidy. This process will assure continuity of care for beneficiaries by mitigating the likelihood that a plan sponsor will drop coverage at a later date because they can no longer afford to cover beneficiaries.

B.3.b.v – Special Enrollment Periods; Exceptional Circumstances

A change in control of a PDP that does not result in a material change to a beneficiary's coverage should not result in a special enrollment period (SEP). A SEP would likely result in beneficiary confusion. Furthermore, it would discourage successful and innovative plans from expanding as the program evolves. A plan sponsor may choose to acquire another plan in order to expand the services provided and/or reduce costs, which would be achievable through improved economies of scale, a broader risk pool, and increased negotiating power associated with representing a larger number of enrollees. However, the increased administrative burden and customer service costs associated with providing for a SEP may discourage plan sponsors from acquiring an existing plan sponsor's program. Ultimately, CMS will want to encourage successful plans to continue innovating and growing to minimize costs both to the government and to beneficiaries. Providing a SEP only when there are material changes to a beneficiary's coverage will help to achieve this goal while also maximizing beneficiaries' choice.

B.4.a – Effective Date of Coverage and Change of Coverage; Initial Enrollment Period

Enrollment should become effective as soon as a beneficiary has been processed and approved, and within a 30-day period. Based on our experience administering a Medicare drug discount card, delaying enrollment until the first of the next month is unnecessary and has caused confusion to the beneficiary and commercial partners, particularly when applications are submitted near the end of a month and activation takes longer than 30 days.

B.5 – Coordination of Beneficiary Enrollment and Disenrollment through PDPs

As a Medicare drug discount card sponsor, we recognize that online and telephonic enrollment provides a cost-effective, timely and secure means of enrolling beneficiaries. CMS should encourage PDPs to provide these enrollment methods to capture similar efficiencies.

B.6 – Disenrollment by the PDP

McKesson recommends that plans offering national networks be authorized to operate in each region. We recognize that the statute authorizes the establishment of regional plans; however, a beneficiary's ability to participate in a plan that does not offer national networks could be impacted by logistical issues, such as extensive travel out of the region or residency close to the borders of a region. Authorizing plans with national networks in each region will serve to maintain continuity of care by preventing unnecessary disenrollment (e.g. if a beneficiary is out of the service area for six months) as well as to minimize cost by reducing additional out-of-network expenses.

B.8 – Part D Information that CMS Provides to Beneficiaries

Community pharmacies have demonstrated they are one of the most effective channels for educating and promoting voluntary enrollment in the Medicare drug discount cards. Therefore, we recommend that CMS utilize the expertise and value of local pharmacists to assist in educating those eligible for the Medicare Part D benefit by providing appropriate funding and by designing campaigns that feature pharmacists as an education channel. Since the education and enrollment of patients represents a significant time and resource commitment for pharmacists, we would also urge that pharmacists be appropriately compensated for providing these valuable services.

McKesson fully supports CMS' goal to steer seniors to those plans that provide the best value to each beneficiary. We agree that a price comparison website is effective in helping seniors understand the drug price component of a plan. Recognizing that the value of a plan extends beyond the price of pharmaceuticals to other important plan elements, such as network size, cognitive and therapy management services, formulary and drug utilization rules, we encourage CMS to broaden the plan features compared on its website. These enhancements will allow beneficiaries to make more fully informed decisions. Those most concerned about pricing can make a plan selection on the basis of price. Those who want to consider other elements, such as inclusion of their local pharmacy or the availability and components of a medication therapy management program, will have the necessary information to make an informed decision.

Based on McKesson's experience with the Medicare drug discount cards, we recommend a number of improvements in websites used as resources for beneficiaries:

1. Any ranking of plan designs according to drug pricing should be done according to the lowest *maximum* price a beneficiary would pay at a network pharmacy, and not the lowest *minimum* price. In today's Medicare drug discount card program, when card sponsors present a range of prices available to a beneficiary in a defined service area, the card sponsors are ranked on Medicare's website according to the lowest minimum price within that range. This ranking

methodology creates the potential for beneficiaries to be misled when the lowest minimum price is only available at a small subset of their network, while the pricing more broadly available within network is significantly higher. Utilizing lowest *maximum* price as a ranking methodology will prevent the presentation of misleading information, drive consistently lower prices and allow beneficiaries to more effectively compare available benefits in their region.

2. CMS and PDP websites and resources should provide information on generic equivalents when they publish information on brand versions of multi-source drugs. Additionally, they should allow for queries by generic name. Currently, in today's drug discount card program, generic drugs can only be found by referencing their branded counterpart.

3. CMS should allow more flexibility to plan administrators in highlighting aspects of their benefits, such as network size, availability and components of cognitive and therapy management services, and formulary and drug utilization rules, so that beneficiaries can choose the plan they believe provides the best overall value, not just the lowest price.

B.9 – Approval of Marketing Materials and Enrollment Forms

As pharmacists are recognized as a trusted source of information, particularly for the senior population, we urge CMS to allow pharmacies to provide information about PDPs that offer the best savings and prescription drug coverage for their customers. Pharmacies should also be allowed to collect and submit enrollment forms, particularly on behalf of those Medicare beneficiaries who may not be comfortable completing an application without assistance.

We recommend more stringent monitoring of the marketing behavior of all MA-PDs and PDPs to ensure compliance across the board with regulations. Furthermore, we suggest that those PDPs that have demonstrated consistent compliance with marketing guidelines during the CMS discount card program should obtain streamlined approval under the "File and Use" program.

B.10 – Information Provided to PDP Sponsors and MA Organizations

From our experience as the administrator of a Medicare drug discount card, we believe it would have been more efficient and effective for all card sponsors to have had access to a list of eligible beneficiaries and their mailing addresses. In order to maximize voluntary enrollment, we recommend that CMS provide PDPs with the names and addresses of all eligible beneficiaries in their coverage region. This data would allow plan sponsors to send written educational materials only to eligible beneficiaries and avoid more costly untargeted mailings.

We believe that telephone marketing will lead to confusion and frustration among the beneficiary population and should not be permitted. After enrollment, however, telephone contact should be permitted and encouraged as an important component of medication therapy management and other pharmaceutical care services. Our experience with the drug discount card program suggests that this population relies on direct contact and educational efforts to answer questions and explain benefits. Direct contact will also allow plan sponsors to maximize customer service and satisfaction.

We do not recommend the marketing of additional products and services to beneficiaries that are unrelated to the Medicare Part D benefit. This would violate the intent of other congressional actions to limit direct marketing to peoples' homes (e.g., "do not call lists").

C - Voluntary Prescription Drug Benefit and Beneficiary Protections

C.1.a – Overview and Definitions; Covered Part D Drug

We commend CMS for establishing a clinically focused, patient-centric prescription drug benefit, and endorse provisions providing for close CMS evaluation and oversight of alternative prescription drug coverage and formulary designs. McKesson also concurs with the inclusion of biological products as covered Part D drugs, and we urge CMS to include provisions that ensure appropriate coverage of these products. Noting that these pharmaceutical products are typically not classified or included in traditional formularies, we urge CMS and the United States Pharmacopeia (USP) to establish distinct classifications and provisions that ensure the appropriate coverage and use of these agents. Since these new, lifesaving products are typically expensive and treat small patient populations, we believe beneficiaries using specialty pharmaceuticals are particularly susceptible to benefit design mechanisms which may discourage their enrollment in the Part D benefit. To this end, we strongly endorse proposed CMS measures which stipulate the composition and activities of Pharmacy and Therapeutics committees, and also recommend CMS scrutiny of step therapy, prior authorization and other utilization controls which might discourage the clinically appropriate use of specialty pharmaceuticals.

C.1.b – Dispensing Fees

McKesson recommends that CMS use Option 1 to define the activities covered by the dispensing fee. Dispensing fees are a critical component of the reimbursement formula for pharmacies and have traditionally covered the physical dispensing activity, quality assurance, and cognitive services relating to the dispensing of every prescription drug, such as when and how to take the medication. Given the market's understanding of dispensing fees, expanding the definition to include pharmaceutical therapy could create confusion and deprive the pharmacist of appropriate compensation that should be provided for additional services.

We commend the provisions in the Medicare Modernization Act which promote the value of medication therapy management programs (MTMPs). These services are critical to improving health outcomes and will be marginalized if pharmacists are not appropriately compensated. MTMPs may not be needed for every prescription; by including these important cognitive services in dispensing fees (e.g. Option 3), accountability and visibility are diluted. To that end, we strongly advocate separate payment for MTMP services as detailed in Part D.2.c.

C.2.a - Standard Prescription Drug Coverage

We strongly endorse the proposed CMS classification of pharmaceutical manufacturer contributions to a patient's drug costs through charitable assistance programs as incurred costs that count toward the enrollee's out-of-pocket costs. As the leading administrator of manufacturer-sponsored patient assistance programs (PAPs), McKesson believes that this provision would create a much needed incentive to manufacturers to maintain and enhance their PAPs, which will provide a privately funded mechanism to help the neediest patients pay for their costs in the coverage gap. Without this provision, needy patients may be disincented to participate in manufacturer-sponsored PAPs because it will delay their access to catastrophic coverage; at the same time, manufacturers may be disincented to offer such programs since they will incur significantly increased financial responsibility due to the delayed onset of patients' eligibility for catastrophic coverage. By allowing this provision, CMS will promote continuity of pharmaceutical care for patients who might otherwise interrupt drug therapy, and avoid more costly interventions which can result from patient non-compliance.

We concur with CMS that HSA, FSA, and HRA expenditures should count toward incurred costs because they are analogous to a beneficiary's bank accounts. In addition, price differentials between 90-day prescriptions by mail and 90-day prescriptions at retail should count as incurred costs.

We presume that expenditures for prescription drugs purchased from foreign sources will not count as incurred costs, given that this practice is illegal. To prevent any misunderstanding, CMS may want to explicitly state that drugs purchased through any channel that the FDA has not deemed to be safe will not count toward incurred costs.

C.4.a – Pharmacy Access Standards

We concur with CMS' goal to ensure broad retail access. Most seniors still prefer to obtain their medicines from their local pharmacist. Furthermore, the importance of pharmacists in explaining the Medicare drug benefit program, its benefits and the appropriate use of medication is well documented.

McKesson concurs with the access standards requirements set out in the proposed regulation, namely that 90 percent of Medicare beneficiaries in urban areas have access to

a pharmacy within two miles; 90 percent of Medicare beneficiaries in suburban areas have access to a pharmacy within five miles; and 70 percent of Medicare beneficiaries in rural areas have access to a pharmacy within 15 miles. However, McKesson recommends that access standards be based on traveling distance and not geographic distance. Particularly in rural areas, "line of sight" distances can be deceiving. Mountain ranges, highways, lakes, rivers and other obstacles can substantially increase traveling time to a pharmacy.

McKesson suggests that regulations clearly state that plan sponsors have to meet these access requirements in each of the proposed Medicare regions. The proposed regulations only require plan sponsors to meet this standard on an average basis across all the regions they serve. The unintended consequences of such an interpretation could be high access in one area and substandard access in another. To this end, we strongly urge CMS to ensure that plan sponsors meet the pharmacy access requirements for each *separate* category of population density (e.g. urban, suburban, rural) in each Medicare region.

We concur that pharmacy access requirements should apply to retail pharmacies only and that plans can choose to add other pharmacies to their network as desired. Long-term care pharmacies, specialty pharmacies, mail order pharmacies and Federally Qualified Healthcare Clinics (FQHCs) can be added to the network, but cannot be used to support the access requirements. Otherwise a "closed door" pharmacy for the exclusive use of long-term care facilities in the area could be used to meet an access requirement when in fact patients in the community who are not residents of the contracted long-term care facility do not have access to this pharmacy.

Finally, if the plan sponsor creates a tiered network of preferred and non-preferred pharmacies with a lower co-pay or other benefit associated with the preferred network, access requirements should apply to the preferred networks. Access standards are designed to provide adequate access to drugs and pharmacy services. If access standards apply only to the broader network, but not to the preferred network, some Medicare beneficiaries could be penalized with higher co-pays because they do not have a preferred pharmacy within their area.

C.4.c – Use of Standardized Technology

Fundamental to spurring adoption of standardized technology is the selection of an identifier that is consistent with the requirements for enrollee identification under the e-prescribing provision. If possible, all plan sponsors should have a consistent standard to recognize beneficiaries. In addition, these standards need to provide enough flexibility so that they can keep pace with technological developments and advancements.

C.7 – Public Disclosure of Pharmaceutical Prices for Equivalent Drugs

The pricing comparison should be between the brand name drug and the Maximum Allowable Cost (MAC) price established by that PDP for the generic equivalent to the branded drug. When a brand name drug is prescribed and the prescriber has not given a "Do Not Substitute" order, we recommend that the pharmacy provide the lowest price of the generic version of that drug available at that pharmacy. It is important to note that most pharmacies do not carry multiple generic drug options for the same generic entity.

To ensure that drug pricing information is equally provided, we recommend that mail order pharmacies should also be required to disclose the availability of a less expensive generic at the time the drug is ordered and prior to its delivery.

D: Cost Control and Quality Improvement Requirements for PDPs

D.2.b – Quality Assurance

In outlining the appropriate elements of a quality assurance system, CMS contemplates electronic prescribing, clinical decision support, educational interventions, bar codes, adverse drug event (ADE) reporting systems and provider and patient education systems, and yet anticipates that plans will not implement all of these elements. McKesson believes that, to qualify as a PDP or MA-PD, plans should, in fact, implement all of these technologies and processes. We believe that some form of clinical decision support will be an essential component of an electronic prescribing system, and every such system will have both provider and patient education as a fundamental feature. We endorse the electronic prescribing standards and process that were delineated in the report issued on April 14, 2004 by the eHealth Initiative, entitled *Electronic Prescribing: Towards Maximum Value and Rapid Adoption.*

We believe that error reporting should not be the primary focus of the quality assurance provisions in the proposed regulations; instead, the focus should be on error prevention. CMS needs to ensure that participating plans provide access to sufficient data in electronic form in real-time to permit the electronic prescribing function to consider those variables before a script is produced. Any error that does occur should receive a detailed review to ensure that the system failures that contributed to that error or event are eliminated.

Although ADEs cannot be predicted, they often can be prevented using computerized systems that monitor patients; provide physician ordering capabilities; integrate pharmacy, patient and lab data; and trace the incidence of ADEs. Use of electronic prescribing systems, bar codes and clinical decision support systems can initiate interventions to mitigate the effects and lessen the severity of reactions.

With respect to reporting measures, McKesson supports creating an environment for health care providers to report ADEs where repercussions are not feared. Peer review

protection supports open and honest reporting for system failures, thereby leading to prevention strategies, better patient outcomes and lower health care costs. Costs of ADEs are very high and patients can suffer irreversible injuries that can result in permanent disability or death.

McKesson encourages CMS to foster or create incentives for quality assurance standards including:

- Complete review of patients' medication history and medical records by providers prior to prescribing;
- Evidence of active participation by pharmacists in consultation with prescribers on medication ordering, interpretation, review and monitoring of medication use;
- Use of clinical informatics and technology to promote patient safety;
- Patient safety research dissemination and education;
- Regular assessment of effective working conditions that promote patient safety and incorporate principles of human factors; and
- Error reporting, analysis, and peer review protections to allow enhanced use of data to identify and measure improvements.

D.2.c - Medication Therapy Management Programs

Congress and CMS have recognized the value provided by cognitive services to better manage drug costs, medical costs and outcomes for patients. We commend lawmakers for requiring that each PDP and MA-PD plan include a MTMP for Medicare beneficiaries. Previous studies have shown that as much as 45% of the general population and 88% of the population aged 65 years and older have one or more chronic conditions, and that more than 75% of all U.S. health care expenditures are related to the treatment of chronic conditions (Hoffman C, Rice D, and Sung HY. *Persons with chronic conditions: their prevalence and costs*. JAMA 1995; 276:1473-1479).

Proposed regulations for MTMPs represent an opportunity to advance the nation towards a coherent, effective approach for managing drug regimens more effectively. As drug regimens become more complex and patients take multiple drugs for concomitant diseases, the need for effective therapy services increases. McKesson believes that outpatient and specialty pharmacies, experts in both pharmaceuticals and therapy, are well suited to support therapy management services.

To achieve its goals, regulations for MTMPs need to include more specific standards for eligibility, benefit and compensation.

Eligibility - McKesson recommends that MTMPs should be made available to all patients who are taking two or more drugs on a long-term basis or are suffering from disease states where non-compliance with prescribed medication therapy might lead to

near-term or immediate ADEs. These disease states include, but are not limited to, diabetes, congestive heart failure, hypertension, asthma, chronic obstructive pulmonary disease, coronary artery disease, oncology, hepatitis C, chronic pain, depression, and dementia, and all require active drug therapy management. Beneficiary enrollment should be voluntary; however, plan sponsors should also be able to document on request that MTMP services have been made available to all eligible Medicare beneficiaries in their plan.

Benefit - McKesson believes CMS should define a consistent standard for MTMP services for plan sponsors. The consistent application of MTMPs across the nation will ensure that beneficiaries, regardless of region or plan sponsor, will have access to the same level of care. Pharmacists participating in multiple plans will also benefit because their MTMPs will remain constant for all beneficiaries. In addition, a baseline standard for care will allow CMS to analyze best practices and track improved health outcomes. The MTMPs should promote adherence to prescription medications, evaluate and monitor patient response to drug therapy, provide counseling on potential side effects and refer patients back to physicians for follow-up. The program should provide written materials upon enrollment that establish the parameters of the program and contain health information relevant to the patient and his/her therapy.

Medication therapy management services are individualized patient care services and will need to be focused on each patient's specific needs. We would like to encourage CMS to consider further guidance regarding the proposed services. McKesson supports the *"Medication Therapy Management Services Consensus Document"*, endorsed by eleven national pharmacy professional organizations. The agreement defines critical issues in support of effective medication management, including:

- The need to formulate a patient-specific treatment plan;
- The importance of monitoring therapy and identifying and resolving medication-related problems;
- The importance of educating patients about their therapy;
- The preference for face-to-face interactions between the pharmacist and the patient; and
- The need for adequate reimbursement consistent with contemporary health care provider rates.

MTMPs should be performed by licensed health care professionals, who have an appropriate level of expertise in providing medication therapy services. Our preference would be that all initial consultations between a qualified health care professional and the patient occur face-to-face, although subsequent consultation can be provided using other communication channels. In person communication will permit the necessary dialogue between a health care professional and a senior, and highlight issues that may not be readily apparent from a phone conversation. However, we recognize that other forms of

communication between licensed health care professionals and patients can be utilized effectively to provide medication therapy management services. As one example, medication therapy services for orphan drugs, administered by specialty pharmacies via telephonic or other forms of communication, have been highly successful in educating patients and ensuring compliance with needed therapies.

Compensation - It is important to differentiate the services provided within an MTMP with those associated with simply dispensing a prescription drug. McKesson strongly endorses appropriate compensation to pharmacists or other health professionals for administering MTMPs on a fee-for-service basis or case rate basis. As the value that MTMPs provide is recognized and measured through outcomes analysis, we believe it should be factored into future criteria for establishing appropriate minimum compensation levels.

We also recommend that CMS establish standard methods to bill for MTMP services. The method of payment needs to consider differences in the mechanisms by which claims for prescription drugs and claims for professional services are handled. The NCPDP Telecommunication Standard may adequately accommodate the requirements for proper billing of some services or service components. To the extent necessary, modifications should be made to the NCPDP standard or to the standard currently in use for the specific care setting (for example, ambulatory care setting) to incorporate additional data elements as necessary.

D.4 – Electronic Prescription Program

McKesson applauds the efforts of the National Committee on Vital and Health Statistics (NCVHS) relative to the development of standards and recommends that they be actively involved in any decision to ratify a standard or to alter the timeframe for a pilot program or full implementation.

Comments were requested regarding additional steps to spur adoption of e-prescribing or to overcome obstacles to implementation. Although incremental reimbursement was discussed, McKesson is concerned that there has not been adequate discussion of the structural and workflow challenges that limit electronic prescribing to less than the ten percent of U.S. physicians, as noted by HHS. These challenges arise from many areas:

1. To support effective e-prescribing and quality assurance, it is essential that a minimum data set be electronically accessible to the provider. As an example, plan sponsors currently are not required to supply critical data to the provider regarding a patient's medication history and known medical conditions. A reasonable condition of participation would be that each plan makes such information accessible to both the patient and to any provider authorized by the patient.

2. Each plan should provide such required information in a consistent, standardized manner so that a single provider or application vendor does not have to use multiple access methods to find critical clinical data depending on the PDP or MA-PD.

3. For code sets as with messaging standards, it is essential to identify and address intellectual property issues prior to adoption. Since standards form a natural monopoly, it is preferable that they be publicly owned.

4. All programs for electronic prescribing assume that there is a means for positive identification of the patient or enrollee. A consistent and accurate means for addressing this issue is as critical for successful implementation of electronic prescribing as it is for successful adoption of the electronic health record (EHR). Consistency in approach for these two important initiatives is crucial to the success of these efforts.

While these comments address system or structural issues impacting adoption, McKesson agrees that differential reimbursement will be required to spur adoption. To that end, we would propose a phased implementation of incentives to compensate physicians for increased use of electronic prescribing tools in their practice. We recommend that phased requirements, as advocated by the Bridges to Excellence program Physician Office Link program (www.bridgestoexcellence.org), be considered. Initial adoption should be compensated at a rate that declines over time; a "full" rate should only be maintained over time by achieving certain performance goals for particular classes of patients. Such a plan encourages both initial use and sustained use over time.

We have serious concerns regarding the adoption of e-prescribing as a stand-alone system as opposed to its inclusion as a critical component of a larger electronic health record. Increasingly, hospitals and physicians are adopting integrated solutions that combine e-prescribing with other components of an EHR system. In fact, isolated e-prescribing applications in the ambulatory environment may not even exist by the time these standards are effective in 2009. To that end, we want to ensure that, if providers adopt an integrated EHR system, they will not lose the incentives uniquely applied to the e-prescribing component of that solution, specifically the safe harbor provisions from the Stark anti-fraud and anti-abuse statute that are noted in the Medicare Modernization Act.

G - Payments to PDP Sponsors and MA Organizations

G.4.a - Requirement for Disclosure of Information; Data Submission

We would recommend that the data transmission to CMS for utilization capture be consistent with the NCPDP format for on-line adjudication or the American Society of Automation in Pharmacy (ASAP) format, a telecommunications format for reporting

Controlled Substance use. Such standards are in use today and would cause minimal impact on existing software solutions.

J - Coordination under Part D Plans with other Prescription Drug Coverage

J.6.e - Tracking True-Out-of-Pocket (TrOOP) costs

McKesson supports and recommends a centralized approach to determining and reporting TrOOP information. This centralized approach should include enrollee costs which are incurred across multiple service providers within the PDP network, as well as any out-of-network incurred costs, including costs covered by manufacturer-sponsored patient assistance and similar charitable programs.

The structure of the coordinating body could be based on the "Common Working File" model which is currently in use and is maintained by CMS for beneficiary enrollment, entitlement, and adjudication data. To that end, we prefer Option 2, as outlined, which would establish a TrOOP facilitation contractor as a single point of contact between payers. To avoid conflicts of interest, the facilitation contractor should not be a PDP. Pharmacies do not have the capability to determine and report TrOOP information to the beneficiary, and, therefore, should not be responsible for having to communicate such information.

R - Payments to Sponsors of Retiree Prescription Drug Plans

In line with the stated goals of the Medicare Modernization Act to provide employers with the incentives and flexibility to maintain prescription drug coverage for their retirees, and as a large national employer, we would like to address the following critical concerns:

R.1.a. – Options for Sponsors of Retiree Prescription Programs

McKesson supports the proposal for employers to contract with one regionally qualified PDP that has a national network instead of several different regional PDPs. A national, rather than a regional, approach for large employers would allow for more efficient and effective administration of benefits and would also provide a consolidated data source for timely and accurate reporting to CMS. Additionally, we suggest that CMS encourage employers to elect the wrap-around option by sharing the savings resulting from the lower cost of reinsurance.

R.2 - The Retiree Drug Subsidy Provision - Definitions

Group Health Plan - We recommend that employers who have groups of individuals with differing subsidy formulae have discretion in declaring whether these groups constitute one or several plans. In this way, employers will be encouraged to aggregate

groups in an actuarially equivalent plan and continue coverage with a subsidy. Only those groups with a very low employer subsidy would be identified for transition to a Medicare Part D plan. Otherwise, some employers will not be able to meet actuarial equivalence with any of the coverage they provide to retirees.

Allowable Retiree Costs – Proposed methods for determination of the net cost of a drug as well as calculation and payment of subsidies recognize the inefficiency of repricing costs after point of sale with the application of discounts, rebates, and chargebacks.

We believe it is in the best interests of CMS, employer sponsors and informed consumers to create an electronic process with access to necessary demographic and eligibility data and to all elements of multiple plan provisions at the point of sale. Such a process would provide immediate data for the calculation of participant out-of-pocket costs and the employer subsidy.

The delays in receipt of employer plan subsidies that are inherent in the current proposal could cause employers to reject the employer subsidy option.

R.3.b.1 - Attestation Requirements

Proposed regulations would require an annual attestation of actuarial equivalence by employer plan sponsors. Annual attestation would impose an additional burden on employer sponsors already burdened with requirements such as those under the Federal Accounting Standards (FAS). As long as no material changes have been made in prescription drug coverage or subsidy from one plan year to another, we recommend that the re-determination of actuarial equivalence and attestation be required only once every three to five years. This would relieve employers of burdensome and costly actuarial work, while the lack of material change would preserve the benefits of participants. In lieu of attestation of actuarial equivalence, the employer sponsor would attest to the lack of any material changes in the plan with their application for a subsidy.

R.5.b – Payment Methodology

Assuming that the true cost of a drug can be reflected at the point of sale, we suggest that the subsidy payment be made on a monthly basis for employers who can provide required data electronically. If “net cost of drug” continues to require recalculation at the end of the reporting period, Alternative 3 would be the most favorable option. It would expedite payments to plan sponsors.

III - Medicare Program; Establishment of the Medicare Advantage Program [CMS-4069-P]

D - Quality Improvement Program

D.*2 - Quality Improvement Program*

We strongly recommend that quality performance incentives be utilized to encourage all providers to participate in quality improvement initiatives. These initiatives provide an important means of improving quality of care through adherence to evidence-based national guidelines of care. Performance incentives might include enhanced payment rates and rewards if quality improvements are demonstrated.

We urge CMS to encourage plan sponsors to tie their quality improvement programs to those of local Quality Improvement Organizations (QIOs) efforts to ensure consistency and optimization of state quality initiatives. CMS has a tremendous opportunity to link all quality improvement programs to improve care, health status, outcomes and beneficiary satisfaction for all beneficiaries. Therefore, it is critical that plan sponsors use the same metrics to measure performance, thereby allowing beneficiaries to compare performance across various plans.

D.4 - Quality Improvement Projects

We commend CMS for recognizing the value of chronic care improvement programs and recommend that careful consideration be given to the design and monitoring capabilities of these chronic care programs. McKesson recommends the adoption of the Disease Management Association of America (DMAA) definition of disease management as its definition of Chronic Care Improvement Programs (CCIP). This definition has been adopted by three national accreditation organizations.

> Disease Management is a system of coordinated healthcare interventions and communications for populations with conditions in which patient self-care efforts are significant. Disease management:
>
> - Supports the physician or practitioner/patient relationship and plan of care
> - Emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies, and
> - Evaluates clinical, humanistic, and economic outcomes on an ongoing basis with the goal of improving overall health.

Disease Management Components include:

- Population Identification processes;
- Evidence-based practice guidelines;
- Collaborative practice models to include physician and support-service providers;
- Patient self-management education (may include primary prevention, behavior modification programs, and compliance/surveillance);
- Process and outcomes measurement, evaluation, and management; and
- Routine reporting/feedback loop (may include communication with patient, physician, health plan and ancillary providers, and practice profiling).

McKesson recommends that MA plans offering an MA-CCIP should be accredited by at least one national accrediting body: the National Committee on Quality Assurance (NCQA), the Joint Commission on Accreditation of Health Care Organizations (JCAHO), or the American Accreditation Healthcare Commission (URAC).

We also recommend that CMS encourage MA-CCIP programs for the following conditions: heart failure, chronic obstructive pulmonary disease, diabetes and coronary artery disease. Criteria to evaluate the effectiveness of a chronic care improvement program are necessary to ensure quality of care is impacted. Measurement of program outcomes should include:

- Measurements of quality improvements using clinical variables, such as daily weight monitoring or ACE inhibitor usage for heart failure programs. Health status and functional status measures should also be included;
- Measurements of utilization improvement, such as reductions in emergency room visits and hospital admissions;
- Measurements of beneficiary and provider satisfaction;
- Overall performance and quality improvement evaluation criteria; and
- Measurement of total cost savings, including all direct costs obtained through the use of either pre/post population analyses or prospective cohort analyses.

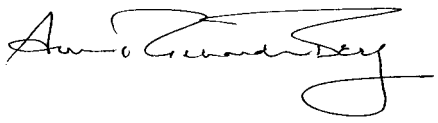
Finally, chronic care improvement programs should address the importance of the physician as a vital member of the care management team. Specific efforts should be made to engage physicians, provide continuing medical education and formulate quality incentive programs to encourage their adherence to evidence-based medicine.

Conclusion

As a major healthcare supply management and information technology company, McKesson appreciates the opportunity to share its views on the proposed regulations to implement the Medicare Prescription Drug Benefit. We applaud the agency's interest in soliciting industry input on these regulations and appreciate your efforts to present realistic and reasonable solutions for consideration. We share your commitment to ensure that these regulations result in a workable and successful program, and we look forward to working with CMS and the Administration on the implementation of the final rule.

Please do not hesitate to contact us with any questions.

Sincerely,



Ann Richardson Berkey
Vice President, Public Affairs

CMS-4068-P-1288

Submitter : Thomas Boudreau **Date & Time:** 10/04/2004 09:10:58

Organization : Express Scripts, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Comment on Title I - Prescription Drug Programs

CMS-4068-P-1288-Attach-1.doc

October 4, 2004

The Honorable Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: File code CMS-4068-P

Dear Dr. McClellan:

Express Scripts appreciates the opportunity to comment on the NPRM for the Medicare Prescription Drug Benefit (CMS-4068-P) that was published in the Federal Register on August 3, 2004.

Express Scripts is one of the largest pharmacy benefit management (PBM) companies in North America, serving thousands of client groups including managed care organizations, insurance carriers, third-party administrators, employers, government and union-sponsored organizations. We currently provide pharmacy benefit services to six million seniors enrolled in a variety of funded retiree health plan arrangements.

Our company strongly supports new federal coverage for prescription drugs to meet the pressing health care needs of the nation's senior and disabled population. We have worked on a bipartisan basis with both the Administration and Congress during the legislative process leading up to passage of the Medicare prescription drug bill. Utilizing a competitive, private sector-based model to administer the new Medicare drug benefit is a sound policy approach to ensure that seniors have access to a choice of high quality, cost effective plans. Express Scripts is currently evaluating a variety of options for participating in the new Medicare drug benefit, including support of our existing employer, government and Medicare Advantage clients. We are also analyzing the requirements associated with bidding to serve the Medicare program as a prescription drug plan (PDP).

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Implementing the new Medicare drug benefit by January of 2006 will present tremendous operational and policy challenges for both the federal government and the private sector. Express Scripts looks forward to working with CMS and other interested parties in refining the draft rule during the coming months to ensure that the new drug benefit is implemented in a way that equitably serves the needs of Medicare beneficiaries, the government, and program contractors.

Express Scripts' comments on the NPRM are divided into two parts: summary comments and recommendations focusing on the structure and implementation of several key elements of the new drug benefit, and more specific comments regarding various technical issues identified in individual sections of the proposed rule (Attachment 1). In addition, we urge consideration of the comments made under separate cover from the Pharmaceutical Care Management Association (PCMA), which is the national trade group for PBMs. The PCMA comments include recommendations on several industry-wide issues contained in the NPRM.

Summary Comments and Recommendations

Express Scripts offers the following summary comments and recommendations regarding the Medicare prescription drug benefit NPRM.

1. Ensure Availability of Pharmacy Benefit Management Tools

Effective cost management of the new Medicare drug benefit necessitates that participating PDP and MA plans be allowed to utilize the full array of pharmacy benefit management tools commonly utilized in the commercial market. In fact, government expenditure estimates regarding the new benefit assume the availability of pharmacy cost management tools as a means to ensure the long term affordability of the benefit, and as a means to promote private sector participation in the offering of risk-based drug plans.

We are encouraged that H.R. 1, and the draft regulation, provides reasonable flexibility to participating entities utilizing various cost management strategies to mitigate unwarranted expenditure growth in the drug benefit and enables the provision of drug plans that are comprehensive and clinically appropriate. While the new Medicare drug benefit limits certain cost management techniques commonly employed in the commercial market, it nonetheless envisions the use of critical pharmacy benefit tools such as formularies, step therapy, prior authorization, pharmacy networks and mail service delivery. We would caution that the imposition of further restrictions on the use of pharmacy benefit tools in the final rule would negatively impact the interest and ability of PBMs and other entities to participate in the program as PDPs.

In particular, Express Scripts believes that the adoption of reasonable and appropriate formulary development guidelines is a critical element of the rulemaking process. We have previously provided separate comments to the United States Pharmacopeia (USP) regarding its proposed Medicare prescription drug model formulary guidelines. It is very important that the final guidelines provide flexibility to PDP and MA plans in the development of clinically appropriate formularies, and to ensure a vigorous competition between drug manufacturers for placement of

prescription products on the formulary. Inclusion of additional drug categories or therapeutic classes in the final USP model guidelines, above the expansive listing already included in the draft, will significantly impair drug plan formulary flexibility, and therefore, negatively impact cost management activities. Creating a reasonable set of formulary guidelines for the Medicare drug benefit will ensure that participating beneficiaries receive a cost effective, safe, and clinically appropriate range of medications.

To effectively manage the drug benefit we also recommend that plan sponsors be provided full flexibility to utilize appropriate step therapy and other utilization management tools at both the Pharmacologic Class and Recommended Subdivision levels. At the Class level, for example, plans should be permitted to implement step therapy programs that permit the use of first line, cost effective therapies prior to the use of second line therapies. For example, at the subdivision level, plan sponsors should be able to ask the prescribing physician to use generic ACE-Inhibitors prior to approving an Angiotensin-II Receptor Blocker, or an NSAID prior to a prescription for a COX-2 agent while allowing the physician to select the second line agent if, in their clinical judgment, the patient should receive the second line agent. Similarly, where appropriate, the plan sponsor should be allowed to ask a prescribing physician to use a first line agent in one category prior to the use of a second line agent in another category yet allowing the physician to select the second line agent if in their clinical judgment it is most appropriate for the patient. We support coupling such utilization management programs with a reasonable exceptions process to ensure the availability of alternative drug therapy regimens when clinically appropriate.

We want to offer our unqualified support and encouragement for another pharmacy benefit tool contained in H.R. 1, and the draft rule, that holds considerable promise to increase patient safety and promote prescription drug compliance—the use of e-prescribing in the Medicare program. E-prescribing is a landmark feature of the Medicare legislation, and in the short term is one of the most important initiatives available to improve the delivery of health care in America.

Express Scripts is encouraged that the National Committee on Vital and Health Statistics (NCVHS) appears to be making good progress in the standards development process for e-prescribing, and that there appears to be broad bipartisan consensus regarding the value of e-prescribing. We encourage continued high level CMS attention to this issue, especially efforts to expedite the implementation timetable for the development of standards and to leverage industry experience in the areas of patient identification, and prescription and benefit information transmission. E-prescribing should be made available to Medicare beneficiaries well in advance of the 2008 statutory deadline.

2. Facilitate/Encourage PDP Stand-Alone Drug Plan Participation

Creation of a viable market of competing private sector PDPs to offer stand-alone drug plans is one of the key challenges involved in implementing H.R. 1. While Express Scripts is exploring possible participation in Medicare as a PDP, there are a number of significant issues/obstacles in the draft rule that could deter interest and participation in this new delivery option. We encourage CMS to take additional measures in the final rule to encourage participation by PBMs in the PDP option, especially in the initial years of the program.

A. Limit Risk Exposure in Startup Years

H.R. 1, and the draft rule, outline the level of insurance/utilization risk that will be borne by full or partial risk PDP vendors interested in offering stand alone drug plans to Medicare beneficiaries. While the federal government will provide subsidies and reinsurance to mitigate potential financial losses incurred by participating PDPs, the level of risk exposure borne by the PDP is potentially significant, which will deter the number of competitive offerings in this option unless the program protects against adverse risk selection.

Given the uncertainties regarding the level of beneficiary participation in the initial years of the benefit, and the lack of data regarding their anticipated level of drug usage, participating PDPs could suffer significant financial losses in the startup years of the program as a result of adverse risk selection unrelated to effective drug plan management efforts. We urge CMS to explore mechanisms to reduce PDP risk exposure in the initial years of the program as a way to encourage the creation of a vibrant PDP market which offers choice to Medicare beneficiaries.

On the critical issue of establishing a workable risk adjustment mechanism for the drug benefit program, CMS should make every effort to spell out and ensure the creation of an average risk pool of beneficiaries for participating PDPs. Drug plans should be rewarded for effective cost and clinical management of their beneficiary population, not on the basis of a favorable draw of lower risk (i.e. lesser utilization) participants. Conversely, PDPs should not be rewarded due to favorable risk selection. Unless the risk adjuster is properly constructed, it is possible that one PDP could do a poor job of effectively managing utilization/cost of their membership, and still benefit financially through a better than average enrollee risk profile, while another plan sponsor could effectively manage their enrolled population but still incur significant financial losses due to adverse selection. Implementation of an effective drug risk adjuster will partially address PDP financial exposure issues. However, PDP and MA plan sponsors must be rewarded for effectively managing the risk, not on the basis of a favorable selection of beneficiaries.

B. PDP Licensure Requirements and Establishment of Regions

The draft rule outlines a process and timetable by which participating PDPs will obtain state insurance licensure and/or a temporary federal waiver regarding licensure and solvency requirements. The NPRM also indicates that a decision will be made by 1/1/05 regarding the establishment of PDP (and MA) contracting regions. Express Scripts believes that these two interrelated activities will be important factors in determining the ability and interest of independent PDPs (i.e. entities not owned or otherwise affiliated with a state licensed insurance entity) to participate in this portion of the program.

The draft rule provides some level of flexibility regarding the requirements for risk bearing PDPs to obtain state insurance licensure in the initial years of the new Medicare drug benefit, and under certain circumstances, requiring initial licensure in only a subset of states in a

region. However, depending on the number of PDP regions established, this flexibility may not be an incentive for PDP participation.

CMS should consider establishing different regions for participating PDP and MA-PD plans. The two offerings have very different characteristics in terms of provider contracts, beneficiary enrollment, and, other substantive operations..

Express Scripts recommends that CMS implement a regional structure that provides PDPs with the flexibility to bid to on either a regional or state specific basis. Under this regional "stacking" approach, CMS would establish multi-state PDP bidding regions. Some of the largest states (e.g. California) may constitute their own region. However, we believe that in certain regions, CMS should allow PDPs the option to bid in only a subset of states in a region. For example, if a mid-atlantic region consisting of New York, New Jersey, Pennsylvania and perhaps several other states is established, PDPs should be given the option of bidding to participate in the entire region or in a subset of states within the region.

This approach would enhance PDP competition, enable entities of differing sizes to determine the level of risk that can be reasonably assumed, and increase the ability of PDPs to aggressively negotiate discounts from other segments of the pharmaceutical chain. In addition, a flexible contracting approach would be consistent and analogous with other provisions of the NPRM that permit local HMOs to submit bids covering only a portion of a state.

Establishment of fifty separate state regions or similar contracting approach for PDPs in the final rule will create a significant problem for PDPs seeking to obtain state licensure or a federal waiver to enable participation in one or more regions. For example, under a regional PDP approach interested PDP entities would be required to obtain upfront licensure (or a federal waiver) in only a subset of states to be served. However, under a fifty region approach state licensure and/or a waiver would be required in each jurisdiction to be served prior to 1/1/06. This would be an extremely difficult task, especially under the tight timeframes required for initiation of the program in 2006.

Express Scripts strongly urges CMS to provide flexibility in the final rule regarding its PDP contracting and licensure requirements.

Attached please find additional technical comments (Attachment 1) on the NPRM. We thank you for the opportunity to comment on these proposed rules and regulations.

Sincerely,

EXPRESS SCRIPTS, INC.
By: /s/ Thomas M. Boudreau
Senior Vice-President and General Counsel

Attachment 1.

Comments on Specific Sections of the NPRM File Code CMS-4068-P

Express Scripts offers the following comments regarding provisions contained within specific sections of the NPRM.

Subsection B – Eligibility and Enrollment

§ 422.50-422.80, §423.34
Auto enrollment of dual eligibles

Comment:

If states and sponsors are to be responsible for auto enrollment of dual eligibles, there must be precise control over the accuracy of the data and explicit operational instructions for sponsors and states. We learned from the discount card experience that marketing and enrollment direct marketing are not efficient and are very expensive. We encourage CMS to early in the process extend auto-enrollment for seniors that are above 150%. The defining point for this group would be adjusted annually as needed but might start at the 300% FPL. This would ensure beneficiaries access a covered drug benefit. It also would assist CMS in controlling Part A and/or Part B costs associated with the lack of drug use/coverage.

Recommendation:

This process should utilize electronic data capture and transfer to be most efficient. A standard process, including file formats, should be established to minimize the requirements for plan sponsors establishing support systems. These auto-enrollment policies and procedures should be standardized for use with other auto-enrollment support services. We would be happy to assist in the formation of the standard process.

Preamble B.5, §423.42
Enrollment mechanisms

Recommendation:

The enrollment process, while supporting paper applications, should include support for technological advances that make data management more accurate and efficient. This should include the use of Internet technologies, appropriate security mechanisms and verifications and confirmations back to the beneficiary of their actions and requests. A system similar to what is in place for FEHBP beneficiaries could be modeled.

Any enrollment system should accommodate those who may need to use alternate forms of communications (through an interpreter or interpretive device), including phone, fax and other forms.

Preamble Section B.6; §423.44, §423.46
Dis-enrollment by the PDP

Comment:

Enrollees should have the primary responsibility for notifying their plan of address changes. This would be consistent with today's processes.

Preamble Section B.8, §423.48
Information CMS provides to beneficiaries

Comment:

While beneficiaries will need information for plan decision making, CMS should ensure that information provided allows for a fair comparison of plans. CMS should specify exactly what plan sponsors should provide when plans will be compared. Lessons from the discount card indicate that a lack of specificity can result in misleading comparisons which results from lack of uniform data submission by plan sponsors.

Preamble Section B.9; § 423.50
Approval of marketing materials and enrollment forms

Comment:

The File and Use process has proved efficient and effective and we support its continued use.

Statute reference 1860D-1(b)(4)(A), Preamble Section B.10
Information provided to PDP sponsors and MA organizations to assist in marketing and outreach.

Comment:

Plan sponsors would benefit from accurate data on Medicare eligibles in the regions they will be servicing. This information should include basic demographics (name, address, city, state, zipcode, DOB, phone number, email address.) This information should be provided to all plan sponsors and not just on request, minimally annually.

Plans should be allowed to specifically designate information that differentiates their plan above and beyond the CMS base standards. Plans should also be allowed to market additional services (e.g. federally approval health-related products and services like HSA products) that plan beneficiaries may be interested in, subject to CMS approval and consistent with the goals and objectives of the Medicare Part D program.

Plans should be allowed to market to existing plan enrollees, including discount card enrollees, via phone, email or direct mail. Beneficiaries may be allowed to select a preferred route of communication.

Plans should be allowed to communicate with existing enrollees without prior CMS approval, within HIPAA guidelines during the 2005 open enrollment period. Drug discount card sponsors should be able to propose Part D drug coverage to beneficiaries who participate in their discount card.

Subsection C – voluntary prescription drug benefit and beneficiary protections

Statute reference 1860D-2(e)(2)(B), Preamble Section C.1.a
Part D versus Part B drug coverage. How can claims be most effectively processed?

Comment:

We understand that a definitive list of Part B drugs is not available and that local coverage decisions may affect coverage determination status. However, PBMs need to process the claim at the point of sale within seconds and the business rules must be clearly defined.

Recommendation:

There needs to be an appropriate set of rules in place to allow the claims routing to identify drugs likely to be covered under Part B versus Part D. A complete list of part B drugs is needed for PDP plans to proceed to prepare for the Part D program. Further, CMS should provide guidance on how it will determine which drugs will be included in Part B and wish drugs will be included in Part D. Any processing rules should be uniform and consistently applied across drug plan sponsors. Pharmacists should be encouraged to solicit from the beneficiary information that will increase the likelihood of the claim being routed to the appropriate plan sponsor. For example, some transplant drugs are only covered when the transplant was Medicare covered. At the point of claims adjudication, today there is no way to know if the transplant was Medicare covered. PBMs can provide specific guidance through messaging.

Statute reference 1860D-2(d)(1)(B); 1860D-15(b)(3)(e)(1)(b). Preamble C.1.b
Dispensing fee defined

Comment

CMS proposes 3 definitions:

1. ingredient cost plus dispensing fee
2. above plus supplies and equipment necessary for the drugs to be administered
3. above plus activities associated with ensuring proper ongoing administration of the drug (nursing visits and clinical pharmacist activities)

The infrastructure today does not allow the claims process to identify that the claim is a home infusion therapy related claim or that the supplies are tied to the medication.

Recommendation:

We support having the dispensing fee include only those activities related to the transfer of possession of the covered part D drug from the pharmacy to the beneficiary (mixing drugs, delivery, overhead). The gaps that exist with home infusion can be covered through an ancillary fee process that is set by the plan sponsor and negotiated with the participating pharmacies.

Preamble Section 2.a
I/T/U pharmacies and HIS beneficiary participation

Comment:

CMS has requested comments on how I/T/U pharmacies and IHS beneficiaries will achieve maximum participation in Part D benefits.

Recommendation:

Allow AI/AN enrollment as with the general population and contract ITU facilities in network as any other retail pharmacy.

Preamble Section C.3.b
Formulary Requirements

Comment:

P&T committee decisions should be binding on the formulary, but the P&T Committee should not be required to be part of tier design, nor should it be required to develop Step Therapy, PA, and generics programs.

Recommendation

CMS should remove the requirement that P&T committees develop UM programs given their ability to handle the workload involved and their level of expertise in program development. It is vital that P&T committees fulfill the role envisions in the Medicare Modernization Act to provide clinical recommendations in developing the formulary. These clinical experts should not be charged with the authority to manage and administer an entire drug benefit plan.

Comment

All members of the P&T Committee should be required to be independent of pharma and have no financial stake in formulary determinations.

Recommendation

We support strengthening the statutory requirement in section 1860D-4(b)(3)(A)(ii) of the Act by requiring all pharmacists and physicians on the P&T committee to be independent and free of conflict. This follows our current business model. To maintain the independence of the P&T committee, their focus should be on the clinical integrity of the formulary. The sponsor has the responsibility to design programs that respect the clinical integrity of the formulary and thus should need to obtain P&T committee approval of the specific programs.

Comment

The determination that a formulary is discriminatory does not sufficiently identify the criteria used to make these determinations. Even plans that follow the USP guidelines could be considered discriminatory based on drugs selected for formulary inclusion.

Recommendation

It is not the structure in and of itself that defines an adequate formulary. It is the application of sound clinical review by independent panels of practicing physicians and pharmacists, commonly referred to as Pharmacy & Therapeutics (P&T) Committees, which results in formularies that meet the needs of plan beneficiaries, while achieving the necessary cost balance to make benefits affordable.

Comment

It appears there is a concern regarding special populations and the drug coverage they will be allowed.

Recommendation

If CMS wishes to increase the number of choices available for certain special populations, they should designate what those populations are and give guidance to PDP plans as to what they determine to be an adequate choice.

Comment

CMS has invited comment on the minimum timeframes for periodic evaluation and analysis of protocols and procedures related to a plan's formulary.

Recommendation

Analysis of treatment protocols should be done as part of an annual update of the formulary to ensure adequate selection of agents to meet the treatment needs of the covered beneficiaries. This reflects current business practices.

Comment

Notification in writing of members and practitioners affected by formulary changes places a large burden on the plan sponsors.

Recommendation

It would be appropriate for plan sponsors to notify beneficiaries in writing if their drug is going off the formulary during the plan year. Professionals should be required to use internet services.

Statute reference 1860D-4(b)(1)(C); Preamble Section C.4.a; § 423.120 Pharmacy Access Standards

Comment

We believe the 'any willing provider' language allows for the participation of all pharmacies in the plan networks.

Recommendation

For a pharmacy to participate as an 'any willing provider" pharmacy, CMS should not require that plans offer anything different from what would be offered to a standard participating pharmacy. Plans should be allowed to negotiate individual terms as the market may dictate. CMS should recognize that there are different services required to meet the needs of enrollees in long term care facilities.

The incentives on both sides would need to be aligned to make it attractive for plans to include infusions pharmacies in the network and sufficient for these pharmacies to want to join.

Preamble Subsection C.4.1
Standard Network contracts

Comment

The pharmacy network inclusion standards must provide adequate access as well as allow for competitive differentiation within the network. We support any means that allows for differentiation in the network with the end result of providing a competitively priced product to the beneficiary.

We would expect any willing provider, at a minimum, to have the ability to process claims electronically using the current standards.

Recommendation

Standard network contracts should not be required to meet 'reasonable and relevant' requirements. Plan sponsors should have the flexibility to craft and be allowed to set the terms of a plan's standard contract. This will create the best network access with the best prices for the beneficiaries.

Statute reference 1860D-4(b)(3)(A); Preamble Subsection C.4.b; § 423.120(b)(1)
Formulary requirements

Comment:

We have submitted comments to the USP. The draft guidelines provide a framework for P&T discussion at the category and class level. Additionally USP's decision to recommend a minimum of one drug from each of the subdivisions mirrors our own approach to formulary development. Any requirement from CMS to alter this recommendation and potentially require more than one drug from each subdivision would hinder our ability to provide a comprehensive and cost-effective formulary.

Plans sponsors should not be precluded from requiring preauthorization, based on sound clinical review and appropriateness, for all listed drugs within individual categories or classes.

Recommendation:

It is very important that the final guidelines provide flexibility to PDP and MA plans in the development of clinically appropriate formularies, and to ensure a vigorous competition between drug manufacturers for placement of prescription products on the formulary. Inclusion of additional drug categories of classes in the final USP model guidelines, above the expansive listing already included in the draft, would significantly impair drug plan formulary flexibility and cost management. Creating a reasonable set of formulary guidelines for the Medicare drug benefit will ensure that participating beneficiaries and the federal government receive the maximum level of discounts

possible as a way to hold down program costs coupled with a clinically appropriate range of medications.

To effectively manage the drug benefit we also recommend that plan sponsors be provided full flexibility to utilize appropriate step therapy and other utilization management tools at both the Pharmacologic Class and Recommended Subdivision levels. At the Class level, for example, plans should be permitted to implement step therapy programs that permit antileukotriene medications to be used only after other more effective and affordable treatments for asthma or allergic rhinitis have been tried. Comparably at the Subdivision level, plan sponsors should be able to promote the use of generic ACE-Inhibitors prior to approving an Angiotensin-II Receptor Blocker, or an OTC NSAID prior to a prescription for a COX-2 agent. We support coupling such utilization management programs with a reasonable exceptions process to ensure the availability of alternative drug therapy regimens when clinically appropriate.

Statute reference 1860D-4(b)(2)(A); Preamble C.4.c; § 423.124
Out of network coverage

Comment:

While we understand the need to provide out of network provisions, cost effective benefits cannot be provided to beneficiaries with paper claims. Additionally, a paper claims process increases the risk associated with not calculating benefit thresholds and may cause a beneficiary to pay more than necessary for medications.

Recommendation:

Minimize the requirements for plan sponsors to retroactively modify claims databases to accommodate paper claims tracking. Should CMS need to require claims modification under specific circumstances, CMS should be specific in the timeline under which these modifications are required, e.g. 60 days.

Preamble Subsection C.5; §423.100, §423.124(b)
Definition of plan allowance

Recommendation:

Agree that out of network pharmacy payment should be reduced to the network contracted rate in order to disincent members from filling scripts at non-participating providers and encourage provider enrollment in the network. This is with the understanding that the enrollee picks up any cost differential. Since the provider has chosen not to participate, any out of network claim would require submission by the member; the member would be responsible for paying any differential owed to the pharmacy.

Subsection C.5, §423.124(b)(2)
Definition of Usual and Customary

Comment:

Standard industry definition - Amount charged cash customers for the prescription exclusive of sales tax or other amounts claimed. CMS would need to retroactively audit

out of network provider's U&C as is currently done with network providers in the commercial business.

Statute reference 1860D-4(k)(1); Preamble Subsection C.7; § 423.132
Public disclosure of pharmaceutical prices for equivalent drugs

Comment:

Information on lowest priced generic drug equivalents provided to enrollees is a valuable means to helping beneficiaries and plans save money.

Recommendation:

This requirement should not be waived for Private Fee for Service (PFFS) plans as there would be many missed opportunities for generic savings.

Subsection D – Eligibility, Election and Enrollment

Subsection D.2.1; §423.153(b)
P&T Committee oversight

Comment:

P&T Oversight for UM programs over the entire drug benefit is a concern based on the workload it would demand of the committee, the resources available and their expertise. There are only limited numbers of P&T committees with limited experts to participate. The current industry standard is to utilize physicians with expertise for specific UM programs and concerns. This alleviates some of the demand on the P&T committee expertise. While some committees pay members for their participation, paying for the additional level of work would significantly increase the costs of the program.

The P&T committee's responsibility with regard to the oversight of UM programs should be limited to the assessment of clinical appropriateness of the tool(s). The operational and policy issues should rest with the plan sponsors.

Recommendation:

The industry standard today is to utilize physicians with expertise to advise on specific UM programs. This process works well and can be facilitated in a variety of practice settings.

The PDP and MA-PD should determine which, if any, of these UM programs are effective.

Subsection D.2.a; §423.153(b)
Prospective utilization review standards

Comments:

OBRA-90 sets forth the standards for a prospective utilization review program in the Medicaid population beyond this there are no clearly defined industry standards.

Recommendation:

We believe the components described in OBRA-90 are adequate to describe the necessary program elements of a cost effective UM program. The choice of which programs should be at the discretion of the plan. How the program is implemented should also be at the discretion of the plan.

Subsection D.2.b
Components and Operation of QA program

Recommendation:

We support an appropriate well defined role for the QIOs, or some outside body, as an oversight body as part of assuring quality across the plan population.

Electronic prescribing as discussed throughout this NPRM is supported in that it would facilitate point-of-service decision making and allow for feedback to the prescriber at the point of care.

Subsection D.2.b
Medication error reporting

Comment:

PBM and plan sponsors have the ability to detect potential medication error and safety issues through the concurrent DUR process. While this process can detect potential drug/age, drug/gender, drug/drug interactions in addition to high dose and ingredient duplication issues there is no ability to detect and report beyond what information is available to the pharmacist at the time of dispensing. Overall, the ability to detect and report medication errors is incomplete. The safety issues are further compounded with "any willing provider' elements since some participants may not meet the standards for detection and reporting of medication errors.

There is a lack of consensus on what constitutes a prescribing error. A paper by Abarca {Abarca, J. *J Am Pharm Assoc. 2004*; 44:136-141} showed there was no consensus between drug interactions as reported in commonly used drug interaction compendia. Given that there is little agreement on what constitutes significant drug interactions, it is premature to report an error rate in prescribing practices without consensus on practice standards.

It is also important to realize that error management systems are encouraged to not be punitive but work toward improving quality. Publishing error rates for a system with good detection versus a system with poor detection would not provide an accurate impression for the consumer.

Recommendation:

Dispensing errors should be under the purview of the state regulatory boards and not the responsibility of the plan sponsor. Without consensus and appropriate supporting systems it is premature to report prescribing errors across plans and error rates should not be published to general consumers.

Statute reference 1860D4(c)(1)(C; Preamble Section D.2.c; § 423.153(d) Medication Therapy Management (MTM) services

Comment:

Because these costs are administrative and must be covered by the plan sponsor in their bid, it is essential that plan sponsors be granted control over who is selected to participate in the program and set the reimbursement rate for activities.

Recommendation:

Considerations such as total cost of therapy, number of drugs and the diseases are the normal ways of targeting today. In the absence of medical claim integration, plan sponsors should be allowed to use drug markers as a surrogate for disease. Plans should be allowed to set the cost trigger for a high-cost beneficiary. Plans should determine the reimbursement rates.

Comment:

There is evidence to suggest that face to face interactions are highly variable and some patients respond better to written information. The literature indicates information preferences (oral, written, other) have been related to education level, age, pharmacy attended and prescription status.

Recommendation:

We believe telephonic and other such means of communicating with individuals- in providing MTM services - are appropriate in many situations and should be supported.

So long as plan sponsors have the flexibility to implement the scope of MTM services, they should have the flexibility to negotiate the costs and reimbursement rates with pharmacy providers.

Comment:

CMS seeks comments on how MTMP services provide through CCIP can be effectively coordinated with MTMP services provided by PDPs.

Recommendation:

Chronic Care Initiative Programs (CCIPs) should take priority over PDP MTMP programs. This may require information sharing from the CCIPs to the PDP sponsors.

Subsection D.2.d; § 423.153(e) Appropriate narcotic prescribing

Comment:

CMS has asked for comments on whether PDP and MA-PD plan sponsors need to determine whether or not physicians are illegally prescribing narcotics.

Recommendation:

Plan sponsors should operate within the law and should not be put in the role of policing prescribing physicians. There should be no repercussions to a plan sponsor for actions taken by a prescriber.

Statute reference 1860D-421(d)(3); Section D.2.e; § 423.153(f)
Prospective drug utilization review

Recommendation:

DUR is an important component of safe and effective use of medication. To exempt PFFS from these programs potentially puts these beneficiaries at risk of drug misadventures.

Statute reference 1850D-4(d); Preamble Section D.3; § 423.156
Consumer satisfaction surveys:

Comment:

We support the centralization of consumer satisfaction surveys as this would facilitate consistency across the survey.

Recommendation:

Plan sponsors should be allowed to conduct their own surveys as deemed necessary by the plan sponsor.

Statute reference 1860D-4(e); Preamble Section D.4; § 423.159
Electronic Prescription drug program

Comment:

We support the NCVHS recommendations which make every effort to acknowledge the industry practices and standards in use today, though also include a number of items which are not yet created or in use and which seek to define improvements for the industry.

We believe that adequate industry experience exists with respect to patient identification, and prescription and benefit information transmission using the RxHub protocols recommended by NCVHS, and therefore no pilot study is necessary.

A key tool in controlling cost is aligning incentives. The real incentives around electronic prescribing should be focusing on changing behavior as it impacts prescribing habits. Stand alone PDPs, as well as MA-PDs, should be allowed to financially incent physicians to participate in electronic prescribing. We support CMS's acknowledgement of incentives that reward 1) formulary compliance, 2) use of lower cost drugs, 3) reduction in adverse drug interactions and 4) efficiencies in filling and refilling prescriptions. Incentives relating only to sending scripts electronically, as opposed to on paper, will not be adequate to drive optimal use of these systems to realize the potential for enhanced quality and cost-savings.

The characterization of the electronic prescribing program inaccurately depicts the true value and goals of the program. We believe that electronic prescribing programs rather than being aimed at providing information to pharmacies, should be aimed at getting the appropriate information to the prescriber at the point of care. Current industry practice already sufficiently deals with providing coverage, benefit and drug-drug interaction information to the pharmacist at the point of dispensing.

Electronic prescribing must ultimately be more than just transcription to pharmacies. The New England Journal of Medicine recently reported the experiences of manual versus electronic prescribing on medication errors. Four Boston clinics were compared for odds of errors in prescribing; two had electronic prescribing, two had pen-and-ink. There were no observable differences among these four practices despite electronic prescribing in two of them. The authors attributed the reason to the fact that the technology only addressed transcription and did not provide any additional decision-support or meaningful information flowing back to the prescribers. The authors estimated that more advanced e-prescribing systems could have prevented 7 of the 20 (35%) of the preventable events, all of which were missed by the minimalist electronic transmission of prescriptions to the pharmacy. (Gandhi, TK. NEJM 2003; 348:1556-64)

While we support the notion that electronic prescribing should not be used to prescribe more frequently or inappropriately steer use to particular drugs, there are instances where electronic prescribing could, and should, be used to appropriately influence medication selection where several choices would be clinically appropriate in terms of therapy, drug selection and/or cost. Plan sponsors should have the ability to share this with the patient and physician at the point of care.

Given the uncertainty of what falls under the provisions of the federal antikickback laws and the physician self-referral laws, industry activities relating to providing incentives for adoption of electronic prescribing will be constrained unless clear safe harbors are promulgated. Without clear safe harbors, any incentive program for physicians involving Medicare providers may be considered risky by industry given the current enforcement environment and the large settlements extracted from providers who find themselves involved in enforcement litigation.

In a number of places, CMS has asked for how to best promote electronic prescribing. The best way to incent adoption is to allow payors (including both PDPs and MA-PD plans) to provide payment differentials, gainsharing programs, and other pay-for-performance plans and incentives so it is financially advantageous for providers to adopt electronic prescribing and deliver the value that it can enable. CMS should also accelerate the acceptance of E-Rxing and infrastructure development through monies to support development and the and establishment of pilot markets as early as 2005.

Subsection F – Submission of bids and monthly beneficiary premiums; plan approval

Determination of 'noncompetitive' and plan evaluation

Recommendation:

CMS should determine a benchmark under which the definition of noncompetitive would open the door for CMS to negotiate with the plan sponsor.

Segmentation of Bid

Comment:

It will be difficult to compare the bids if they are broken up into separate segments

- Administrative costs
- Aggregate costs
- Benefit structure
- Plan management

Would the sponsor need to be competitive in the aggregate or on each element? Plan sponsors have concern regarding the clarity of these elements in the overall evaluation process.

Recommendation:

The bid as a whole should be evaluated for any changes and/or re-negotiation.

Formulary Review

Comment:

CMS has proposed the ability to review formularies for compliance.

Recommendation:

CMS should be aware that any mandated changes to the formularies, other than compliance with the USP guidelines, will affect the plan's ability to control costs through rebates and other price concessions.

§423.286(d)(3)
Rules Regarding Premium

Comment:

A proposed bid penalty of 1% may not be sufficient to control adverse selection. While a 1% penalty may be close to the increases seen in the commercial market, this is a market where there is no adverse selection potential.

Recommendation:

There is no mechanism to risk adjust when adverse selection occurs across all plans in a region therefore there should be some sort of adjustment to address the adverse selection that may occur. One way to adjust this is to match premium to the health status risk of the enrollee who enrolls late.

Late Enrollment Penalties

Recommendation:

Late enrollment penalty payments should be paid upfront as with other premium payments. The plans are taking the risk on these enrollees and should therefore be allowed to collect and receive the late enrollment penalties as soon as they are due.

Subsection G – Payments to PDP sponsors and MA organizations offering MA-PD plans for all Medicare beneficiaries for qualified prescription drug coverage

CMS should provide specific guidance on how payments will be determined and how participants will be counted (e.g. eligibility during the month).

Despite the potential for adverse selection hitting all plans, there is no provision for risk adjustment that would allow CMS to meet the requirement of budget neutrality.

Frequency of data feeds

Recommendation:

Annual submission should be adequate. Plan sponsors could supply additional data on a quarterly basis should there be a need for data conciliation.

Rebate admin fees

Comment:

We believe that admin fees for administering rebates should not be included in assessment of rebate fees.

Recommendation:

The rebate factor that is a reduction of each and every claim to account for the rebate should not include rebate admin fees. This factor could be adjusted as part of the annual bidding process.

Low-income subsidy beneficiaries

Comment:

Risk adjustment methodology has raised concerns over how to account – or not account - for the low income subsidy individuals and the effect on adverse selection.

Recommendation:

These individuals should be serviced in a separate plan with separately determined rates. If they are in the plan, there must be adjustment factors to the degree there is adverse selection brought on to a plan by the low income enrollees.

Subsection I – Compliance with state law

Statute reference 1860D-12(a); Preamble section I.1; § 423.401

Comments:

A requirement for licensure in each state places a tremendous burden on any prospective PDP plans sponsors and potentially the states.

Recommendation:

We support national solvency standards and licensure requirements to more specifically address differences in state laws.

Subsection J – Coordination under Part D with other prescription drug coverage

Statute 1860D-24(c)(1); Subsection J.6; §423.464(e)

SPAP programs

Comment:

A qualified SPAP offering a wrap around program may eliminate the incentive for members to utilize cost effective choices in lower tiers if SPAP wrap coverage reduces beneficiary cost sharing to zero or minimal cost shares.

Recommendation:

State Pharmacy Assistance Program (SPAPs) should be incented to provide more coverage for first tier (specifically generic products) items and limited coverage for second or third tier.

Statute 1860D-23(c)1; Subsection J.6.c
Part D versus Part B POS claims processing

Comment:

The processing of Part D or Part B products at the point of sale is not clearly defined to the point where claims could be accurately adjudicated at the point of sale. To know if a Part B drug should be submitted under Part D would require ICD-9 codes. While this is supported in the 5.1 claim file format, the data must be entered by the pharmacist who must obtain this from the physician.

Recommendation:

CMS should create a clear point-of-sale set of business rules for determining whether a claim is processed to a part B or part D plan. A mechanism should be in place to know if beneficiaries have Part B coverage. We are willing to work with CMS to aid in understanding POS claims processing and help identify pertinent solutions.

Statute 1860D-23(c)1; Subsection J.6.c
Medicare supplier and cross-over claims

Comment:

CMS is suggesting when a Part B claim is denied that it be submitted automatically to the plan sponsor for submission to Part D. DMEs are not equipped to supply this information to third party payors today.

Recommendation:

If the pharmacy receives a reject from a Part B Medicare supplier, the pharmacy should be responsible for re-submitting the claim to the PDP or MA-PD. This a standard practice in the industry today. It is critical for CMS to identify for plan sponsors explicitly what will be covered under Part B now and the criteria for coverage under Part B in the future.

Statute 1860D-2(b)4(C); Subsection J.6.e; §422.106(c)
Options for tracking TrOOP

Comment:

CMS has proposed two options for tracking TrOOP: plans routing and tracking TrOOP on their own or the use of a Troop Facilitation Contractor. Requiring that each PDP

establish connections with all of the appropriate Medicaid plans and other secondary insurance providers would be cost prohibitive.

Recommendation:

A TrOOP Facilitation Contractor would create one central point of contact for the plans and allow for data to be gathered and stored in a consistent format. This process should also include information on the processing priority of all the 'other insurance information' that an enrollee may have. There should be an established set of rules for determining the processing priority to eliminate the need for reversals, re-billings, and recalculations of TrOOP. There should be designated procedures for reversals to foster consistent processes.

Comment:

There are different rules that are needed to determine which dollars are applied to the TrOOP balance and which are not. This determination needs to be reported and explained to members. Therefore, the detail information needs to be available to the PDPs. If the TrOOP facilitator kept the balance information all PDP's would need real-time access to the information for claims adjudication and member calls.

Recommendation:

We recommend the TrOOp facilitator only transfer Post Adjudication claim information from other payors to the PDPs. The PDPs should keep track of the TrOOP balances.

Comment:

There is no current real-time standard to allow the information from a primary or secondary payer to be transmitted back to the PDP. The amount of time needed to develop this standard will not allow it to be available by 2006. However, the NCPDP Post Adjudication Standard is close to completion and could be used. This is a batch standard.

Developing batch processes are cheaper than real-time processes. Since, there is no real incentive for other payors to send the transaction information back to the PDP, the most cost effective method should be chosen.

The main argument for real-time transfer of TrOOP information is to allow the claim to be adjudicated against the most accurate TrOOP balance. However, even in a real-time environment, there are many scenarios in which that would not occur.

a. Up to four claims can be submitted within the same pharmacy transaction. All of these claims are processed by the primary payor before the pharmacy submits them to the secondary payor. Therefore, the information from the secondary payor, even if sent real-time, is not available until after the completion of the total transaction.

b. Even if each claim was submitted separately, first to the primary and then to the secondary, it is possible that the real-time transaction might not

make it back to the primary in time for the processing of the next claim. I would estimate that this would take up to fifteen minutes.

c. Even if the claims were processed in the deliberate manner described above and a sufficient amount of time was left between transactions to ensure the TrOOP balance was up to date, there would still be system outages and communication problems that would affect some portion of these transactions.

There is no situation where it is crucial that the dollars from other payor be applied real-time. Dollars from other payors that would reduce the members TrOOP totals will be applied as they are received. The current indemnity products manage incoming dollars that move the total amounts up and down and across tier boundaries. There is no clear business benefit on receiving secondary dollars in a real-time environment versus batch.

Some of the other payors such as, Worker's Comp and Auto Insurance would be paid using medical processes, which will require the use of paper claims. Therefore, not all of the other payors will be able to respond in a real-time mode, even if the infrastructure was built.

Recommendation:

It is recommended the TrOOP information be transmitted in a batch mode versus real-time using the NCPDP Post Adjudication Standard.

Subsection K – Application procedures and contract with PDP sponsors

Comment:

While we understand the need to assure compliance with the program guidelines and for CMS to understand and hold plans accountable, the expectations of the contracting plan once awarded the contract place a heavy burden on the plan for data provision and reporting. Ultimately this increases the administrative costs of providing the benefit which increases the costs for all involved.

Recommendation:

CMS should establish de minimis threshold for reporting, e.g. reporting set at a dollar or claim threshold.

Comment:

The use of a standard contract to address any willing pharmacy provider could have the adverse effect of raising prices to the beneficiary by shifting the negotiating leverage to the providers from the plans.

Recommendation:

Standard network contracts should not be required to meet 'reasonable and relevant' requirements. Plan sponsors should have the flexibility to craft and be allowed to set the

terms of a plan's standard contract. This will create the best network access with the best prices for the beneficiaries.

We support consistent auditing requirements across PDP and fallback plans.

Subsection M – Grievances, coverage determinations and appeals

Preamble M.5.b; § 423.566(c)
Expedited determinations

Comment:

The preamble of subsection M.4 indicates that the prescribing physician may request expedited determination or an expedited re-determination on behalf of the enrollee and that this physician need not be appointed an authorized representative of the enrollee.

Recommendation:

Today's processes often require information from the physician in order to make the coverage determination. We support that only the enrollee, their authorized representative or the physician may initiate a request. However, it should be recognized that few, if any, of these requests will be administered with enrollee provided information only.

PDPs should be allowed to request or require written or verbal certification from the physician that the drug is medically necessary to treat the enrollee's condition as part of the process in making these determinations. This information should be kept as a part of the medical record.

Partial Fills

Comment:

Regarding "expedited coverage determinations" or authorizations, MA-PDs and PDPs provide call center services for addressing coverage determinations. Some state Medicaid agencies limit partial fills to weekends, when agency/MCO is not open.

Recommendation:

"Expedited coverage determinations" at the point of sale (e.g., retail pharmacy), including partial fills, should be allowed only when the call center is not open within the next 24 hours. The MA-PDs and the PDPs should be allowed to determine any times for which partial fills are to be considered. Our experience suggests that broad authorization for partial fills lowers the effectiveness of formulary and other clinical programs.

Preamble M.5.b
Reconsiderations

Comment:

CMS has requested comments on whether reconsiderations should be automatically referred to the IRE or on request only.

Recommendation:

We agree with CMS's analysis of the cost of coverage determinations (section 6.b) and support that the Independent Review Entity (IRE) reviews occur on request rather than automatically.

Preamble M.5.c; § 423.578(C)(3)
Exception period

Comment:

The preamble indicates that once a beneficiary has an approved exception, they are entitled to continue receiving refills for as long as the physician continues prescribing the drug and for as along as the drug continues to be considered safe and effective for treatment of the enrollee's condition.

Recommendation:

An indefinite exception is not consistent with today's current processes and prevents plans from taking subsequent advantage of cost saving mechanisms and new evidence available. The standard of practice today is to require an annual re-approval.

Preamble M.8; § 423.564
Pre-emption

Comment:

CMS has requested comments on the pre-emption issue and whether specific state grievance requirements that should be incorporated into Federal regulatory requirements.

Recommendation:

Part D plans are federal programs and it is inefficient to operate under federal and state requirements which may vary. Federal law should clearly preempt state law to promote effective operation of the grievance process.

IRE Determinations

Comment:

Plan sponsors may be concerned that determinations of the IRE may become precedent setting for future grievance decisions.

Recommendation:

When creating or advising the IRE with regard to their review process, their review should be limited to whether the plan followed their criteria or did not follow their criteria; IRE's should not be making medical judgments.

Subsection P- Premiums and cost-sharing subsidies for low-income individuals

Statute reference 1860D-14(a)(3)(B)(i); Preamble P.2; § 423.774
Application for Low income subsidy

Comment:

An enrollee can go to the state Medicaid office or the Social Security office to apply for a low income subsidy. This creates the potential that an enrollee would have multiple determinations.

Recommendation:

One group should be responsible for making the final determination even if the ability to apply was allowed at either site.

Statute reference 1860D-14(a)(2)(A); Preamble P.3.b; § 423.46
Sliding scale premiums

Comment:

The process for determining a sliding scale premium for beneficiaries in the >135-150% FPL group should be implemented in a manner that claims processors can easily and effectively implement.

Recommendation:

From an operational perspective, a fixed split of the premium between the beneficiary and CMS would accomplish the same objective and ease the implementation and beneficiary understanding. (For example, 135-140, x%; 141-150, x%). It would be easier to support from a call center and beneficiary support perspective.

Subsection R – Payments to sponsors of retiree prescription drug plans

Preamble R.2.d
Creditable coverage and notification

Recommendation:

A standard language template should be provided that establishes consistency and supports compliance with the provision to provide creditable coverage notification.

The notice should be allowed to be sent with other plan materials to maximize plan efficiency

General considerations for employers

Express Scripts Inc. supports national employers with PBM services and CMS wishes to help employers continue to offer retiree benefits. With this in mind, we wish to echo many of the comments and recommendations from the American Benefits Council in support of our employer clients.

- Swift issuance of guidance for the employer market relating to methodologies and actuarial assumption for determining actuarial equivalence, the process for obtaining waivers, and the allocation of employer and retiree dollars.
- We encourage flexibility for PBMs and PDPs that support employers. We request allowing the waivers to extend to these groups for the purposes of supporting employer plans. For example, a PBM or PDP supporting an employer should be able to elect to solely serve employer groups without also being required to open enrollment to beneficiaries also in the service area but unaffiliated with the employer.

CMS-4068-P-1289

Submitter : Ms. Kathleen Jaeger **Date & Time:** 10/04/2004 09:10:07

Organization : Generic Pharmaceutical Association

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

CMS-4068-P-1290

Submitter : Deanne Birch **Date & Time:** 10/04/2004 09:10:31

Organization : Region D DAC - IV A Team

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4068-P-1290-Attach-1.doc

Region D DMERC Advisory Committee
IV A Team
10480 Perkins Ave. North
Stillwater, MN 55085

October 4, 2005
CMS (Centers for Medicare and Medicaid Services)
Re: Medicare Prescription Drug Improvement and Modernization Act

The Region D DMERC Advisory Committee, (Region D DAC) IV-A Team is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

The Medicare Region D DAC is a nonprofit volunteer organization comprised of HME providers, Home Infusion Providers, State and national associations, manufacturer supporters and industry consultants. The primary function of the DAC is to serve as a communications vehicle between the home medical equipment (HME) industry and CIGNA Healthcare Medicare Administration (CIGNA Medicare), the region D DMERC. **The IV A Team** is representative of a large number of Home Infusion Providers within Region D (17 states) that participate as part of this DAC volunteer organization. This group of professional providers has years of experience and great expertise in the delivery and management of Home Infusion Therapy. A very large portion of our patient population consists of Medicare beneficiaries for those services that have been covered under the Part B DMERC program. Therefore, we feel it is imperative to provide comment to CMS on behalf of this segment of the Region D DAC.

The Region D DAC IV-A Team appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal,

intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients in the PIDD community, this new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

* Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it

does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm <http://www.nhianet.org/perdiemfinal.htm> .

* CMS should establish specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require specific standards for home infusion pharmacies under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the X12N 837 P billing format for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should mandate that prescription drug plans maintain open formularies for infusion drugs to ensure that this population of vulnerable patients has appropriate access to necessary medications.

The Region D DAC IV A Team submits our availability to CMS as a resource for further comment and dialogue on this important issue. Thank you in advance for your consideration of these important issues.

Sincerely,

Region D IV A Team Members
The DMERC Region D Advisory Committee
Mike Hayden – IV A Team Leader
mhayden@alternacare.net
Deanne Birch – Asst... IV A Team Leader
dbirch@infusioninnovations.com

CMS-4068-P-1291

Submitter : sirotkin **Date & Time:** 10/04/2004 09:10:27

Organization : community of Vermont eders

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

see attached document- your first address failed

CMS-4068-P-1291-Attach-2.doc

CMS-4068-P-1291-Attach-1.doc

P.O. Box 1276, 79 River Street, Heritage II, Suite 1, Montpelier, VT 05602
802-229-4731 cove@vermontelders.org www.vermontelders.org

The Community of Vermont Elders (COVE) has been in existence for 25 years and has been continually working on pharmaceutical assistance for Vermont elders since 1986. Over these past 18 years we have seen significant success in raising legislative awareness of the problems low to moderate income seniors have faced in meeting their prescription needs.

For about a decade now, with the help of an 1115 waiver and the federal matching funds it provides, elderly Vermonters below 150% of poverty who do not qualify for traditional Medicaid are entitled to almost full coverage for their prescriptions at a premium of $13/mo or $156 per year;. The cost to those seniors between 150% and 175% of poverty, under the same waiver, is slightly higher at $17/mo, or $204 per year.

Now, with MMA and its proposed regulations, our long evolving state pharmacy programs are being placed in serious jeopardy. It is sadly ironic that a significant percentage of low to moderate income Vermont seniors may be punished by a federal law that clearly designed to help them. This could be a classic case of Vermont being punished for being a leader on the very issue MMA seeks to address.

It is critical that your regulations acknowledge the unique comprehensive prescription drug benefit Vermont (with federal assistance and encouragement) already provides low and moderate income seniors through our 1115 waiver. Vermont's unique circumstances (i.e.already existing full RX coverage with federal matching funds) and MMA's potential impact on these beneficiaries) was not specifically acknowledged or addressed in the legislation. Because of the specific and critical importance of this oversight to Vermont and its pharmacy beneficiaries, we limit our comments to this broad yet crucial concern. We will leave to others the many detailed comments you will no doubt receive on other critical areas of general applicability to seniors nationwide.

The two broad yet critical comments COVE wishes to make are as follows:

1) Continuation of Pharmacy Only 1115 Waiver- the regs should directly state that nothing in the MMA specifically precludes CMS from continuing existing 1115 Rx waivers; and any inconsistencies between existing waivers and the final regulations should be interpreted to do no harm to existing beneficiaries of comprehensive 1115 Rx only waiver programs. Without this provision, it would be hard for the regs to meet the legislative intent of helping seniors with their drug costs in those states that already had significant federal matching pharmacy programs.

2) **Clawback-** The basic concept of the clawback is to mitigate the added costs to the federal government and the potential windfall to the states caused by the federal government essentially taking over the full costs of assistance to dual eligible beneficiaries under part D. Thus, if Vermont's 1115 waiver was allowed to continue as a federally matched wrap around to part D benefits, Vermont's cost under the 1115 waiver would go down (as those drugs covered by Part D would now be 100% federally funded, as opposed to the present 60% federal match under the 1115 waiver). Under these circumstances – increased cost to the feds and decreased cost to Vermont – one might correctly argue that the claw back should apply (even though these beneficiaries are not technically dual eligibles).

HOWEVER, if the waiver is not allowed to continue, then the very basis for a clawback does not exist. In fact, discontinuing Vermont's waiver will save the federal government millions of dollars as an overwhelming majority of our waiver beneficiaries will not be eligible for low income subsidies under Part D. The federal government will be paying far less for these beneficiaries Part D benefits than their present contribution to the full drug coverage these seniors receive under our state waiver programs.

Moreover, no one can seriously argue that Vermont will see any windfall or savings from this group. Indeed, it is likely that without a waiver Vermont will try to hold these seniors harmless by replacing the lost federal matching dollars with state only dollars, causing a major net loss in funds to the state. At the very least Vermont would continue to appropriate the 40% state funds it had been putting into the waiver, so as to minimize the cut in benefits these seniors will face on 1/1/06 (assuming they are then converted from full waiver coverage to the limited coverage under Part D). Under either scenario Vermont's budget would see no net gain from MMA for these beneficiaries.

With the federal contribution decreasing and the state's contribution increasing (or at best staying even), applying the clawback to these particular populations would defy the basic rationale underlying the clawback. It would add insult to injury; and would make it that much harder on the state of Vermont, and ultimately on the seniors these joint federal-state waivers had admirably assisted, to continue the level of assistance previously provided.

Michael Sirotkin, Esq.
COVE Legislative Advocate
Sirotkin & Necrason, PLC
33 Court Street
Montpelier, VT 05602

P.O. Box 1276, 79 River Street, Heritage II, Suite 1, Montpelier, VT 05602
802-229-4731 cove@vermontelders.org www.vermontelders.org

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2) **Clawback-** The basic concept of the clawback is to mitigate the added costs to the federal government and the potential windfall to the states caused by the federal government essentially taking over the full costs of assistance to dual eligible beneficiaries under part D. Thus, if Vermont's 1115 waiver was allowed to continue as a federally matched wrap around to part D benefits, Vermont's cost under the 1115 waiver would go down (as those drugs covered by Part D would now be 100% federally funded, as opposed to the present 60% federal match under the 1115 waiver). Under these circumstances – increased cost to the feds and decreased cost to Vermont – one might correctly argue that the claw back should apply (even though these beneficiaries are not technically dual eligibles).

HOWEVER, if the waiver is not allowed to continue, then the very basis for a clawback does not exist. In fact, discontinuing Vermont's waiver will save the federal government millions of dollars as an overwhelming majority of our waiver beneficiaries will not be eligible for low income subsidies under Part D. The federal government will be paying far less for these beneficiaries Part D benefits than their present contribution to the full drug coverage these seniors receive under our state waiver programs.

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Michael Sirotkin, Esq.
COVE Legislative Advocate
Sirotkin & Necrason, PLC
33 Court Street
Montpelier, VT 05602

CMS-4068-P-1292

Submitter : Valrie Wilbur **Date & Time:** 10/04/2004 09:10:25

Organization : Medicare Policy Coalition

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

National Health Policy Group

Improving Payment and Performance for High-Risk Beneficiaries

October 4, 2004

Center for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

ATTENTION: CMS - 4068- P

Dear Sirs:

The National Health Policy Group appreciates the opportunity to submit comments on the Notice for Proposed Rule Making, which will establish requirements for the Medicare Prescription Drug Program, on behalf of the Medicare Policy Coalition for High Risk Beneficiaries (MPC).

The Medicare Policy Coalition is an alliance of Medicare Advantage Plans and providers that have made a unique commitment to serving high-risk beneficiaries such as the frail elderly and adult disabled. MPC members have a strong interest in the Special Needs Plan designation and other aspects of the Medicare Advantage proposed rule affecting high-risk Medicare beneficiaries as they all currently offer special programs of care for these beneficiaries, many under Medicare demonstrations. Special Needs Plans offer a potential vehicle for the demonstrations to transition to permanent plan status and for non-demonstrations to intensify their focus on targeted beneficiary groups. They also provide a vehicle for more traditional plans and provider networks to develop a specialization in serving special needs beneficiaries.

Thank you for your consideration of our views on the implementation of the Medicare Modernization Act of 2003. If you have any questions regarding the attached comments, please do not hesitate to contact us at 202-264-1508.

Sincerely,

Richard J. Bringewatt Valerie S. Wilbur
President Vice President
Chair, Medicare Policy Coalition Co-chair, Medicare Policy Coalition

801 Pennsylvania Avenue, Suite 245, Washington DC 20004 (202) 624-1516 Fax: (202) 737-6462 www.nhpg.org

CMS-4068-P-1293

Submitter : Mr. Raj Rai **Date & Time:** 10/04/2004 09:10:32

Organization : Option Care, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Pls see attached comments

CMS-4068-P-1293-Attach-1.doc

Option Care Inc. is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Option Care Inc. is one of the leading providers of Home Infusion Services. We service patients in 33 states through a network of over 120 national pharmacies. Option Care has been in business for over 25 years. We serviced over 100,000 patients last year through our company and franchised locations. Our payor mix reflects reimbursement from various sources such as managed care organizations, insurance companies, self-insured employers and Medicare and Medicaid programs.

Option Care Inc. appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B *has not resulted in additional access to home IVIG under Medicare.* We see this

as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

- **Dispensing fee option 3** is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm .

- CMS should establish **specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies** to ensure adequate enrollee access to home infusion therapy under Part D.

- CMS should require **specific standards for home infusion pharmacies** under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

- CMS should adopt the **X12N 837 P billing format** for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

- CMS should **mandate that prescription drug plans maintain open formularies for infusion drugs** to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Raj Rai
CEO
Option Care Inc.

CMS-4068-P-1294

Submitter : Ms. Collin Conway **Date & Time:** 10/04/2004 09:10:46

Organization : student pharmacist

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

As a future pharmacist, Medication Therapy Management will be an exciting part of my practice. The training and education we receive as students make us well trained to provide pharmacy services to elderly patients with multiple chronic disease states.

A couple comments as follows: 1) it would be wonderful if plan providers provided up to date information on patients to all people on the health care team (patient and pharmcist) who are eligible for these services so that we may inform them if they qualify 2) once a patient becomes eligible for services, they should qualitfy for one year so that we may maintain a relationship and allow us to work together to manage their drug therapy

Thank you so much for your consideration of these comments and I look forward to helping my patients in the future. Thank you

CMS-4068-P-1295

Submitter : Mr. Benjamin Loy **Date & Time:** 10/04/2004 09:10:01

Organization : PDX-NHIN-Rx.com

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P Baltimore, MD 21244-8014

Re: CMS-4068-P

Dear Sir or Madam:

PDX, Inc. appreciates the opportunity to submit written comments to the Department of Health and Human Services (HHS) concerning the impact on our companies and our retail pharmacy customers of the proposed HIPAA Privacy Rule changes.

PDX, Inc., a major provider of retail pharmacy software to retail pharmacy, was established in 1985 in Granbury, Texas and was preceded by pc1, Inc., a software application provider primarily directed toward independent pharmacies. PDX is the most widely distributed single code-based pharmacy application used in North America. PDX and its affiliated companies provide pharmacy technology to a customer base of approximately 1,000 independent pharmacies and over 60 chains comprising an additional 9,000 chain pharmacies. PDX has software installations in all 50 states, District of Columbia, Puerto Rico, the U.S. Virgin Islands and most of the provinces of Canada. As such, PDX has a good understanding of the technology issues facing the retail pharmacy industry.

Our comments are provided in an effort to assist HHS in making the implementation of Medicare Part D, the most significant health initiative of recent history, as successful as possible.

Subpart B?Eligibility and Enrollment.
The preamble states that CMS is considering the establishment of the Medicare beneficiary eligibility and other coverage query system using the HIPAA 270/271 eligibility query. Information collected under this section for the purpose of TrOOP application would be available to be queried by pharmacies to facilitate proper billing.

However, since a significant number, if not the majority, of the providers under the Plan D program will be retail pharmacies it is only reasonable that these entities be allowed to use the eligibility standard to which they are accustomed and that is consistent with the HIPAA Final Transactions and Code Sets Rule.

? 162.1202 Standards for eligibility for a health plan.
The Secretary adopts the following standards for the eligibility for a health plan transaction:
(a) Retail pharmacy drugs. The NCPDP Telecommunication Standard Implementation Guide, Version 5 Release 1, September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1 Release 0, February 1, 1996. The implementation specifications are available at the addresses specified in ? 162.920(a)(2).

Therefore, we request that CMS include support for the NCPDP on-line real-time eligibility transaction contained in NCPDP Telecommunication Standard Version 5 Release 1 as this is the most commonly used format for retail pharmacy and that a requirement for retail pharmacy to change to using the X12N-270/271 batch eligibility formats would impose a significant obstacle to the Medicare drug benefit program.

Sincerely,

Benjamin E. (Ben) Loy, R.Ph.
Sr. VP Inudstry Relations

PDX-NHIN-Rx.com

CMS-4068-P-1296

Submitter : Dr. Barbara Manard **Date & Time:** 10/04/2004 09:10:17

Organization : American Association Homes and Services for the Ag

Category : Long-term Care

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

SUBPART AGENERAL PROVISIONS

LTC residentsincluding those in hospital-based facilities--must be able to access LTC pharmacies without paying out of network prices that are higher than in network prices

The proposed rule recognizes that LTC facilities generally contract with specialized pharmacies (LTC pharmacies) that provide important services to LTC residents, enhancing safe pharmacy practices in LTC facilities. A critical question for design of the new Part D program is this: What happens if the LTC pharmacy contracted with by a resident?s LTC facility is not in the network of the enrollee?s Part D plan? In Subpart A, CMS gives four examples of situations when a plan will be required to all an enrollee to use a non-network pharmacy and includes the situation of the out of network LTC pharmacy used by a LTC resident.

AAHSA agrees with this formulation so long as it does not mean that LTC residents will be required to pay the higher prices frequently associated with out of network transactions. Plans must be explicitly prohibited from charging LTC residents out of network prices for using a LTC facility's LTC pharmacy when that pharmacy is not part of the plan's network.

Furthermore, since hospital-based LTC facilities typically get pharmacy services from the affiliated hospital's pharmacy, the definition of LTC pharmacy must be sufficiently inclusive so that residents/patients in hospital-based LTC facilities have the same access to pharmacy services (without paying out of network prices) as residents/patients of free-standing LTC facilities that contract with typical LTC pharmacies.

CMS-4068-P-1296-Attach-1.doc

CMS-4068-P-1296-Attach-2.doc

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 309-G
200 Independence Avenue, SW
Washington, DC 20201
Attn: CMS-4027-P

Re: Comments on Medicare Program; Medicare Prescription Drug Benefit, Proposed Rule, 69 *Federal Register* 46632, August 3, 2004, CMS-4068-P

To Whom It May Concern:

The American Association of Homes and Services for the Aging (AAHSA) appreciates the opportunity to comment on the Proposed Rule, published in the Federal Register on August 3, 2004, to implement a new voluntary Medicare prescription drug benefit (Medicare Part D) as specified in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108-173, signed into law December 8, 2003.

AAHSA represents 5,600 mission-driven, not-for-profit nursing homes, home health, continuing care retirement communities, assisted living, senior housing facilities, and community service organizations. Every day, our members serve more than one million older persons across the country. AAHSA is committed to advancing the vision of healthy, affordable, ethical long-term care for America. Our mission is to create the future of long-term care.

We recognize the challenge faced by CMS in developing these rules and appreciate the effort of the Administrator and staff to meet this challenge in a timely fashion. We look forward to continuing to work with CMS to better assure smooth implementation of this complex new program for the Medicare beneficiaries served by our members.

INTRODUCTORY COMMENT

Need for a second round of comments before the final rule and access to interim products of the congressionally mandated study of LTC pharmacy issues

The proposed rule leaves a very large number of issues, large and small, either unaddressed or addressed principally as questions to reviewers for guidance**.** We are very concerned that advice and comments offered by us and others, while appropriate given one set of assumptions about a final system, will be substantially off base in terms of a more fully defined system. Failure to obtain public comments on a more fully developed set of rules is very likely to lead to a far greater number of errors and unintended

consequences than if another round of comments before the final rule were permitted. We therefore recommend that CMS issue an interim final rule with opportunity for further comment (even if this is an abbreviated comment period) prior to the final rule.

The problem of inadequate information on which to make decisions about recommendations is particularly grave with respect to rules regarding long term care (LTC) facilities. Recognizing the particular complexities of this sector, about which there is very little research or public information available, Congress directed the Secretary to conduct a thorough study of practice for pharmacy services provided to patients in LTC facilities (MMA, section 107). The results of that study are critical to understanding important issues raised in the proposed rules and developing an appropriate set of final rules. CMS notes in the Statement of Work issued August 25 with the request for quotation (RFQ) for potential bidders on the project that "[t]he goal of the research is to inform the Centers for Medicare and Medicaid Services in its development of Part D policy affecting long-term care pharmacies serving Medicare beneficiaries, as CMS ramps up for the launch of Part D." Further, CMS states "the contractor will … develop a set of options for ways in which the LTC pharmacy system can be smoothly and effectively integrated into Part D, and conduct a critical analysis of the relative pros and cons of each option."

Congress required that this research be completed by June 2005 (eighteen months after enactment) and the work plan outlined in the August 2004 RFQ suggests that that is approximately when the work will be completed, although some helpful interim products are specified in the first few months of the project. This essential study has obviously not been available to those commenting on this proposed set of rules. We therefore request that interim products of this project be made available to the public to the extent that these are prepared prior to the interim final rule we recommend and that the final rule contain an explanation of how the completed study will inform the Part D plan's operation in LTC facilities.

While CMS does not generally make interim study products available to the public, we believe that doing so in this case, coupled with a second round of public comments prior to a final rule, would considerably enhance the chances for a reasonable, equitable, and effective final rule on this complex topic.

SUBPART A—GENERAL PROVISIONS

LTC residents—including those in hospital-based facilities--must be able to access LTC pharmacies without paying out of network prices that are higher than in network prices

The proposed rule recognizes that LTC facilities generally contract with specialized pharmacies ("LTC pharmacies") that provide important services to LTC residents, enhancing safe pharmacy practices in LTC facilities. A critical question for design of the new Part D program is this: What happens if the LTC pharmacy contracted with by a resident's LTC facility is not in the network of the enrollee's Part D plan? In Subpart A,

CMS gives four examples of situations when a plan will be required to all an enrollee to use a non-network pharmacy and includes the situation of the out of network LTC pharmacy used by a LTC resident.

AAHSA agrees with this formulation so long as it does not mean that LTC residents will be required to pay the higher prices frequently associated with out of network transactions. Plans must be explicitly prohibited from charging LTC residents out of network prices for using a LTC facility's LTC pharmacy when that pharmacy is not part of the plan's network.

Furthermore, since hospital-based LTC facilities typically get pharmacy services from the affiliated hospital's pharmacy, the definition of LTC pharmacy must be sufficiently inclusive so that residents/patients in hospital-based LTC facilities have the same access to pharmacy services (without paying out of network prices) as residents/patients of free-standing LTC facilities that contract with typical LTC pharmacies.

SUBPART B—ELIGIBILITY AND ENROLLMENT

The rule allows inadequate time to ensure that all dual eligibles are appropriately enrolled in Part D, thus a delay of the duals' transfer from Medicaid to Medicare or another solution is required.

The proposed rule states that dual eligibles will be automatically enrolled in a PDP or MA-PDP, if they do not enroll themselves, by the end of the initial enrollment period, which, under section 423.36 is November 15, 2005 to May 15, 2006. However, Medicaid's drug benefit for dual eligibles will end on January 1, 2006. This means that duals could face a four and one-half coverage gap.

To enhance the dual's opportunity to select their own plans, we recommend that the transfer of duals be delayed for at least six months. This may require a change in the law and recommend that the Secretary pursue this option.

If it is not possible to delay the transfer, CMS needs to develop a workable alternative that will assure that duals are properly covered in appropriate Part D plans.

The need to develop a workable plan that does not rely on service providers to ensure than all LTC residents and other frail elderly receive the help they need to understand and select an appropriate plan

We are concerned that the proposed rules do not sufficiently specify how special needs populations (cognitively impaired elderly, frail elderly living alone without access to help from family or friends, residents of LTC facilities, and so forth) will obtain the information and help they need to select and sigh up for a plan. AAHSA's experience with the Prescription Drug Card in many settings (senior housing, assisted living, nursing facilities) taught us how difficult it is for even our own computer and Internet savvy staff to understand how to make wise choices. This new program is considerably more

complicated, as CMS is aware. We believe that SHIPS, Area Agencies on Aging, and other similar groups can provide the kind of detailed help needed, but they need additional resources to do the job.

AAHSA is also concerned that CMS not rely on providers of aging services to explain the new program or to help select a plan for the beneficiaries they serve. AAHSA fully intends to assist its members in the same kinds of voluntary educational activities that were undertaken with respect to the Medicare-approved Drug Card. Many of our state affiliates and members across the continuum of aging services worked hard to provide educational materials and forums for the beneficiaries they serve. We expect many to do the same with the new Part D program. But it would be particularly inappropriate, we believe, for providers of aging services to be expected to help beneficiaries actually select a plan.

SUBPART C—BENEFITS AND BENEFICIARY PROTECTIONS

The definition of "long term care facility" needs to assure that residents of facilities that rely on LTC pharmacies continue to have appropriate access to these pharmacies

The proposed rule asks for advice about how the term "LTC facility" shall be defined. The question presumably arises because the law explicitly gives CMS the authority to promulgate rules that include standards with respect to access for enrollees in "long term care facilities," but does not define that term. In the proposed rule, CMS says that it limited the definition to nursing facilities and skilled nursing facilities, based on the agency's understanding that "only those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long term care pharmacies" (69 Fed. Reg. at 46648-49).

There are, however, other types of facilities, notably including "assisted living facilities," that sometimes contract exclusively with LTC pharmacies. Many assisted living facilities serve populations identical to those found in some nursing home: there is substantial overlap among the populations, making the specialized services of LTC pharmacies attractive to a reportedly growing number of assisted living facilities. Therefore, the residents of these facilities need the same kinds of special rules to preserve access to the new Medicare Part D benefit as do residents of nursing facilities, where both are served by contracted LTC pharmacies.

Including assisted living facilities under the definition of "LTC facility" *strictly for the purpose of Part D* may be the only way to accomplish the important goal of assuring access to LTC pharmacies, at no higher (out of network) price, for residents of these facilities, as for those in nursing homes. But if a different way could be found to accomplish the same goal, that would be better. The assisted living movement has worked hard to define its philosophy and services as unique and there is concern that there might be some unintended consequences of defining assisted living as "long term care facilities" in a federal rule. An additional challenge of including assisted living

facilities under the definition of LTC facility is that there is no national definition of assisted living, although most states do define those or similar types of facilities (with definitions varying from state to state).

Letting the market evolve before promulgating a rule regarding plan's contracting with long-term care pharmacies

The proposed rule suggests two possible ways to balance the need to preserve access to LTC pharmacies and appropriate cost containment and asks for comments on which would be best. The two ways suggested are (1) encouraging plans to contract with LTC pharmacies and (2) requiring plans to contract with LTC pharmacies.

CMS expresses concern that LTC pharmacies will be in too strong a negotiating position if plans are required to contract with LTC pharmacies. It is not clear if that would be the case; in fact, it is extremely difficult to determine what the effect of either approach would be.

We therefore recommend that CMS specify that LTC residents who use LTC pharmacies that are out of network may not be charged out of network prices, but leave it to the plans to determine how best to make that work. This is likely tantamount to encouraging plans to contract with LTC pharmacies.

Access to appropriate formularies

The use of formularies is well established in many environments including hospitals, nursing homes, long term care pharmacies, and health plans. They can be tools to promote high quality pharmacy practices and responsible cost containment, or they may be used in ways that actually increase costs over all and/or prevent access to needed and appropriate therapy.

We are therefore reluctant to argue that LTC residents or others must have fully open formularies and recommend instead that CMS require that long term care residents have access to special formularies, meeting at a minimum the requirements set forth by the American Society Consultant Pharmacists for long term care populations.

We also recommend that residents of LTC facilities and others with similarly complex pharmacy needs be given a minimum six month grace period before being transitioned to any new formulary. It will take time to get medications changed, if that needs to happen.

SUBPART P—PREMIUMS AND COST-SHARING FOR LOW-INCOME INDIVIDUALS

The definition of "institutionalized individual" should include those in nursing facilities, skilled nursing facilities, and those receiving home and community based services under a Medicaid waiver

Dually eligible "institutionalized" individuals are to receive special benefits with respect to cost sharing arrangements. We believe that the definition should therefore include those who similarly have extremely limited ability to pay for services (and from whom collecting co-pays would be a serious problem in many cases); namely, those who are receiving services under a Medicaid home and community based waiver. These individuals must meet institutional acuity criteria and in some instances (perhaps many) may be living in a residential setting (e.g., a board & care home) where they are able to retain only a small personal care allowance, similar to those on Medicaid in nursing homes.

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Respectfully submitted,

Barbara Manard, Ph. D.
Vice President
Long term care/Health Strategies
American Association of Homes and Services for the Aging

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 309-G
200 Independence Avenue, SW
Washington, DC 20201
Attn: CMS-4027-P

Re: Comments on Medicare Program; Medicare Prescription Drug Benefit, Proposed Rule, 69 *Federal Register* 46632, August 3, 2004, CMS-4068-P

To Whom It May Concern:

The American Association of Homes and Services for the Aging (AAHSA) appreciates the opportunity to comment on the Proposed Rule, published in the Federal Register on August 3, 2004, to implement a new voluntary Medicare prescription drug benefit (Medicare Part D) as specified in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108-173, signed into law December 8, 2003.

AAHSA represents 5,600 mission-driven, not-for-profit nursing homes, home health, continuing care retirement communities, assisted living, senior housing facilities, and community service organizations. Every day, our members serve more than one million older persons across the country. AAHSA is committed to advancing the vision of healthy, affordable, ethical long-term care for America. Our mission is to create the future of long-term care.

We recognize the challenge faced by CMS in developing these rules and appreciate the effort of the Administrator and staff to meet this challenge in a timely fashion. We look forward to continuing to work with CMS to better assure smooth implementation of this complex new program for the Medicare beneficiaries served by our members.

INTRODUCTORY COMMENT

Need for a second round of comments before the final rule and access to interim products of the congressionally mandated study of LTC pharmacy issues

The proposed rule leaves a very large number of issues, large and small, either unaddressed or addressed principally as questions to reviewers for guidance**.** We are very concerned that advice and comments offered by us and others, while appropriate given one set of assumptions about a final system, will be substantially off base in terms of a more fully defined system. Failure to obtain public comments on a more fully developed set of rules is very likely to lead to a far greater number of errors and unintended

consequences than if another round of comments before the final rule were permitted. We therefore recommend that CMS issue an interim final rule with opportunity for further comment (even if this is an abbreviated comment period) prior to the final rule.

The problem of inadequate information on which to make decisions about recommendations is particularly grave with respect to rules regarding long term care (LTC) facilities. Recognizing the particular complexities of this sector, about which there is very little research or public information available, Congress directed the Secretary to conduct a thorough study of practice for pharmacy services provided to patients in LTC facilities (MMA, section 107). The results of that study are critical to understanding important issues raised in the proposed rules and developing an appropriate set of final rules. CMS notes in the Statement of Work issued August 25 with the request for quotation (RFQ) for potential bidders on the project that "[t]he goal of the research is to inform the Centers for Medicare and Medicaid Services in its development of Part D policy affecting long-term care pharmacies serving Medicare beneficiaries, as CMS ramps up for the launch of Part D." Further, CMS states "the contractor will … develop a set of options for ways in which the LTC pharmacy system can be smoothly and effectively integrated into Part D, and conduct a critical analysis of the relative pros and cons of each option."

Congress required that this research be completed by June 2005 (eighteen months after enactment) and the work plan outlined in the August 2004 RFQ suggests that that is approximately when the work will be completed, although some helpful interim products are specified in the first few months of the project. This essential study has obviously not been available to those commenting on this proposed set of rules. We therefore request that interim products of this project be made available to the public to the extent that these are prepared prior to the interim final rule we recommend and that the final rule contain an explanation of how the completed study will inform the Part D plan's operation in LTC facilities.

While CMS does not generally make interim study products available to the public, we believe that doing so in this case, coupled with a second round of public comments prior to a final rule, would considerably enhance the chances for a reasonable, equitable, and effective final rule on this complex topic.

SUBPART A—GENERAL PROVISIONS

LTC residents—including those in hospital-based facilities--must be able to access LTC pharmacies without paying out of network prices that are higher than in network prices

The proposed rule recognizes that LTC facilities generally contract with specialized pharmacies ("LTC pharmacies") that provide important services to LTC residents, enhancing safe pharmacy practices in LTC facilities. A critical question for design of the new Part D program is this: What happens if the LTC pharmacy contracted with by a resident's LTC facility is not in the network of the enrollee's Part D plan? In Subpart A,

CMS gives four examples of situations when a plan will be required to all an enrollee to use a non-network pharmacy and includes the situation of the out of network LTC pharmacy used by a LTC resident.

AAHSA agrees with this formulation so long as it does not mean that LTC residents will be required to pay the higher prices frequently associated with out of network transactions. Plans must be explicitly prohibited from charging LTC residents out of network prices for using a LTC facility's LTC pharmacy when that pharmacy is not part of the plan's network.

Furthermore, since hospital-based LTC facilities typically get pharmacy services from the affiliated hospital's pharmacy, the definition of LTC pharmacy must be sufficiently inclusive so that residents/patients in hospital-based LTC facilities have the same access to pharmacy services (without paying out of network prices) as residents/patients of free-standing LTC facilities that contract with typical LTC pharmacies.

SUBPART B—ELIGIBILITY AND ENROLLMENT

The rule allows inadequate time to ensure that all dual eligibles are appropriately enrolled in Part D, thus a delay of the duals' transfer from Medicaid to Medicare or another solution is required.

The proposed rule states that dual eligibles will be automatically enrolled in a PDP or MA-PDP, if they do not enroll themselves, by the end of the initial enrollment period, which, under section 423.36 is November 15, 2005 to May 15, 2006. However, Medicaid's drug benefit for dual eligibles will end on January 1, 2006. This means that duals could face a four and one-half coverage gap.

To enhance the dual's opportunity to select their own plans, we recommend that the transfer of duals be delayed for at least six months. This may require a change in the law and recommend that the Secretary pursue this option.

If it is not possible to delay the transfer, CMS needs to develop a workable alternative that will assure that duals are properly covered in appropriate Part D plans.

The need to develop a workable plan that does not rely on service providers to ensure than all LTC residents and other frail elderly receive the help they need to understand and select an appropriate plan

We are concerned that the proposed rules do not sufficiently specify how special needs populations (cognitively impaired elderly, frail elderly living alone without access to help from family or friends, residents of LTC facilities, and so forth) will obtain the information and help they need to select and sigh up for a plan. AAHSA's experience with the Prescription Drug Card in many settings (senior housing, assisted living, nursing facilities) taught us how difficult it is for even our own computer and Internet savvy staff to understand how to make wise choices. This new program is considerably more

complicated, as CMS is aware. We believe that SHIPS, Area Agencies on Aging, and other similar groups can provide the kind of detailed help needed, but they need additional resources to do the job.

AAHSA is also concerned that CMS not rely on providers of aging services to explain the new program or to help select a plan for the beneficiaries they serve. AAHSA fully intends to assist its members in the same kinds of voluntary educational activities that were undertaken with respect to the Medicare-approved Drug Card. Many of our state affiliates and members across the continuum of aging services worked hard to provide educational materials and forums for the beneficiaries they serve. We expect many to do the same with the new Part D program. But it would be particularly inappropriate, we believe, for providers of aging services to be expected to help beneficiaries actually select a plan.

SUBPART C—BENEFITS AND BENEFICIARY PROTECTIONS

The definition of "long term care facility" needs to assure that residents of facilities that rely on LTC pharmacies continue to have appropriate access to these pharmacies

The proposed rule asks for advice about how the term "LTC facility" shall be defined. The question presumably arises because the law explicitly gives CMS the authority to promulgate rules that include standards with respect to access for enrollees in "long term care facilities," but does not define that term. In the proposed rule, CMS says that it limited the definition to nursing facilities and skilled nursing facilities, based on the agency's understanding that "only those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long term care pharmacies" (69 Fed. Reg. at 46648-49).

There are, however, other types of facilities, notably including "assisted living facilities," that sometimes contract exclusively with LTC pharmacies. Many assisted living facilities serve populations identical to those found in some nursing home: there is substantial overlap among the populations, making the specialized services of LTC pharmacies attractive to a reportedly growing number of assisted living facilities. Therefore, the residents of these facilities need the same kinds of special rules to preserve access to the new Medicare Part D benefit as do residents of nursing facilities, where both are served by contracted LTC pharmacies.

Including assisted living facilities under the definition of "LTC facility" *strictly for the purpose of Part D* may be the only way to accomplish the important goal of assuring access to LTC pharmacies, at no higher (out of network) price, for residents of these facilities, as for those in nursing homes. But if a different way could be found to accomplish the same goal, that would be better. The assisted living movement has worked hard to define its philosophy and services as unique and there is concern that there might be some unintended consequences of defining assisted living as "long term care facilities" in a federal rule. An additional challenge of including assisted living

facilities under the definition of LTC facility is that there is no national definition of assisted living, although most states do define those or similar types of facilities (with definitions varying from state to state).

Letting the market evolve before promulgating a rule regarding plan's contracting with long-term care pharmacies

The proposed rule suggests two possible ways to balance the need to preserve access to LTC pharmacies and appropriate cost containment and asks for comments on which would be best. The two ways suggested are (1) encouraging plans to contract with LTC pharmacies and (2) requiring plans to contract with LTC pharmacies.

CMS expresses concern that LTC pharmacies will be in too strong a negotiating position if plans are required to contract with LTC pharmacies. It is not clear if that would be the case; in fact, it is extremely difficult to determine what the effect of either approach would be.

We therefore recommend that CMS specify that LTC residents who use LTC pharmacies that are out of network may not be charged out of network prices, but leave it to the plans to determine how best to make that work. This is likely tantamount to encouraging plans to contract with LTC pharmacies.

Access to appropriate formularies

The use of formularies is well established in many environments including hospitals, nursing homes, long term care pharmacies, and health plans. They can be tools to promote high quality pharmacy practices and responsible cost containment, or they may be used in ways that actually increase costs over all and/or prevent access to needed and appropriate therapy.

We are therefore reluctant to argue that LTC residents or others must have fully open formularies and recommend instead that CMS require that long term care residents have access to special formularies, meeting at a minimum the requirements set forth by the American Society Consultant Pharmacists for long term care populations.

We also recommend that residents of LTC facilities and others with similarly complex pharmacy needs be given a minimum six month grace period before being transitioned to any new formulary. It will take time to get medications changed, if that needs to happen.

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Respectfully submitted,

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American Association of Homes and Services for the Aging

CMS-4068-P-1297

Submitter : Mr. David Viele **Date & Time:** 10/04/2004 09:10:18

Organization : First Health Serivces Corporation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attached comments

CMS-4068-P-1297-Attach-1.doc

First Health Services Corporation
Comments on the Medicare Prescription Drug Benefit Proposed Rules
October 4, 2004

First Health Services Corporation is submitting comments on the Medicare Prescription Drug Benefit Proposed Rules. These comments are intended to improve the quality of the Medicare Part D program, to limit the disruption to the Medicaid dual eligibles, and enhance the benefits provided to the Part D enrollees. The Part D prescription drug program has been described as following a commercial model, and yet in a number of areas CMS is contemplating dictating how a PDP must operate by creating operational requirements in the rules. First Health Services has spent a considerable amount of time reviewing the proposed rules and hopes that CMS will consider our comments as the rules are finalized. Our comments are intended to be constructive with the goal to provide an effective Medicare Prescription Drug Program in January 2006.

Comments on the Medicare Prescription Drug Benefit Proposed Rules

B. Eligibility and Enrollment (Federal Register page 46637)

2. Part D Enrollment Process (§423.34) (Federal Register page 46638)

In implementing the automatic enrollment process for full benefit dual eligible individuals, we are considering which entity is best suited to perform the automatic and random enrollment function. The options include CMS or the State performing this function, or a contracted entity or entities on their behalf. If we (or a contractor on our behalf) performed the auto assignment, we would expect consistent, clear oversight of the process, thus making the process uniform nationally; this might also reduce the need to transmit data from CMS to the States. However, this would be highly dependent on receiving timely, accurate Medicaid eligibility data from States and would also make us responsible for a new national workload of indeterminate size.

An alternative is for States (or their contracted entities) to be responsible for performing the automatic enrollment. This approach may be appropriate because States have experience with random assignments through their Medicaid programs and have more immediate access to changes in Medicaid eligibility. We would define random assignment; establish standards for notification, and so forth, to ensure consistency. If we were to pursue this option, we could consider this function as necessary for the proper and efficient administration of the State plan. We would need to provide States with accurate and timely Part D data. States could be compensated for this effort through Federal financial participation (FFP) in their administrative expenses or through contractual or other arrangements. We invite comment on the most appropriate method of performing automatic assignment of dual eligibles and the appropriate entity to do so.

Comment: CMS has solicited comment on the question of whether the federal government (CMS or its contractor) or the States (or their contracted entities)

should have responsibility for administering the "random" automatic enrollment process for full benefit dual-eligible individuals who do not otherwise enroll in an MA-PD or PDP. *See* 69 Fed. Reg. 46,639 (Aug. 3, 2004). CMS suggests that State responsibility for this function might be appropriate because they have more immediate access to Medicaid eligibility changes and experience with random assignments through their Medicaid programs.

First Health Services opposes imposing this additional administrative burden, which CMS accurately describes in the Federal Register as "a new national workload of indeterminate size," on the States. As a threshold matter, the governing legislation is clear that this responsibility should fall upon the federal government. Section 1860D-1(b)(1)(C) of the Act unambiguously directs that, if there is more than one prescription drug plan available to a full-benefit dual eligible individual who has failed to enroll in a PDP or MA-PD plan, "*[t]he Secretary shall enroll* such an individual on a random basis among all such plans in the PDP region" (emphasis added).

Given this express designation of responsibility, neither the Secretary nor CMS has authority, by administrative regulation, to impose responsibility for the auto-enrollment function on the States. The preamble to the proposed rule suggests that administrative costs of auto-enrollment activities by the States might have to be borne, at least in some substantial part, by the States themselves. Moreover, even if administrative costs of carrying out this function were to be fully federally reimbursed (as would be more appropriate, given that the Part D program falls within the federal Medicare program, not the joint state/federal Medicaid program), it would nevertheless constitute a substantial, additional administrative burden on the States that they are not equipped to perform.

As the preamble to the proposed regulation acknowledges, CMS' assumption of the auto-enrollment responsibility will further the goals of national uniformity in, and facilitate federal oversight over, the process. Auto-enrollment will require accurate and timely information flow between CMS and the States in any event. There is no reason to assume that transmission of accurate Medicaid eligibility data from the States to CMS would be inherently any more problematic than transmission of accurate and timely Part D data from CMS to the States. Accordingly, First Health Services believes there is no legitimate rationale for transferring to the States an administrative responsibility that Congress clearly indicated should fall upon the federal government.

4. Coordination of Beneficiary Enrollment and Disenrollment through PDPs (§ 423.42) (Federal Register page 46641)

— Section 1860D–1(b)(1)(A) of the Act authorizes us to establish a process for enrollment in and disenrollment from prescription drug plans. We have outlined the coordination of enrollment and disenrollment through PDP organizations in the regulations at §423.42. A Part D eligible individual who wishes to make, change, or

discontinue an enrollment during applicable enrollment periods may do so by filing an enrollment with the PDP directly. We envision a paper enrollment form process and recognize the opportunity for other possible mechanisms that may prove secure, convenient for beneficiaries, and valuable to the efficient administration of the program. We request comments on other possible enrollment mechanisms that address data security and integrity, privacy and confidentiality, authentication, and other pertinent issues.

Comment: In order to ensure that as many beneficiaries as possible enroll in a PDP prior to implementation of a random, auto-enrollment process, we believe it is strongly advisable to facilitate the participation of the SPAPs [and other state agencies] in assisting beneficiaries with their enrollment in a PDP. While we believe that it would be inappropriate to require States to assume responsibility for the random auto-enrollment of all full benefit dual-eligible individuals, States should be permitted to voluntarily assist their residents, including dual eligibles, with the enrollment process. Such voluntary participation in the enrollment process by States will provide SPAPs with greater ability to facilitate the smooth transition of their populations into the Part D program. It will also ease the burden on the federal government of carrying out the auto-enrollment function under § 423.34, by diminishing the number of individuals who need to be auto-enrolled.

Medicare's experience with the drug discount card has demonstrated that seniors and other vulnerable populations often will not enroll on their own initiative in a program such as the Part D benefit, despite the advantages of the benefit being offered. The statute authorizes the random auto-enrollment of full-benefit dual-eligibles in a Part D program, but does not include the wider population of potential Part D beneficiaries in this provision. Accordingly, States should be given broad authority to create their own mechanisms to support the enrollment process and to assist individuals enroll in Part D benefits.

In order to achieve widespread beneficiary access to the current drug discount card, it has been necessary for SPAPs to execute applications for their members (with opt-out procedures, instead of affirmative actions required by beneficiaries to obtain the card). Similarly, SPAPs should be authorized to assist the beneficiaries they serve by completing PDP applications for their beneficiaries, as long as each beneficiary is fully informed of the enrollment assistance being provided by the SPAP, and his or her right to decline or opt out of that service prior to the start of the Medicare Part D benefit. While the First Health Services believes that CMS should bear responsibility for implementing the random auto-enrollment of dual-eligibles, mandated by Congress in the event such individuals are not otherwise enrolled in a Part D plan, First Health Services believes that SPAPs [and other State entities] should be given express authority – to the extent they have the resources and desire to do so – to assist in the enrollment of *any* of their qualified Part D beneficiaries prior to CMS' auto-enrollment.

Accordingly, we seek amendment to both § 423.34(b) and § 423.42(a) in order to clarify that a State may assist an individual with completion of the individual's PDP

application, including executing the application on the individual's behalf, or may otherwise assist an individual in the Part D enrollment process, as long as the individual is provided an opportunity to decline this assistance or "opt-out" of any available PDP.

6. Disenrollment by the PDP (§ 423.44) (Federal Register page 46641)

We are particularly interested in receiving comments about the requirement to disenroll individuals from a PDP if they no longer reside in the service area. Under the MA rules at 42 CFR 422.74, individuals who are out of the service area for more than 6 months will be disenrolled, unless the MA plan offers visitor or traveler benefits. We recognize the inherent difference between PDPs and MA plans (in particular, the range of services each provides) and that it may not be reasonable to apply the disenrollment requirements established under MA in the same way for PDPs. For example, while we have a limit on the length of time an MA enrollee may be out of the service area, this limit may not be necessary as long as there are specific assurances from the PDP that individuals will have access to PDP benefits while out of the area (provided the individual remains in the United States). For example, a regional PDP may either have a corporate or other relationship with a PDP in another region or have a network of pharmacies in other regions (or nationwide) that would provide access to prescription drugs outside of the region on the same basis as in-network pharmacies within the enrollee's region of residence. We would appreciate any comments on this area.

Comment: PDP's need the ability to disenroll an individual from their plan if the individual no longer resides in the service area, in the same manner as MA plans currently disenroll individuals. The disenrollment requirements should be the same for PDP's and MA plans. Since the PDP regions are not yet known, a PDP's relationship with pharmacies outside of the contracted region is unknown. PDP's may not be working in contiguous regions and may only have contracts with pharmacies within the region, therefore they will not have the capability of providing pharmacy coverage on the same basis as they have with in region pharmacies. If a state is a region, a larger number of PDP's will be in a position to provide services to the region. Not all PDP's may be able to provide the same access to drugs outside of the region. Pharmacy contracts are specific to a distinct geographical area, and discounts can vary between regions.

We plan to establish re-enrollment guidelines under the MA program for optional disenrollment for nonpayment of premium and disruptive behavior. We recognize, however, that this policy may not be appropriate for PDPs. If the individual is prohibited from re-enrolling in each of the MA plans available in an area, original Medicare is always available to provide and deliver services to that that individual. Under the PDP infrastructure, if the individual was prohibited from re-enrolling in each PDP available, there is no other option available. We would appreciate comments regarding the applicability of prohibiting re-enrollment in a PDP.

Comment: PDP's need the ability to disenroll an individual for non payment of premiums. PDP's are less concerned about disruptive behavior, since the PDP is only providing a pharmacy benefit. PDP's rely on all sources of revenue to be able to provide the pharmacy benefit. Without payment of premiums, one of the fund sources is removed, and the PDP's plan loses actuarial soundness. A process could be established where an individual would be re-enrolled upon payment of back premiums, and an agreement signed by the beneficiary for automatic payment of premiums through an EFT process.

8. Part D Information that CMS Provides to Beneficiaries (§ 423.48) (Federal Register page 46642)

We propose building on our experience in implementing the drug discount card price comparison Web site as we develop requirements for the Part D price comparison Web site, and we are seeking comments on how to provide information in the drug benefit to help achieve maximum drug savings.

Comment: In the Medicare Discount Drug card Program, the guidelines for the production of the price files has been unclear and thus interpreted differently by sponsors in the program. Our interpretation has been that these price files reflect our negotiated discount with our pharmacy network members. Others in the program have interpreted this to also include rebate discounts. With this kind of variance, prices on the Price File Comparison web site have been misleading for the member.

The multiple step process that is required and the lack of clarity make it difficult if not impossible to get through these screens successfully. Members have indicated that this process is confusing and have therefore not taken advantage of the comparison process.

The complexity of drug pricing and the negotiated rates and rebate discounts do not lend themselves to this type of inquiry – it has lead to confusion and concern for members. Production and publication of formularies with all drugs, their associated price and generic equivalents would appear to be less confusing.

The process of providing rebates at the point of sale is not a standard practice in the industry and has caused problems – adopting a similar model to that of Medicaid or even a commercial plan seems to make more sense and still serves to discount the cost of the drug to the member, if administered correctly. This way the network discount is applied at the point of sale, drug claims are submitted to the manufacturers retrospectively, rebates are returned to the sponsor and in our recommended case these rebates are then returned to the plan for use in reducing the cost of coverage. The usefulness of a pricing website is questionable without specific guidance from CMS on what the site is to contain.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections (Federal Register page 46646)

1. Overview and Definitions (§ 423.100) (Federal Register page 46646)

a. Covered Part D Drug (Federal Register page 46646)

— We are concerned that the aforementioned exclusion of outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer (or its designee) as a condition of sale (item 7 above) may prove too narrow to address inappropriate tying arrangements. We may consider expanding this exclusion and solicit public comments on how to reduce the risk of abusive tying arrangements.

We intend to ensure that the Part D benefit ''wraps around'' Part B drug benefits to the greatest extent possible. For example, Part D would cover immunosuppressive drugs furnished to Medicare beneficiaries who did not have their transplant paid for by Medicare (e.g., a beneficiary who had his or her transplant paid for by a private insurer when he or was employed, and the beneficiary has now enrolled in Part B). Part D could pay for these immunosuppressive drugs for these beneficiaries since Part B is prohibited by statute from paying for them. Therefore, we are soliciting comments concerning any drugs that may require specific guidance with regard to their coverage under Part D, and any gaps that may exist in the combined ''Part D & B'' coverage package.

Comment: There are concerns with CMS attempting to mandate the interactions between the PDP and the drug manufacturers. In a majority of instances, PDP's have the flexibility to obtain drugs in the same categories or classifications from multiple manufacturers. Tying arrangements are an issue between the PDP and the manufacturers, and not CMS. As long as the PDP complies with the formula requirements developed by the USP and adopted by CMS, the issue of which drugs are covered by the PDP can not be controlled by CMS. The Medicare Part D prescription drug benefit requires the establishment of formularies, in order for the PDP to operate successfully within the capitation rates created by CMS. Specific guidance on what drugs should be covered by Part D providers is not necessary.

b. Dispensing Fee (Federal Register page 46647)

— Because the statute is ambiguous on the meaning of ''dispensing fee,'' in this proposed rule we are not proposing a specific definition of ''dispensing fee,'' but instead are offering three different options we believe would be reasonable, permissible definitions of the term. We invite comments on each of the definitions proposed below.

Option 1: The dispensing fee would include only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including

charges associated with mixing drugs, delivery, and overhead. The dispensing fee would not include any activities beyond the point of sale (that is, pharmacy follow-up phone calls) or any activities for entities other than the pharmacy. Option 1 would differentiate between ''dispensing'' a covered Part D drug and ''administering'' one in order to restrict the scope of these fees to include only those charges for pharmacy services related to the preparation and delivery of a covered Part D drug. Under option 1, the dispensing fee could not include any charges associated with administering the drug once the drug has already been transferred to the beneficiary. Thus, for example, the fee would not include any professional fees (such as skilled nursing services), durable medical equipment (such as an external infusion pump or an IV pole), supplies (such as tubes and dressings), or even follow-up telephone calls from the pharmacy to the patient to check on the patient's progress with the drug.

Comment: First Health Services prefers this definition of dispensing fee as it is consistent with the definition used by NCPDP and is standard practice in the industry.

Option 2: The dispensing fee would include the activities included in Option 1, but in addition would include amounts for the supplies and equipment necessary for the drugs to be provided in a state in which they can be effectively administered.

Comment: The interpretation of this option is that it includes things such as the preparation of a compound drug. Typically a compound drug will have a variable dispensing fee for the complexity that is involved in its preparation. First Health Services does not see this as a replacement for option one but rather a variant that should be used for these compounded drugs that require more in the way of preparation and supplies in the pharmacy.

Option 3: The dispensing fee would include the activities in Option 2, but in addition would include activities associated with ensuring proper ongoing administration of the drugs, such as the professional services of skilled nursing visits and ongoing monitoring by a clinical pharmacist.

Comment: NCPDP has already provided for this type of pricing over and above the standard dispensing fee. Systems and transactions are available and used for the pricing and payment of professional services for the pharmacy in the preparation of drugs and the administration of drugs. In addition there are also professional services fees already in existence for use by nursing services care givers for the actual administration of drugs – we do not feel that this should be part of a dispensing fee in pharmacy.

However, we also recognize that options 2 or 3 would eliminate current gaps in coverage relative to home infused drugs. We have limited options 2 and 3 to cases of home infusion because this is the only circumstance we know of where the additional services associated with administering the drug would not already be covered under Medicare Part

A or B and would be necessary to ensure effective delivery of the drug. (For example, infusion therapy provided in a hospital outpatient setting or in a physician office could be covered under Part B. Infusion therapy by a hospice could be covered as part of the hospice benefit, if a patient meets the conditions for hospice care.) However, there may be related issues with respect to the administration of other drugs (for example, vaccines and inject able long-acting antipsychotic drugs), and we solicit comments regarding any implications for our proposed options

Comment: The point of sale systems in place today can and do support multiple variations of dispensing fees based on the drug or the amount of effort that is required to prepare and possibly administer the medication. Provider participation agreements can and are structured to support this multiple tier fee structure already. Once defined, these agreements can be executed and administered within the POS systems through the process of building rules for each instance. Then at the time the drug is requested and dispensed the pharmacists identify the scenario and the system handles the pricing. In addition the POS system can handle specialty care – such as home infusion. In our system a pharmacy, group of pharmacies or whatever set of providers can be identified and credentialed to handle specialty drugs such as home infusion, oncology drugs and so forth. Systems can handle the process as long as it meets NCPDP standards and the logic can be entered into the system.

2. Requirements Related to Qualified Prescription Drug Coverage (§ 423.104) (Federal Register page 46649)

a. Standard Prescription Drug Coverage (Federal Register page 46649)

We request comments regarding the treatment of health savings account (HSAs) vis-a`-vis our definition of ‘‘group health plan,’’ ‘‘insurance or otherwise,’’ and ‘‘third party payment arrangements.’’ Our strong preference is not to treat HSAs as group health plans, insurance or otherwise, or third party payment arrangements and therefore to allow HSA contributions to count toward incurred costs, since we see these funds as essentially analogous to a beneficiary’s bank account. We also seek comments on how to treat FSAs, health reimbursement accounts (HRAs), and Medicare savings accounts (MSAs), relative to our definitions of group health plan, insurance or otherwise, and third party payment arrangements.

Comment: All three types of savings accounts should be treated the same, and not be treated as an insurance plan. The HSA’s , FSA’s and HRA’s are created using the beneficiaries own funds. How the beneficiary uses these funds is up to him or her. Using the accounts to purchase prescription drugs should not be treated differently than if the drugs were used to pay for physician visits. CMS should not count these accounts as health insurance.

a). Pharmacy Access Standards (Federal Register page 46655)

We are interpreting the access standard under § 423.120(a)(1) such that a prescription drug plan or regional MA–PD plan would have to meet or exceed the access standards across each region in which it operates, and a local–MA–PD plan would have to meet or exceed the access standards in its local service area. In other words, a prescription drug plan or regional MA–PD that operates in a multi-region or national service area could not meet the access standards proposed in § 423.120(a)(1) by applying them across the entire geographic area serviced by the plan; instead, it would have to meet the standards in each region of its multi-region or national service area. We believe that such an interpretation maximizes plan flexibility while assuring the best possible access to pharmacies for Part D enrollees, and we request comments on our proposed approach.

Comment: Consideration should be given to the access standards for adjacent regions, as border pharmacies will serve more than one region. Without counting these pharmacies across multi-regions the access these pharmacies provide is not recognized. PDP's should be able to identify pharmacies outside of the region that will provide access within the region in which they have applied as a sponsor. Medicare beneficiaries are loyal customers to their pharmacies, they will continue to use their border pharmacies, as they have learned to trust the advice of their pharmacist. In some rural states, the access standards may have to be relaxed, as the TRICARE rural access standard may not be possible to meet due to a lack of pharmacies.

1. Overview and Definitions (423.100) (Federal Register page 46646)

c. Long-Term Care Facility (Federal Register page 46648)

We request comments regarding our definition of the term long-term care facility in § 423.100, which we have interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act, or a nursing facility, as defined in section 1919(a) of the Act. We are particularly interested in whether intermediate care facilities for the mentally retarded or related conditions (ICF/MRs), described in § 440.150, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. It is our understanding that there may be individuals residing in these facilities who are dually eligible for Medicaid and Medicare. Given that payment for covered Part D drugs formerly covered by Medicaid will shift to Part D of Medicare, individuals at these facilities will need to be assured access to covered Part D drugs. Our proposed definition limits our definition to skilled nursing and nursing facilities because it is our understanding that only those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies. However, to the extent that ICF/MRs and other types of facilities exclusively contract with long-term care pharmacies in a manner similar to skilled nursing and nursing facilities, we would consider modifying this definition.

Comment: As a result of the Olmstead decision, states have been moving seniors and persons with SSI benefits from institutions into less restrictive placements.

These placements include ICF/MR facilities for the disabled, community care, and assisted living facilities for the aged. In addition to these less restrictive institutional settings, states have implemented waiver programs for home and community based care as an alternative to placement in a nursing home. Medicare beneficiaries spend down their assets until they are forced into nursing homes. These alternatives provide Medicare eligible beneficiaries with a choice of placement. Exclusive contracts with a long term care pharmacy should not be the deciding factor on whether or not to extend the definition of long term care facility to other forms of housing other than traditional nursing homes; the beneficiaries' qualification for Medicare and their placement should be the deciding factor. States can identify Medicare eligible individuals who were institutionalized, and can also identify those individuals that, if it were not for the Olmstead decision or an 1115 waiver, would be institutionalized. These individuals are low income Medicare beneficiaries; having a Medicare prescription benefit at no cost will allow their income to be used for daily living expenses and not on prescriptions.

2. Requirements Related to Qualified Prescription Drug Coverage (423.104) (Federal Register page 46649)

a. Standard Prescription Drug Coverage (Federal Register page 46649)

We seek comments on how I/T/U pharmacies and IHS beneficiaries will achieve maximized participation in Part D benefits.

Comment: IHS beneficiaries will be eligible for the Medicare Part D benefit and the PDP must provide access, at a minimum, to the beneficiaries in accordance with TRICARE standards. Many of the IHS beneficiaries use I/T/U pharmacies, however many of these I/T/U pharmacies do not provide the wide range of drugs often found on the formulary of a PDP. PDP's will need to contract with I/T/U pharmacies in order to provide access to the IHS beneficiaries, and will need to encourage the I/T/U pharmacy to expand the number of drugs provided. PDP's will need to work with these pharmacies to provide outreach and education materials, and encourage the pharmacy to assist in enrolling IHS beneficiaries into Medicare Part D.

We are considering allowing prescription drug plans and MA–PD plans to count I/T/U pharmacies toward their network access requirements, provided: (1) Such pharmacies are under contract with the plan; and (2) it would be impossible or impracticable for the plan to meet the access standard in rural areas of its service area without the inclusion of an I/T/U pharmacy (or pharmacies) in that count because there is not a sufficient number of non-I/T/U pharmacies in those areas willing or able to contract with the PDP sponsor or MA organization in accordance with its terms and conditions. We invite comments on this proposed exception to our pharmacy access rules, including any impact it might have on pharmacy access for non-AI/AN Part D enrollees residing in those areas.

Comments: I/T/U pharmacies should be counted toward the network access standards as long as they are under contract with the PDP. Since these pharmacies serve a portion of the Medicare population, their absence in the access standards would skew the results. All pharmacies under contract serving the Medicare population should be included in the access standard calculation. Since these pharmacies can only serve the IHS populations, the pharmacy and the population they serve could be removed from the access standard calculation. Typically, commercial pharmacies exist for non IHS populations in the same communities that have I/T/U pharmacies.

— However, it is our goal to balance convenient access to long-term care pharmacies with appropriate payment for dispensing fees of efficient facilities. To the extent that we require plans to contract with long-term care pharmacies, it is our goal to assure that long-term care pharmacies charge reasonable dispensing fees to plans (and indirectly to CMS through the direct subsidy paid to prescription drug plans and MA–PD plans). We welcome comments regarding how to balance convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies under the provisions of the MMA.

Alternatively, we would not require that plans contract with long-term care pharmacies and would, instead, strongly encourage PDP sponsors and MA organizations offering MA–PD plans to negotiate with and include long-term care pharmacies in their plans' pharmacy networks. We seek public comment regarding the advantages and disadvantages of these two approaches.

Comments: Long Term Care pharmacies serve a target group of Medicare beneficiaries living in nursing homes. There are 5-6 national long term care pharmacy chains that serve nearly 80% of the nursing home industry. PDP's need the ability to negotiate with these pharmacies without the requirement from CMS that PDP's must contract with them. Publishing the fact that PDP's must contract with the LTC pharmacies will place the PDP at a disadvantage. PDP's will need the LTC pharmacies to meet the access standards; this need will encourage the PDPs to contract with the LTC's. Allowing the LTC pharmacies to count toward the access standards provides a benefit to the PDP to contract with the LTC pharmacies.

Similarly, we are considering two options for assuring access to I/T/U pharmacies by AI/AN Part D enrollees per the provisions of section 1860D–4(b)(1)(C)(iv) of the Act.

Another option for assuring access to I/T/U pharmacies under Part D would be not to require that plans contract with I/T/U pharmacies and, instead, to strongly encourage PDP sponsors and MA organizations offering MA–PD plans to negotiate with and include I/T/U pharmacies in their plans' pharmacy networks. We are concerned, however, that—in the absence of a contracting requirement—plans may make assumptions regarding the

administrative costs (whether real or perceived) of contracting with I/T/U pharmacies and may not actively solicit the inclusion of these pharmacies in their networks. It is our understanding that I/T/U pharmacies are not currently well integrated in commercial pharmacy networks. The lack of I/T/U pharmacies in Part D plan networks would render enrollment in Part D of little use to AI/AN beneficiaries who rely primarily on I/T/U facilities for their health care. We encourage comments regarding these two approaches, their advantages and disadvantages, and their ramifications for AI/enrollees who are eligible to enroll in Part D.

Comment: By allowing a PDP to consider the I/T/U pharmacy as part of their pharmacy access requirement, the PDP will have an incentive to contract with I/T/U pharmacies. PDP's will have an incentive to include I/T/U pharmacies in their network in order to gain access to the potential enrollees. There would be negative ramifications if PDP's did not contract with I/T/U pharmacies as a large majority of AI/AN beneficiaries utilize I/T/U pharmacies.

We seek comments on how I/T/U pharmacies and IHS beneficiaries will achieve maximized participation in Part D benefits.

Comments: IHS beneficiaries will be eligible for the Medicare Part D benefit, and the PDP must provide access to the beneficiaries in accordance with TRICARE standards at a minimum. Many of the IHS beneficiaries use I/T/U pharmacies, however many of these I/T/U pharmacies do not provide the wide range of drugs often found on the formulary of a PDP. PDP's will need to contract with I/T/U pharmacies in order to provide access to the IHS beneficiaries, and will need to encourage the I/T/U pharmacy to expand the number of drugs provided. PDP's will need to work with the I/T/U pharmacies to understand their role as a provider, and to understand the reliance by IHS beneficiaries on these pharmacies. PDP's will also need to work with these pharmacies to provide outreach and education materials, and encourage the pharmacy to assist in enrolling IHS beneficiaries into Medicare Part D.

3. Establishment of Prescription Drug Plan Service Areas (423.112) (Federal Register page 46655)

— Section 1860D–11(a)(1) of the Act requires that a prescription drug plan's service area encompass an entire PDP region, as established by us under § 423.112(b), and § 423.112(a) of our proposed rule codifies that requirement. However, as provided under § 423.112(e) of our proposed rule, a prescription drug plan can be offered in more than one PDP region (provided the plan encompasses the entire PDP region for each region where offered), as well as nationally.

Section 1860D–11(a)(2) of the Act provides us with the authority to establish PDP regions, and such PDP regions must be established in a manner that is consistent with the establishment of MA regions under 42 CFR 422.445 of our proposed rule. Section

1860D–11(a)(2)(B) stipulates that PDP regions must be, to the extent practicable, consistent with MA regions as established under section 1858(a)(2) of the Act. As provided under § 423.112(b)(2), however, if we determine that access to Part D benefits would be improved by establishing PDP regions that are different than MA regions, we may establish PDP regions that vary from MA regions. Section 423.112(d) of our proposed rule would continue to receive federal Medicaid grants under section 1108 of the Act to compensate them for drug coverage provided to Part D eligible individuals under specific conditions.

We intend to initially designate both PDP and MA regions by January 1, 2005. In accordance with section 1858(a)(2)(C)(i) of the Act, there will be between 10 and 50 PDP regions within the 50 States and the District of Columbia and at least one PDP region covering the United States territories. The PDP regions, like the MA regions, will become operational in January 2006.

We conducted a public meeting on July 21, 2004, in order to obtain broad public comment on the methodology we should use in establishing both the PDP regions and MA regions for MA regional plans, which would operate as preferred provider organizations (PPOs).

Comment: First Health Services believes that the establishment of PDP regions consistent with MA regions (as described in proposed § 422.55) is of far less importance than establishing PDP regions that are defined by individual State boundaries. It is critical to a number of operational aspects of Part D benefits administration that each State should be a separate PDP region. As the Proposed Rule seems to acknowledge, existing SPAPs will play a critical role in coordinating benefits with the PDPs for the most vulnerable populations to be served under the Part D program, as well as in providing "wrap-around" coverage for beneficiaries within these populations. The administrative complexities and burden of effectuating these goals will be enormously – and unnecessarily – increased to the extent that the boundaries of PDP regions are not consistent with the State boundaries defining the relevant SPAP service areas.

For example, it will be difficult for a PDP sponsor to effectively tailor its benefits and formulary so as best to serve individuals transitioning from an SPAP to a PDP, if the PDP must coordinate its program and benefits with multiple SPAPs that have differing formularies and benefit structures in place. Similarly, other aspects of the establishment and operations of PDPs, (e.g., compliance with State licensure requirements under § 423.401(a)(1)) would be substantially more complex if PDP regions were to be established to encompass service areas in more than one State.

First Health Services also believes that creating a separate PDP service area for each State will promote beneficial competition between potential PDP sponsors. In fact, the establishment of large, multi-State regions would be anti-competitive because only a small number of potential, corporate PDP sponsors would be of sufficient size to be able to bid for such large, multi-State service areas. However, if

separate PDP services areas are designated for smaller States, a greater range of potential PDP sponsors will realistically be able to bid on a service area contract and offer services.

First Health Services therefore urges CMS to amend § 423.112(b)(2) to clarify that the boundaries of MA regions will not be adopted to determine PDP regions except where such MA regions are defined by individual State boundaries. This proposal amendment fully complies with the statutory language authorizing the Secretary to establish PDP regions which differ from MA regions if the establishment of such different regions "would improve access to benefits under this part." *See* Section 1860D-11(a)(2) of the Act. Coordinating the efforts of the PDPs and the SPAPs, and increasing competition between PDPs, will ultimately improve beneficiary access to Part D benefits.

b. Formulary Requirements (Federal Register page 46659)

— To the extent that a PDP sponsor or MA organization uses a formulary to provide qualified prescription drug coverage to Part D enrollees, it would be required to meet the requirements of § 423.120(b)(1) and section 1860D–4(b)(3)(A) of the Act to use a pharmaceutical and therapeutic (P&T) committee to develop and review that formulary. As a note of clarification, we interpret the requirement at section 1860D–4(b)(3)(A) of the Act that a formulary be ''developed and reviewed'' by a P&T committee as requiring that a P&T committee's decisions regarding the plan's formulary be binding on the plan. However, we request comments on this interpretation. In addition, it is our expectation that P&T committees will be involved in designing formulary tiers and any clinical programs implemented to encourage the use of preferred drugs (e.g., prior authorization, step therapy, generics programs).

Comment: In issuing its proposed regulations, CMS has asked for commentary on the coordination between SPAPs and PDPs and suggestions of additional areas in which such coordination would be beneficial for the individuals to be served under Medicare Part D. First Health Services believes that effective coordination between the SPAPs and PDPs will be central to ensuring that uninsured and low-income individuals receive the assistance they need from both State programs and Medicare Part D, and urges CMS to more explicitly authorize and facilitate such coordination in the key area of establishing formularies.

Continuity of pharmaceutical treatment is of great importance to effective disease management and appropriate healthcare. As the proposed regulations themselves seem to acknowledge, PDP formularies must be developed with appropriate consideration of the point that – especially for older individuals – it is often therapeutically counter-productive, or even dangerous, to abruptly change medications. Accordingly, we believe that coordination of formulary development between SPAPs and PDPs is especially important and should be expressly encouraged by the Part D rules. It must be anticipated that a large number of

individuals will be transferring from state pharmaceutical assistance to Part D coverage through a PDP, with the likelihood that the SPAP will prospectively be providing those individuals with "wrap-around" benefits. In such cases, PDP development of formularies that are different from the formularies offered by the SPAPs serving the same beneficiaries could create a situation that would be confusing and potentially highly detrimental to beneficiaries' care.

To resolve these problems, First Health Services urges the Secretary to revise the regulatory provisions with respect to formulary development in two ways. First, the regulations should make clear that formulary development is one area in which SPAPs and PDPs are encouraged to closely coordinate their activities. Second, we strongly urge the Secretary to include in the regulations a provision that would permit a PDP to be deemed in compliance with the formulary requirements under § 423.120(b)(1) and (b)(2), upon appropriate certification by the PDP and an SPAP with which it is coordinating on benefits issues, that the PDP is adopting the SPAPs formulary and that the SPAP's formulary substantially meets the requirements of § 423.120(b)(1) and (b)(2). Such a regulatory change would provide PDPs with the flexibility that will be required in order to fully coordinate with an SPAP regarding formulary composition, thereby ensuring a smooth transition for beneficiaries whose primary drug coverage is transferred from an SPAP to a PDP.

As PDPs and MA-PDs coordinate benefits with secondary payers such as SPAPs, or when drug plans include in their networks certain pharmacies, such as 340B entities, we recognize that a duplicate rebate problem may arise; *i.e.*, a manufacturer may be expected to pay both a rebate negotiated with a Part D drug plan and an additional rebate negotiated or required under a different state or federal program. The risk of manufacturers paying duplicate rebates on the same drug is inevitable if CMS is successful in encouraging supplemental drug coverage by secondary payers, such as wrap-around coverage by SPAPs. [69 Fed. Reg. 46,633 (Aug. 3, 2004)]. However, while the drug industry's concern about duplicate discount arrangements is justified, we do not believe that it is the role of the Secretary to address this problem. The Medicare prescription drug benefit relies on market forces to set drug prices, and we believe that market forces will ensure that the matter of duplicate rebates is handled appropriately. Furthermore, we do not believe that the MMA provides CMS with the authority to prohibit duplicate rebate arrangements, and we believe that an attempt by CMS to do so would prove ineffective due to the complex interrelationships of multiple state and federal drug discount programs.

Drug manufacturers, as they negotiate rebates with PDPs and MA-PDs, can take the matter of duplicate rebates into account in their discussions with Part D drug programs, and undoubtedly will do so. Drug companies are in the best position to assess the unique facts surrounding potential duplicate discount arrangements, and to determine the level of risk involved and how best to address the problem. Manufacturers are knowledgeable regarding what rebates and discounts are already being offered to entities such as SPAPs, other federal payers such as

TRICARE or the Federal Employee Health Benefit Program (FEHBP), and 340B provider pharmacies. If the manufacturers choose to provide PDPs or MA-PDs with rebates that supplement these other rebates and discounts, they are free to do so. Alternatively, if manufacturers want to limit payment of rebates to PDPs and MA-PDs, they have this option too. Ultimately, market forces will lead to a solution that is acceptable to all parties.

The government has taken this non-regulated approach to the duplicate discount issue in comparable situations. In the context of interfaces between the Medicaid program and the 340B drug discount program, federal administrative mechanisms that otherwise protect manufacturers from being required to give duplicative discounts to Medicaid and 340B entities are lifted when a State chooses to outsource administration of its Medicaid drug benefit to a private party, typically a health maintenance organization that is paid on a capitated basis. Because the government considers payment of manufacturer rebates to such HMOs to be "voluntary" (as they will be for PDPs and MA-PDs under Part D), the drug manufacturer and HMO are left to resolve the potential duplicate discount problem through private negotiation.

Furthermore, we do not believe that CMS has the legal authority to promulgate a regulation that prohibits duplicate rebate arrangements. There is no statutory provision that provides authority for such a regulation and, indeed, such an action is precluded by section 1860D-11(i) of the Social Security Act, which states that "the Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors." This statutory provision effectively prohibits CMS from promulgating a rule regulating the amount of rebates between Part D drug plans and manufacturers, even in order to avoid duplicate rebates. Instead, in accordance with the clear legislative intent of this noninterference provision, CMS must leave the matter of duplicate rebates to the manufacturers and the drug plans.

It is also worth noting that, even if CMS had the authority to promulgate a regulation designed to avoid duplicate discount problems, no provision could adequately address the intricacies of the many state and federal rebate and discount arrangements that are potentially affected. CMS would have to anticipate every potential secondary rebate or discount, and would have to craft a solution that is specific to each rebate or discount scenario. For example, one federal law mandates that drug manufacturers not sell above a discounted price to 340B entities, while a different federal statute (administered by a different federal agency) dictates the discount under the TRICARE program. A CMS regulation would have to be reconcilable with both statutes. Discounts or rebates offered to SPAPs, on the other hand, are often governed by state laws. While we recognize that in the MMA Congress has generally preempted state laws governing PDPs and MA-PDs (*see* Sections 1856(b)(3) and 1860D-12(g) of the Social Security Act), there is no such authority to preempt state laws governing drug manufacturers and SPAPs. Accordingly, CMS may not regulate what rebates or discounts SPAPs obtain from drug manufacturers. As this small sample of considerations suggests, it would be

virtually impossible to draft a duplicate-discount rule adequately addressing the peculiarities of every state and federal drug discount program.

a).Pharmacy Access Standards (Federal Register page 46655)

We are interpreting the access standard under § 423.120(a)(1) such that a prescription drug plan or regional MA–PD plan would have to meet or exceed the access standards across each region in which it operates, and a local–MA–PD plan would have to meet or exceed the access standards in its local service area. In other words, a prescription drug plan or regional MA–PD that operates in a multi-region or national service area could not meet the access standards proposed in § 423.120(a)(1) by applying them across the entire geographic area serviced by the plan; instead, it would have to meet the standards in each region of its multi-region or national service area. We believe that such an interpretation maximizes plan flexibility while assuring the best possible access to pharmacies for Part D enrollees, and we request comments on our proposed approach.

Comments: Consideration should be given to the access standards for adjacent regions, as border pharmacies will serve more than one region. Without counting these pharmacies across multi-regions the access these pharmacies provide is not recognized. PDP's should be able to identify pharmacies outside of the region that will provide access within the region in which they have applied as a sponsor. Medicare beneficiaries are loyal customers to their pharmacies, they will continue to use their border pharmacies, as they have learned to trust the advice of their pharmacist. In some rural states, the access standards may have to be relaxed, as the TRICARE rural access standard may not be met due to a lack of pharmacies.

We invite comments as to minimum timeframes for periodic evaluation and analysis of protocols and procedures related to a plan's formulary by PDP plans and MA organizations offering MA–PD plans (for example, quarterly, annually

Comment: Since a PDP can only change their formulary at the start of each year, the minimum time frame for reviewing a plan's formulary should be annually.

5. Special Rules for Access to Covered Part D Drugs at Out-of-Network Pharmacies (§ 423.124) (Federal Register page 46662)

— Section 1860D–4(b)(1)(C)(iii) of the Act requires us to establish pharmacy access standards that include rules for adequate emergency access to covered drugs. Section 1860D–4(b)(2)(B)(i) of the Act mandates that we develop, adopt, or recognize standards relating to a standardized format for a card or other technology for accessing negotiated prices to covered Part D drugs by Part D enrollees. We reviewed the definition of an ''emergency medical condition'' (see § 422.113(b)(1)(i) of our proposed rule) under the MA program to determine whether the ''prudent layperson'' standard was an appropriate

standard for ascertaining whether the need for a covered Part D drug constitutes an emergency. However, we do not believe that the definition of an emergency medical condition, or a variation thereof, is entirely appropriate to prescription drugs. To the extent that a physician (or other prescriber) prescribes a covered Part D drug, we consider that covered Part D drug to likely be medically necessary. The issue of urgency or emergency is difficult to determine from a clinical perspective, however.

Comment: There are many categories and classes of drugs with multi-source drugs available to treat the same symptoms. To mandate that a prescription by a physician must be filled with the drug he or she prescribes removes flexibility from the PDP. While a drug prescribed by a physician should be medically necessary, physicians can not be given the authority to prescribe whatever drug they wish, and the PDP expected to cover that drug in its formulary. Authority of this level would undermine the entire formulary process. A PDP should be required to provide a drug in the category the physician is prescribing from, and not a specific drug.

We believe that enrollees under the aforementioned circumstances could not reasonably be expected to access a network pharmacy and must therefore be assured access to an out-of-network pharmacy as provided under § 423.124(a) of our proposed rule. We request comments on our proposed out-of-network access requirements. We are aware that routine access to out-of-network pharmacies by Part D enrollees may undermine a plan's cost-savings incentives. However, provided adequate access is assured under § 423.124(a), PDP sponsors and MA organizations offering MA–PD plans would have some flexibility to design their out-of-network coverage policies. PDP sponsors and MA organizations offering MA–PD plans may therefore

Comment: First Health Services believes that when a PDP meets or exceeds the TRICARE standards for access there should be no reason for a beneficiary to access an out of network pharmacy. These standards would easily provide emergency access to a beneficiaries needs. The only exception that should be allowed would be for prescriptions needed after an emergency room visit, when local pharmacies are closed. In that case the beneficiary would be allowed to access the drug from the hospital pharmacy. Other than this situation, beneficiaries must be expected to use network pharmacies. Since CMS is requiring PDP's to meet the TRICARE standards, CMS is setting access standards that provide adequate access to prescription drugs for all beneficiaries. PDP's must have the flexibility to restrict the use of out of network pharmacies.

Section 423.124(b)(1) of our proposed rule would require that the Part D enrollee be liable for any cost-sharing, including a deductible, that would have otherwise applied had the covered Part D drug been obtained at a network pharmacy. Such cost-sharing would be applied relative to the plan allowance for that covered Part D drug, which we propose defining in § 423.100 as the amount prescription drug plans and MA–PD plans use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at out-of-network pharmacies in accordance with the requirements of proposed

§ 423.124(b). We request comments on how to further define the term ''plan allowance.'' Our understanding is that it is current industry practice to define the plan allowance as the lowest of the contractual discount offered to pharmacies in a plan's standard contract (as described above, we are soliciting public comment regarding whether we should require PDP sponsors and MA organizations to offer a standard contract to all pharmacies), maximum allowable cost (MAC), or the pharmacy's usual and customary price (described below).

Comment: In our experience, standard practice is to contract with network pharmacies using the lesser of usual and customary, network discount percent, or in the case of a generic, the FUL or MAC.

In an instance when a member used an out of network pharmacy, they would pay the reverse of the above – we typically see that they are charged the greater of U&C, the pharmacy discount, or the FUL/MAC price.

In addition to this cost-sharing, and as provided under proposed § 423.124(b)(2), the enrollee would be responsible for any difference in price between the out-of-network pharmacy's usual and customary (U&C) price and the plan allowance for that covered Part D drug. The term ''usual and customary price'' refers to the price that a pharmacy would charge a customer who does not have any form of prescription drug coverage.

We request public comments regarding our definition of usual and customary price. We are concerned that, given our proposed out-of-network access policy, pharmacies may increase their U&C prices to increase their total reimbursement. This would be prejudicial not only to beneficiaries in need of out-of-network access, but also to uninsured individuals purchasing drugs at retail pharmacies, and we seek feedback on permissible ways to prevent such an outcome.

Comment: First Health Services agrees with the definition used for usual and customary. The only way that this can be established and monitored is to periodically review the dispensing practices of pharmacies both in and out of network. This is currently standard practice to determine suspected fraudulent behavior and is quite easy to determine by evaluating trends in dispensing for in network and out of network both prior to start up of the program and then periodically throughout the life of the program.

— When an enrollee purchases a covered Part D drug at an out-of-network pharmacy consistent with § 423.124(a) of our proposed rule, the cost-sharing he or she pays relative to the plan allowance ($22.50 in the example above) counts as an incurred cost against his or her annual out-of-pocket threshold because such out-of-network access to a covered part D drug is a covered benefit under those circumstances. As with the price differential that a beneficiary could incur by purchasing an extended supply (for example, 90-day) of covered Part D drugs purchased at a retail pharmacy rather than a mail-order

pharmacy (discussed in section II.C.4.a of this preamble), the price differential between out-of-network pharmacies' U&C costs and the plan allowance would also be counted as an incurred cost against a beneficiary's annual out- of-pocket threshold. We seek comments on our proposal that this price differential be counted as an incurred cost against the out-of-pocket threshold consistent with the definition of ''incurred cost'' in § 423.100 of the proposed rule. Under this approach, plans would be required to explicitly account for such price differentials in the actuarial valuation of their coinsurance in their bids. In addition, any such differential would also count toward the deductible for covered Part D expenditures between $0 and the plan's deductible. We welcome public comments regarding our proposed payment rules for covered Part D drugs obtained at out-of-network pharmacies when enrollees cannot reasonably obtain those drugs at a network pharmacy.

Comment: The cases in which a beneficiary "cannot reasonably obtain" drugs at a network pharmacy will be very limited. Since PDPs must meet the TRICARE standards for access, urban beneficiaries will have a pharmacy within 3 miles of their home, and suburban beneficiaries will have a pharmacy within 5 miles of their home. With this level of accessibility, beneficiaries should be restricted to obtaining their medications at network pharmacies only. Only in a case of an emergency when network pharmacies are unavailable should a beneficiary be allowed to go to an out of network pharmacy and have their expenditures counted as out of pocket expenses. It will be extremely difficult to incorporate the actuarial valuation of out of network expenditures in bids, since there isn't anyway to determine what level of out of network purchases will be made if CMS allows the proposed level of flexibility in the rules.

6. Coordination of Benefits with Other Providers of Prescription Drug Coverage (Federal Register page 46700)

a. Coordination with SPAPs

— We do not know how SPAPs will actually choose to coordinate with Medicare drug plans, and we welcome comment in this regard—particularly from States. We would like to better understand what SPAPs plan to do in 2006 relative to Part D interaction (such as in payment of premiums or claim-specific wrap-around), and how Medicare can assist State preferences in this regard. Our goal is to make the coordination of benefits process as functional for the beneficiary, pharmacy, and States as possible.

We assume that some SPAPS will pay Part D plans' premiums on behalf of enrollees. For SPAPs that choose to wrap-around coverage rather than paying premiums, we propose to include SPAP information in a coordination of benefits system described below. In this way, pharmacies will know that a claim should be sent to the SPAP following adjudication by the Part D plan.

We request comment on this proposed approach, including the feasibility of the approach for SPAPs and the ease of administration for pharmacies. We also request comment on whether or not SPAPs that choose to coordinate benefits on a wrap-around basis should

be required to provide feedback on how much of the remainder of the claim they have actually paid. Since SPAP payments count as true out-of-pocket spending toward catastrophic coverage, the Part D plans could simply assume that any amounts not paid by the Part D plan and sent to an SPAP for reimbursement would count toward calculating TrOOP. We are concerned that we may need information from SPAPs to determine more precisely the SPAP contribution or payment. But we are also mindful of systems implications for States and would appreciate comments in this regard, particularly from SPAPs

Comment: First Health Services believes that the proposed regulation presently designated § 423.464(e)(1)(ii) is inconsistent with the underlying statutory provision it purports to implement, and that its promulgation in final form would therefore be *ultra vires* and invalid. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") contains an "anti-discrimination" provision that is incorporated into the definition of State Pharmacy Assistance Program ("SPAP") within the meaning of Part D of the Medicare Act. See Section 1860D-23(b)(2) of the Social Security Act, as amended, 42 U.S.C. § 1395w-133(b)(2). Specifically, under the statutory provision, a qualifying SPAP must be one "which, *in determining eligibility and the amount of assistance to Part D eligible individuals under the Program*, provides assistance to such individuals in all Part D plans and does not discriminate based upon the Part D plan in which the individual is enrolled." (Emphasis added).

The plain meaning of the statute is that an SPAP – in order to be accorded "qualified" status under the Medicare Part D Program – may not "discriminate based upon the Part D plan in which the individual is enrolled" in the specific context of "determining eligibility and the amount of assistance to Part D individuals." The words of the statute limit the applicability of the "non-discrimination" requirement to that particular context – determinations of eligibility and amount of benefits – and do not extend to "discrimination" or preferential treatment in any other matters. Thus, the statutory provision may be construed to prohibit a qualifying SPAP from promoting individuals' enrollment in a "preferred" PDP by restricting an individual's eligibility for SPAP assistance or affording the individual a lesser amount of assistance as a consequence of the individual's enrollment in a different PDP. The language enacted by Congress makes no reference to, and does *not* restrict, "discrimination" based upon the plan an individual enrolls in, as long as the disparate treatment of an individual or particular pharmacy plan pertains to some activity or matter other than determinations of beneficiaries' eligibility and/or amounts of assistance.

The proposed regulation, by contrast, would expand this clearly limited non-discrimination provision well beyond the words employed by Congress. The proposed definition of an SPAP states that a State program will be considered an SPAP for Part D purposes only if it "[p]rovides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls." See 69 Fed. Reg. 46,832 (Aug. 3, 2004), proposed to be

codified at 42 C.F.R. § 423.464(e)(1)(ii). In other words, the regulation entirely ignores the statutory limitation of the referenced "discrimination" to differential treatment relative to "determinations of eligibility and amount of benefits," and instead appears to prohibit qualifying SPAPs from engaging in "discrimination" of any kind based on the PDP in which a beneficiary enrolls. Indeed, the preamble to the proposed Part D regulations appears to go even further, by stating flatly that an SPAP "may not steer beneficiaries to one plan or another through benefit design *or otherwise*." 69 Fed. Reg. at 46,697 (emphasis added). Thus, the proposed regulation sets out an exceptionally broad rule, far beyond that contained in the governing statute. Under this administrative interpretation of the law, there would appear to be no permissible means of implementing an SPAP's preference for a particular PDP to facilitate "wrap-around coverage" and minimize confusion for seniors and pharmacists under any circumstances.

First Health Services believes the putative non-discrimination rule that appears in the Proposed Rule and its preamble is incorrect and invalid as a matter of law. It is well established that an administrative regulation is invalid to the extent that it is inconsistent with the statutory provision it seeks to implement. See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837, 843-44, 104 S. Ct. 2778, 2782-83 (1984), ("Chevron") and other authorities cited at note 12 therein. It is equally well established that a statute may not properly be construed by simply ignoring the inclusion of certain words in the legislation. See, e.g., Alaska Department of Environmental Conservation v. EPA, _____ U.S. _____, _____ n.13, 124 S. Ct. 983, 1002 n.13. (2004) (Reiterating that it is a "cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.") See also TRW, Inc. v. Andrews, 534 U.S. 19, 31, 122 S. Ct. 441, 449 (2001); Bennett v. Spear, 520 U.S. 154, 173, 117 S. Ct. 1154, 1166 (1997).

The interpretation of the non-discrimination provision set forth in the Proposed Rule and its preamble gives no effect at all to the words "in determining eligibility and the amount of assistance to Part D eligible individuals under the Program." This critical limitation on the type of "discrimination" Congress expressly intended to prevent has impermissibly been read out of the statute altogether. The resulting, much broader formulation of a non-discrimination rule applicable to qualifying SPAPs is contrary to the plain meaning of the governing statute, and therefore invalid. Importantly, this revision of the statutory standard cannot be styled as the responsible agency simply "filling in the gaps" left by Congress in its legislation. It is often permissible, of course, for an agency responsible for a statutory scheme to resolve ambiguities in the legislation and "fill in" certain "gaps" in areas as to which Congress chose to be silent and explicitly or implicitly delegated authority to the agency to further elucidate a provision of the statute by regulation. See Chevron at 2782, citing Morton v. Ruiz, 415 U.S. 199, 231, 94 S. Ct. 1055, 1072 (1974). This is permissible, however, only where Congress has not spoken to the precise matter at issue. See Chevron at 2781 (where "Congress has directly spoken to the precise

question at issue" the agency "must give effect to the unambiguously expressed intent of Congress.") In the MMA, Congress has directly spoken to the definition of an SPAP and explicitly defined the type of "discrimination" in which a qualifying SPAP may not engage. There is no "gap" to fill in this regard. As the Supreme Court has observed, "[t]here is a basic difference between filling a gap left by Congress' silence and rewriting rules that Congress has affirmatively and specifically enacted." Mobil Oil Corporation v. Higginbotham, 436 U.S. 618, 625, 98 S. Ct. 2010, 2015 (1978).

In summary, the proposed regulation portrays a much broader and very different non-discrimination rule than is contained in the statute, and is inconsistent with the express statutory language establishing limitations on that rule Under the statute's express language, a qualifying SPAP would quite plainly be permitted to encourage beneficiaries to enroll in a "preferred" PDP by any otherwise legal means that does not constitute disparate treatment of individuals in respect to determinations of eligibility for, or the amount of, assistance. In other words, while a Part D qualifying SPAP would be required to provide the same amount of "wrap-around" coverage to an individual in an alternative plan as would be provided to the individual if enrolled in a "preferred" PDP designated by the SPAP, this would not prevent the SPAP from implementing a preference for a given PDP through other means. CMS, in its proposed regulations, has rewritten this statutory rule so as apparently to prohibit *any* kind of SPAP activity that might grant preference to a given PDP or steer beneficiaries to a particular PDP; the law does not permit this substitution of agency policy for clearly expressed legislative intent.

The final regulations should include a revision of Section 423.464(e)(1)(ii) so that the rule conforms to the express language and intent of Congress in prohibiting qualifying Part D SPAPs from employing determinations of beneficiaries' eligibility or amount of benefits to favor one PDP over another; but the CMS regulations may not validly expand this statutory rule to preclude any preferential treatment of a PDP by an SPAP.

As PDPs and MA-PDs coordinate benefits with secondary payers such as SPAPs, or when drug plans include in their networks certain pharmacies, such as 340B entities, we recognize that a duplicate rebate problem may arise; *i.e.*, a manufacturer may be expected to pay both a rebate negotiated with a Part D drug plan and an additional rebate negotiated or required under a different state or federal program. The risk of manufacturers paying duplicate rebates on the same drug is inevitable if CMS is successful in encouraging supplemental drug coverage by secondary payers, such as wrap-around coverage by SPAPs. 69 Fed. Reg. 46,633 (Aug. 3, 2004). However, while the drug industry's concern about duplicate discount arrangements is justified, we do not believe that it is the role of the Secretary to address this problem. The Medicare prescription drug benefit relies on market forces to set drug prices, and we believe that market forces will ensure that the matter of duplicate rebates is handled appropriately. Furthermore, we do not believe that the MMA provides CMS with the authority to prohibit duplicate rebate

arrangements, and we believe that an attempt by CMS to do so would prove ineffective due to the complex interrelationships of multiple state and federal drug discount programs.

Drug manufacturers, as they negotiate rebates with PDPs and MA-PDs, can take the matter of duplicate rebates into account in their discussions with Part D drug programs, and undoubtedly will do so. Drug companies are in the best position to assess the unique facts surrounding potential duplicate discount arrangements, and to determine the level of risk involved and how best to address the problem. Manufacturers are knowledgeable regarding what rebates and discounts are already being offered to entities such as SPAPs, other federal payers such as TRICARE or the Federal Employee Health Benefit Program (FEHBP), and 340B provider pharmacies. If the manufacturers choose to provide PDPs or MA-PDs with rebates that supplement these other rebates and discounts, they are free to do so. Alternatively, if manufacturers want to limit payment of rebates to PDPs and MA-PDs, they have this option too. Ultimately, market forces will lead to a solution that is acceptable to all parties.

The government has taken this non-regulated approach to the duplicate discount issue in comparable situations. In the context of interfaces between the Medicaid program and the 340B drug discount program, federal administrative mechanisms that otherwise protect manufacturers from being required to give duplicative discounts to Medicaid and 340B entities are lifted when a State chooses to outsource administration of its Medicaid drug benefit to a private party, typically a health maintenance organization that is paid on a capitated basis. Because the government considers payment of manufacturer rebates to such HMOs to be "voluntary" (as they will be for PDPs and MA-PDs under Part D), the drug manufacturer and HMO are left to resolve the potential duplicate discount problem through private negotiation.

Furthermore, we do not believe that CMS has the legal authority to promulgate a regulation that prohibits duplicate rebate arrangements. There is no statutory provision that provides authority for such a regulation and, indeed, such an action is precluded by section 1860D-11(i) of the Social Security Act, which states that "the Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors." This statutory provision effectively prohibits CMS from promulgating a rule regulating the amount of rebates between Part D drug plans and manufacturers, even in order to avoid duplicate rebates. Instead, in accordance with the clear legislative intent of this noninterference provision, CMS must leave the matter of duplicate rebates to the manufacturers and the drug plans.

It is also worth noting that, even if CMS had the authority to promulgate a regulation designed to avoid duplicate discount problems, no provision could adequately address the intricacies of the many state and federal rebate and discount arrangements that are potentially affected. CMS would have to anticipate every potential secondary rebate or discount, and would have to craft a solution that is

specific to each rebate or discount scenario. For example, one federal law mandates that drug manufacturers not sell above a discounted price to 340B entities, while a different federal statute (administered by a different federal agency) dictates the discount under the TRICARE program. A CMS regulation would have to be reconcilable with both statutes. Discounts or rebates offered to SPAPs, on the other hand, are often governed by state laws. While we recognize that in the MMA Congress has generally preempted state laws governing PDPs and MA-PDs (*see* Sections 1856(b)(3) and 1860D-12(g) of the Social Security Act), there is no such authority to preempt state laws governing drug manufacturers and SPAPs. Accordingly, CMS may not regulate what rebates or discounts SPAPs obtain from drug manufacturers. As this small sample of considerations suggests, it would be virtually impossible to draft a duplicate-discount rule adequately addressing the peculiarities of every state and federal drug discount program.

Separate Qualifications of an SPAP Component (Proposed 423.4640)

Under the proposed rule, in order for a State program to qualify as a SPAP for purposes of Medicare Part D, the State program must satisfy the criteria set forth at 42 C.F.R. § 423.464(e)(1).

Comment: States often use SPAPs to cover significantly varying populations (the regulations also encourage the creation of new SPAPs as a means of facilitating "wrap-around" coverage). For example, the needs of a very low-income beneficiary may be significantly different than the needs of a non-Medicare, non-Medicaid individual who is at 200% of the federal poverty level ("FPL"). States must take such differences into account when designing SPAP programs. As a result, some States may have established or may develop SPAP programs with different "components" that offer significantly different benefits to different populations.

First Health Services believes that the proposed regulations should be amended to clarify that an SPAP may have both "qualifying" and "non-qualifying" components for purposes of meeting the Medicare Part D definition of an SPAP. For example, a State program may have a component dedicated to providing supplemental care to dual-eligibles, a separate component for coverage of individuals between 135% and 150% of the FPL, and a component for individuals above 150% of the FPL. These components might be operated separately, with different enrollment mechanisms and rules. If one component does not meet one of the criteria set forth at 42 C.F.R. § 423.464(e)(1), this should not disqualify the remaining components that meet the definition of an SPAP for purposes of Medicare Part D.

There is precedent for such a model in the concept of a "hybrid entity" under regulations implementing the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). *See* 45 C.F.R. § 164.103. Under HIPAA, a single entity may designate both "covered" and "non-covered" components, so that the entire entity is

not inappropriately and unfairly constrained by the requirements of the HIPAA regulations. We believe a similar model should be developed under the Part D regulations to accommodate the varying needs of SPAPs.

Changes to Formulary (Proposed 423.120)

Under the proposed regulations, a PDP sponsor or MA organization generally may not alter the therapeutic categories and classes of its formulary other that at the beginning of each plan year (§ 423.120(b)(3)). Additionally, such an entity may not remove a drug from its formulary, or make a change in the preferred or tiered cost-sharing status of a drug, without providing at least 30 days notice to CMS, affected enrollees, authorized prescribers, pharmacies, and pharmacists (§ 423.120(b)(5)). Finally, a PDP sponsor or MA organization may not remove a drug from its formulary, or make a change in the preferred or tiered cost-sharing status of a drug, between the beneficiary election period and 30 days after the beginning of the contract year (§ 423.120(b)(6)).

Comment: First Health Services believes that the regulations should be amended to clarify that the above restrictions do not preclude a PDP sponsor or MA organization from adjusting its formulary after the time of its bid (on or before March 1, 2005) and before the initial enrollment period for beneficiaries (November 15, 2005), as long as such adjustments do not have the effect of violating other applicable requirements respecting formularies. Such adjustments may be necessary in order to achieve the coordination between an SPAP and a PDP sufficient to ensure that disruptive transitions in drug therapies are avoided for the SPAP's beneficiaries.

Accordingly, the regulations should be clarified to state that, as long as 30 days notice is provided to CMS, such a formulary change is permissible. Specifically, since any such changes would occur prior to the benefit year (*e.g.*, before January 1, 2006), and prior to the beneficiary election period (*e.g.*, proper to November 15, 2005), it should be made clear that no notice would be required for affected enrollees, authorized prescribers, pharmacies, and pharmacists (since the plan would not yet be in effect).

7. Public Disclosure of Pharmaceutical Prices for Equivalent Drugs (§ 423.132) (Federal Register page 46665)

— Finally, as provided in § 423.132(c)(5) of our proposed rule, we propose waiving the public disclosure requirement in § 423.132(a) under such circumstances as we deem to be impossible or impracticable. We request comments on the appropriateness of the circumstances we have proposed for waiver of the requirements in § 423.132(c), as well as any additional circumstances we may wish to consider. We note that a similar public disclosure requirement was waived for endorsed discount card sponsors under the

Medicare Prescription Drug Discount Card (42 CFR 403 and 408) for covered discount card drugs dispensed under several of the same circumstances as those described above.

— In § 423.132(d)(1) of our proposed rule, we propose waiving the requirement that information on differential prices between a covered Part D drug and generic equivalent covered Part D drugs be made available to prescription drug plan and MA–PD plan enrollees at the point of sale when prescription drug plan enrollees obtain covered Part D drugs in long-term care pharmacies. Long-term care pharmacies generally provide drugs directly to the skilled nursing facilities and nursing facilities where the patient resides, not directly to the patient, under a medical benefit. They also engage in a significant coordination of benefits effort that would require that at least some claims be processed off-line, and not in real time. Given the manner in which long-term care pharmacies provide prescription drugs to residents of long-term care facilities, as well as the way in which they process claims, it would be impracticable for these pharmacies to provide beneficiaries with information regarding covered Part D drug price differentials at the point of sale. Although long-term care network pharmacies would be exempt from the requirement that information about lower-priced generic alternatives be provided at the point of sale, they would not be exempt from the public disclosure requirement in § 423.132(a) altogether. We request comments regarding appropriate standards with regard to the timing of such disclosure by long-term care pharmacies to the institutionalized Part D enrollees they service. We note, as well, that under § 423.132(d)(2) of our proposed rule, we may modify the timing of the public disclosure requirement under such other circumstances as we deem compliance with that requirement to be impossible or impracticable.

Comment: Since beneficiaries in LTC facilities have no out of pocket costs, CMS should waive the public disclosure requirement for LTC pharmacies. PDP's will be contracting with LTC pharmacies for discounts and the best price available. Requiring the LTC pharmacies to comply with the public disclosure requirement does not seem to satisfy any purpose, as most LTC beneficiaries do not have a choice of pharmacies.

(Federal Register page 46666)

2. Cost and Utilization Management Programs, Quality Assurance Programs, Medication Therapy Management Programs (MTMP), and Programs to Control Fraud, Abuse, and Waste(§ 423.153)

a. Cost Effective Drug Utilization Management (Federal Register page 46666)

— We believe that a cost-effective drug utilization management program could also employ the use of prior authorization, step therapy, tiered cost-sharing, and other tools to manage utilization. We are aware that these are tools commonly used today to manage pharmacy benefit costs for many commercial and State programs. We believe that the competitive bidding and premium setting processes, combined with the requirements for transparency and information availability, provide powerful incentives for plans to innovate and adopt the best techniques available. We invite comment on whether there

are industry standards for cost effective drug utilization management and whether CMS should adopt any of these standards for PDPs and MA–PDs.

Comment: There are no industry standards that must be followed. The Pharmacy Benefit Management industry and government programs all have utilization management tools. The use of prior authorization, while used in both commercial and government programs, is constantly under attack by the pharmacy manufacturing industry. This is especially true in government programs. CMS should not establish and require a standard for the PDP's. This regulation goes beyond the authority of CMS, as it directs how a PDP must operate a portion of its business.

Although we have not included proposed regulations, we are considering for the final rule a requirement that these tools should be under the direction and oversight of a Pharmacy and Therapeutics Committee to ensure an appropriate balance between clinical efficacy and cost effectiveness. We seek comments on this issue. We also seek comments on requiring the direct involvement of a Pharmacy and Therapeutics Committee not only with cost containment measures, but also with other areas of quality assurance and medication therapy management. Again, although we have not included proposed regulations requiring this standard, we are considering this standard for our final rule.

Comment: P&T committees should focus on the clinical and therapeutic value of the drugs on the PDP formulary. P&T committees are not full time commitments as physicians and pharmacists typically do not work for the PDP. Requiring the P&T committee to be responsible for cost containment measures is outside the realm of what a P&T committee sees as their primary responsibility. The PDP is responsible for cost containment measures, as these measures are necessary for the PDP to operate within its bid. Quality assurance is also a responsibility of the PDP and not the P&T committee. P&T committees could assist the PDP in developing the medication therapy management programs, but the day to day operations of the program is the responsibility of the PDP. The P&T committee is an advisory committee to the PDP.

b. Quality Assurance (Federal Register page 46667)

—We note that the MMA does not define or explain the term ''medication error.'' Nevertheless, we believe a common definition is important. In the future, we may require quality reporting that includes error rates. We could use this information to evaluate plans. In addition, we may publish this information for enrollees to use when comparing and choosing their individual plans. Therefore, we particularly invite comments on how we could evaluate PDPs and MA–PDs based on the types of quality assurance measures and systems they have in place, how error rates can be used to compare and evaluate plans, and how this information could best be provided to beneficiaries to assist them in making their choices among plans.

Medication error reduction programs and requirements have been discussed in many venues and various definitions of ''medication error'' have been used. For example, in its proposed rule requiring bar codes on most human drug products, the Food and Drug Administration adopted the following definition of a medication error:

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (See 68 FR 12500 (March 14, 2003)). This definition of ''medication error'' is identical to that used by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). (See National Coordinating Council for Medication Error Reporting and Prevention, ''What is a Medication Error?'' (Undated)).

We are citing this definition in this preamble as one that we would use initially in interpretive guidance. We believe that this definition could be applied to, and include, adverse drug events and interactions as they pertain to quality assurance. As the state of industry practice evolves, we may, from time to time, update this definition by manual issuance. We invite comments on this definition.

Comment: Use of the POS/ProDUR capability of most pharmacy systems has built in edits and controls, both clinical and financial, that looks for such errors. If used, the POS/ProDUR systems can look for adverse drug to drug, drug to diagnosis, drug to gender, drug to age, and various other interactions when one drug is being administered and another is added to the therapy regimen. If used appropriately, the system will tell the pharmacist that there is a possible reaction or interaction that should be evaluated further by the dispensing pharmacist of the physician prescribing the medicine. First Health Services' experience has shown that many potential medication errors are avoided when the system is set up and used properly. Contributors to this problem have been documented as unclear handwriting on the part of the physician, transposition of information into the pharmacy system, unclear understanding on the part of the member.

Systems and processes have been put in place over the past several years to handle these errors and reduce the possibility of them occurring. Implementation of practice management systems that automatically print out a prescription rather than relying on the physician to hand write have improved legibility. A recent implementation of Eprescribing in the doctor's office has shown, in Florida Medicaid, that errors can be further reduced if the physicians have access to the ProDUR edits and rules in their office through use of a hand held PDA device. Subsequent automated distribution of these electronic scripts directly to the pharmacy can further reduce the risk of error.

Implementation of clinical management programs are a must where clinicians for the pharmacy benefit manager review dispensing and prescription trends for physicians and pharmacies and follow up with educational interventions when problems with dispensing or prescribing are seen.

5. Quality Improvement Organizations (QIO) Activities (§ 423.162) (Federal Register page 46672)

— We have been consulting, on an individual, organization by organization basis, with representatives from pharmacy benefit managers, managed care organizations, programs that have monitored drug utilization, and others who have utilized pharmacy claims data. We welcome comments related to the collection and use of information for providing quality improvement assistance related to Part D.

Comment: First Health Services uses this process in our normal business processes. Claims utilization data are reviewed by clinical pharmacy staff to determine appropriateness of prescribing practices, dispensing practices and many other areas. This data is used to show if there are education or other initiatives that need to be taken with the member population, the pharmacy providers who dispense drugs or the physicians who prescribe drugs. Intervention with these parties takes the form of letters stating any problems seen with practice; recommendations for change and can possibly result in face to face educational sessions.

There are two ways to perform this function – make the PDP responsible for conduct and reporting, or request data to be sent. If data is to be sent, then the request must take advantage of standard data definitions so that accurate comparisons can be made between data and sponsors.

This process is similar to the currently implemented Retrospective DUR process performed in Medicaid and many other commercial health plans.

F. Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation (Federal Register page 46674)

2. Requirements for Submission of Bids and Related Information (Federal Register page 46674)

— We are interested in providing information to potential bidders to help eliminate the uncertainty of drug trend for Medicare beneficiaries and in delaying the submission of pricing information as long as we can under the law and consistent with our need to inform beneficiaries. We solicit comment on the nature of any additional information needed to prepare bids and suggestions for any other methods that the bid submission process could be structured to provide for later pricing data submission.

Comment: PDP's need information on drug expenditures for seniors. While there is no central collection point for this information, a number of Medicare managed care plans provide prescription drug coverage. The sharing of expenditure information for non-Medicaid seniors will prove beneficial in the preparation of bids. PDP's need the final Part D final rules by January 1, 2005 so bid preparation can begin. CMS could allow the PDP's to submit their applications without the pricing information by the June 6, 2005 deadline. CMS could then begin the review and approval process of the non-financial information. Negotiations between CMS and PDP's must be completed on an expedited basis. In order to educate beneficiaries and to allow sufficient time for outreach efforts by PDP's, contracts should be awarded by mid August 2005.

7. National Average Monthly Bid Amount (Federal Register page 46683)

We welcome comments on the existence of regional price variation in drug prices and on any factors that could lead to that variation. As part of carrying out the Congress' requirement that our geographic adjustment methodology be ''appropriate,'' we believe the method would first require gathering data from PDPs and MA–PDs on regional drug prices. Therefore, we may not implement a geographic adjuster for the first few years of the program unless we have acquired sufficient information on pricing to accurately characterize that variation. If we were to determine that there is significant geographic variation in prices, we anticipate that we would announce the adjustment factors in advance of the bidding process for any year in which geographic adjustment would be applied to bids in the calculation.

Comment: Certain areas of the United States require geographical adjustments in the first year of PDP operation. Alaska and Hawaii, at a minimum, would require a geographical adjustment. Such and adjustment could initially be calculated by comparing spending for Medicaid fee-for-service dual eligibles in those States to that of other States.

8. Rules Regarding Premiums (Federal Register page 46684)

— We note that achieving very high (indeed, virtually universal) access to prescription drug coverage for beneficiaries who participate in Part D was a key Congressional consideration in enacting MMA. We would encourage comments from insurers, actuaries, and others with experience, data, or expertise in this area. We are particularly interested in receiving comments on the most appropriate level for the late enrollment penalty, the likelihood of whether a $.36 per month of delay penalty (that is, 1 percent for each month of delayed enrollment) constitutes an adequate safeguard against selection bias, and the importance of strongly encouraging widespread enrollment to maximize the affordability and stability of Part D premiums.''

Comment: A late penalty of 1% or an estimated penalty of $.36 per month will not constitute safeguard against selection bias, and is not enough of a penalty to encourage enrollment into a PDP. While widespread enrollment is a major goal of congress, there are alternate ways to develop wide spread enrollment. The Part D program encourages the coordination of benefits between SPAP's and PDP's. This coordination would be greatly enhanced by allowing SPAP's to auto enroll their members into a PDP. The auto enrollment process proved to be beneficial to the Medicare prescription drug card program. Seniors as a group will not enroll in health care programs without encouragement, this will be especially true for enrollees in SPAP's. Auto enrollment would also eliminate the potential of late enrollments for this sizable group of seniors.

G. Payments to PDP Sponsors and MA Organizations Offering MA-PD Plans for All Medicare Beneficiaries for Qualified Prescription Drug Coverage (Federal Register page 46685)

4. Requirements for Disclosure of Information (§ 423.322) (Federal Register page 46686)

a. Data Submission (Federal Register page 46686)

— As provided under sections 1860D–15(c)(1)(C), 1860D–15(d)(2) and 1860D–15(f) of the Act and in § 423.322 of our proposed regulations, we would condition program participation and payment upon the disclosure and provision of information needed to carry out the payment provisions. Such information would encompass the quantity, type, and costs of pharmaceutical prescriptions filled by enrollees that can be linked to individual enrollee data in our systems; that is, linked to the Medicare beneficiary identification number (HIC#). We would appreciate comments on the content, format and optimal frequency of data feeds. We believe that more frequent feeds than annually (weekly, monthly, quarterly) would allow us to identify and resolve data issues and assist the various payment processes. We are evaluating our minimum data requirements with regard to prescription drug claims. Our goal would be to determine the least burdensome data submission requirements necessary to acquire the data needed for purposes of accurate payment and appropriate program oversight. Our view is that we will need at least the following data items for 100 percent of prescription drug claims for the processes discussed below:

- Beneficiary name (first, middle initial, last).
- Beneficiary HIC#.
- Beneficiary birth-date.
- Eleven-digit NDC code.
- Quantity dispensed.
- Prescription drug cost before co-payment (ingredient cost, dispensing fee, sales tax amount).
- Beneficiary co-payment amount, and

- Date prescription filled.

Comment: PDP's have the capability of submitting prescription utilization data to CMS on a monthly basis, and in any format required. The PDP point of sale system, coupled with the enrollment information, will contain sufficient information to allow payments to be made on a beneficiary basis by CMS. All of the information listed above is included in the point of sale system. Submitting data on these time frames will allow CMS to complete the risk corridor evaluations and re-insurance subsidy calculations and payments on an ongoing basis rather than months after the close of the year. Similarly, PDP's can provide prescription utilization on a daily basis for persons with low income subsidies. Daily utilization for these groups of beneficiaries will allow the low income subsidy program to function as a fee for service program. The Medicare drug discount card currently operates on a fee for service program, where sponsors submit utilization daily to CMS for repayment of the drug claim. CMS pays the sponsor for the cost of the program within 24 hours. This process has worked well for the discount card program and sponsors. Without a fee for service reimbursement system, PDP's will be advancing millions of dollars to pharmacies for the payment of prescription drugs while waiting for reimbursement from CMS. The PDP point of sale system will have all of the information needed to implement a fee for service type program for the low income subsidy beneficiaries

We assume that ingredient cost and dispensing fee reflect point of sale price concessions in accordance with purchase contracts between plans (or their agents, such as PBM's) and pharmacies, but do not reflect subsequent price concessions from manufacturers, such as rebates. We anticipate that we will need similar data on prescription drug claims for appropriate risk-adjustment, reconciliation of reinsurance subsidies, and calculation of risk sharing payments or savings, and program auditing. Data will also be required for assessing and improving quality of care. We will welcome comments on the nature and format of data submission requirements for the following processes:

- Risk adjustment process would require 100 percent of drug claims in order to develop and calibrate the weights for the model for this new benefit. Consequently, PDP sponsors and MA organizations offering MA–PD plans would be required to submit 100 percent of prescription drug claims for Part D enrollees for the coverage year. Risk adjustment would require the submission of prescription drug agent identifying information, such as NDC codes and quantity, in order to allow the standardized pricing of benefits in the model. Because we would use standardized pricing, cost data on each prescription is not a requirement for risk adjustment, although it is needed for other purposes.

- The reinsurance subsidy payment process would require 100 percent of claims for each enrollee for whom the plan claimed allowable reinsurance costs. (Although reconciliation of the reinsurance subsidy does not require NDC codes or quantities, it does require member, cost and date of service data.) All claims for enrollees with expenses in excess of the out-of-pocket limit would be necessary to verify that the costs were allowable because the totality and order in which the claims are incurred

would define which claims would be eligible for reinsurance payments. While the start of reinsurance payments begins with claims after the out-of-pocket threshold has been reached, which is $5,100 in total spending (2006) for defined standard coverage, it may be associated with a higher dollar total spending amount under alternative coverage. Whatever the level, we would need to receive all claims by date of service including the amount of beneficiary cost sharing in order to determine the occurrence of the out-of-pocket threshold. Any plan-incurred costs for claims for supplemental benefits cannot be included in determining whether the out-of-pocket threshold has been met.

- The risk sharing process would require 100 percent of claims for all enrollees for the calculation of total allowable risk corridor costs. The plan would need to segregate costs attributable to supplemental benefits from those attributable to basic benefits since supplemental benefit costs are not subject to the risk corridor provisions. Again, all claims would be necessary to verify that the costs were allowable because the order in which the claims were incurred would help determine whether the claims were solely for basic coverage. For instance, a claim processed between a beneficiary's deductible and initial coverage limit (in standard coverage) would count towards risk sharing, but another claim (processed identically but immediately after the initial coverage limit has been reached) would not. Unlike the reinsurance subsidy, which is limited to individuals with expenses in excess of the out-of-pocket threshold, risk sharing involves costs (net of discounts, chargeback's and rebates, and administrative costs) for all enrollees for basic coverage, but only those costs that are actually paid by the sponsor or organization. Because all plans participate in risk sharing, potentially all claims for all Part D enrollees in all plans must be reviewed. Like the reinsurance reconciliation, risk sharing does not require NDC codes or quantities, but does require member, cost, and date of service data.

- The program audit process would require at least a statistically valid random sample of all Part D drug claims. We believe that several points of reference including HIC#, cost, date of service, and NDC code would be required for unique identification of individual claims in any random sample drawn from the population. If we receive 100 percent claims to support the payment processes, this sample could be drawn from our records. We believe it would be useful to obtain the prescribing physician's National Provider Identifier (NPI) number, as required by the administrative simplification provisions of HIPAA, in the elements of collected data for purposes of fraud control once it is available. Prior to May 2007 when the NPI is expected to be used, we would be interested in alternative means for identifying the physician prescriber. (Nothing in this data collection discussion should be construed as limiting OIG authority to conduct any audits and evaluations necessary for carrying out our proposed regulations.)

Comment: The Medicare drug discount card program has shown that this level of information is available in the sponsors' POS and enrollment systems. The only item that would be a problem is the provider's NPI number on the claims. This is not information currently collected unless the prescription is for a narcotic drug.

Other than the NPI number for each claim, the rest of the data can be provided to CMS on regularly scheduled basis.

b. Allowable Costs (Federal Register page 46687)

— Section 1860D–15(b)(2) and 1860D–15(e)(1)(B) of the Act and § 423.308 of our proposed regulations, specify that to determine ‘‘allowable costs’’ for purposes of both the reinsurance and risk corridor payments, only the net costs actually paid after discounts, chargeback's, and average percentage rebates, as well as administrative costs, are to be counted. We encourage comments on appropriate methodologies and data sources that can be used in making these adjustments. For example, we would like to receive comments on how price concessions (discounts, chargeback's, rebates, or any other periodic financial remuneration) would be most accurately and efficiently applied to prescription drug claims data to satisfy this requirement. We would also be interested in any information or data on the effect on costs such adjustments can be expected to yield. We are particularly interested in how data would be appropriately allocated and applied to the reinsurance subsidy tied to individual expenses in excess of the out-of-pocket limit.

Comment: Point of Sale systems are designed to handle pharmacy network discounts, deductibles, co-pays and other prescription related services and fees. They have historically not been used to provide a rebate to the member in a distinct and discreet way at the point of sale. Use of a standard Medicaid or commercial model for the negotiation, tracking and collection of rebates is preferred, as these models have proven track records. This provides for a process of applying negotiated rebate rates to the claims retrospectively, then submitting them to the manufacturer for payment and finally returning these rebates to the plan sponsor for use in covering the cost of administering the plan and providing coverage for members. This process is simpler to administer and does not modify the industry standard transaction data sets.

First Health Services does subscribe to the philosophy that these rebates should be returned to the plan sponsor rather than being retained by the PDP. The PDP should only receive an administrative fee for the handling of the rebates.

c. Coverage Year (Federal Register page 46687)

— In § 423.308 we propose that the term ‘‘coverage year’’ would mean a calendar year in which covered Part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than 3 months after the end of the year. In other words, drug

claims paid past the close of the 3-month period would not be considered part of that coverage year (or the next), and would not be used to calculate that year's payments or in reconciling risk adjustment payments for the year.

This limit would be imposed in order to provide timely closure for payment determination processes such as reinsurance, risk corridors and employer subsidies. While the period of 3 months would be significantly less than the fee-for-service Medicare medical claims standard of 18 months, we believe that a shorter period is warranted due to the highly automated and point of sale nature of prescription drug claim processing. We understand that the vast majority of prescriptions are not filled without the claim being simultaneously processed and therefore, there is a much shorter claims lag to be considered. We believe that the number and value of drug claims that would potentially be missed would be immaterial, consisting primarily of paper claims. The 3-month close-out window would not limit the liability of the plan or its claims processing contractor for reimbursing any lagging claims, but would simply establish a timely cut-off for finalizing payments. Any rebates for the coverage year not reflected in the fourth quarter data (sent to close out the year) must be credited against future payments. Although we are closing the year for claims purposes, the plan must account for all rebates that occur throughout the coverage year and send us all the data.

A shorter period would allow for payment processes that are dependent on the knowledge of total allowable costs for each coverage year to be concluded on approximately the same schedule as other reconciliations involving enrollment or risk adjustment data. On this schedule, calculations of risk sharing could begin as soon as five to six months after the close of the payment year. If the claims submission standard were a longer period, final reconciliations would be significantly delayed. We are interested in receiving comments on this timetable, specifically whether we should adopt a shorter or longer period than 3 months, and including data with which to estimate the proportion and value of drug claims that could be excluded with a 3-month close-out window.

Comment: The majority of claims are submitted and paid within the 90 day window described in this rule. From a processor viewpoint, there is very little reason for any longer period of time. It is the pharmacy and the member that determine when a claim is processed. If all parties know of the amount of time limitation then we see no problem with a 90 day rule.

5. Determination of Payment (§ 423.329) (Federal Register page 46688)

b. Risk Adjustment (Federal Register page 46688)

— Any risk adjustment methodology we adopt should adequately account for low-income subsidy (LIS) individuals (and whether such individuals incur higher or lower-than average drug costs). Our risk adjustment methodology should provide neither an incentive nor a disincentive to enrolling LIS individuals, and we request comments on this concern and suggestions on how we might address this issue.

Our particular concern is that a risk adjustment methodology, coupled with the statutory limitation restricting low-income subsidy (LIS) payments for premiums to amounts at or below the average, could systematically underpay plans with many LIS enrollees (assuming LIS enrollees have higher costs than average enrollees). If the risk-adjustor fails to fully compensate for the higher costs associated with LIS recipients, an efficient plan that attracts a disproportionate share of LIS eligible individuals would experience higher costs to the extent the actual costs of the LIS beneficiaries are greater than the risk-adjustment compensation. Failing to discourage enrollment by LIS beneficiaries in 2006, the plan would experience higher than expected costs in that year and presumably be driven to reflect these higher costs (due to adverse selection, not efficiency) in its bid for 2007. In this hypothetical, plans would have a disincentive to attracting a disproportionate share of LIS beneficiaries. One possible solution would be to assure that the initial risk-adjustment system, which will be budget neutral across all Part D enrollees, does not under compensate plans for enrolling LIS beneficiaries. In fact, to the extent that an initial risk-adjustor might at the margin tend to overcompensate for LIS beneficiaries, plans would have a strong incentive to disproportionately attract such beneficiaries. Plans could attract LIS beneficiaries both by designing features that would be attractive to such beneficiaries but also by bidding low. We would appreciate comments on this concern and suggestions on how we might address this potential problem.

Comment: PDP plans should first be compensated for premium underpayment for LIS enrollees when actual plan expenditures exceed the plan's target amount. After this initial level of reimbursement (when required), risk corridor computations should be applied as usual.

d. Reinsurance Subsidies (Federal Register page 46689)

ii. Payment of Reinsurance Subsidy (Federal Register page 46689)

— Since allowable reinsurance costs can only be fully known after all costs have been incurred for the payment year, we would propose to make payments on an incurred basis to assist PDP sponsors and MA organizations with cash flow. Under § 423.329(c)(2)(i), we would provide for payments of reinsurance amounts based on plan actual reinsurance-eligible allowable costs with a one-month lag period. In other words, no payments would be made until enrollees reached the true out-of-pocket threshold. This would require timely submission of drug claim data. In this approach rebates would be recognized in the month after they were received and would be offset against the previous month's actual costs.

Alternatively, we could consider payments of reinsurance amounts on a monthly prospective basis based on the reinsurance assumptions submitted and negotiated with each plan's approved bid. We would take these assumptions into account in developing either a plan-specific or program-wide approach. We note that any program-wide approach involving some kind of average of the amounts included in the bids would have

to adjust for the fact that plans providing enhanced alternative benefits would incur lower reinsurance costs. We are also aware that allowable reinsurance costs would be predominantly incurred in the latter parts of the coverage year and are considering the most appropriate methodology for distributing interim payments. One possible approach would require the submission of a schedule of the estimated timing of incurred allowable reinsurance costs along with the bid. For example, we might take schedules from each plan or we could propose an incremental schedule (X% of the total in January, Y% in February, etc.). We are aware that the prospective payment of estimated costs would create an incentive to overstate reinsurance, however, and are interested in ensuring that payments are not excessive. Since equal payments would be most compatible with our systems, in the first two years of the program (and for the first two years of new plans thereafter) we could also consider another approach paying 1.12th of the net present value of estimated allowable reinsurance costs in each month of the coverage year. The net present value would be calculated on the basis of all estimated reinsurance payments due at the end of the year and discounted by the most recently available rate for one-year Treasury bills. We would welcome comments on these approaches and on the appropriate treatment of interest in such a system.

Comment: PDP plans will be required to track actual enrollee spending on a daily basis. As such, plans will be aware on a daily basis of their reinsurance-related expenditures. To limit plan funding of reinsurance expenses and to avoid advance CMS payment for such expenses, it is recommended that plans invoice CMS daily (similarly to the way Medicare Discount Card transitional assistance is paid) and CMS reimburse plans within 48 hours.

6. Low-Income Cost-Sharing Subsidy Interim Payments (Federal Register page 46690)

— We are aware that low-income cost sharing would not necessarily be incurred evenly throughout the coverage year and are considering the most appropriate methodology for distributing interim payments. Since equal payments would be most compatible with our systems, in the first two years of the program (and for the first two years of new plans thereafter) we are considering an approach paying 1.12th of the net present value of estimated low-income cost sharing in each month of the coverage year. The net present value would be calculated on the basis of all estimated costs due at the end of the year and discounted by the most recently available rate for one-year Treasury bills. An alternative approach would require the submission of a schedule of the estimated timing of incurred low-income cost sharing along with the plan bid. For example, we might take schedules from each plan or we could propose an incremental schedule (X% of the total in January, Y% in February, etc.). We are aware that the prospective payment of estimated costs creates an incentive to overstate low-income cost sharing, and are interested in ensuring that our interim payments are not excessive. We would welcome comments on these approaches and on the appropriate treatment of interest in any methodology. For subsequent years of the program, we are considering an approach of paying 1.12th of the two-year prior year's actual expenses. Such an approach would need

to be trended forward by an appropriate index to account for expected growth in plan costs. In other words, in 2008 the interim payments would be based on actual reconciled low-income cost sharing subsidy payments for 2006 trended forward by an estimated two-year growth factor. Again, any reconciliation at the end of the year would need to be based on the sponsor providing adequate information in order to determine the subsidy amounts for the year. If the sponsor could not provide such information, interim payments would be recovered. In addition, the low-income payments would be subject to the same inspection and audit provisions applying to the other payments made under section 1860D–15 of the Act.

Comment: PDP plans will be required to track actual enrollee spending on a daily basis. As such, plans will be aware on a daily basis of their low-income subsidy-related expenditures. To limit plan funding of subsidy expenses and to avoid advance CMS payment for such expenses, it is recommended that plans invoice CMS daily (similarly to the way Medicare Discount Card transitional assistance is paid) and CMS reimburse plans within 48 hours.

8. Retroactive Adjustments and Reconciliation (§ 423.343) (Federal Register page 46693)

— We also request comment on the remedy that should be imposed in the event a PDP sponsor or MA organization offering an MA–PD plan fails to provide us with adequate information regarding risk-sharing arrangements. In the case of risk corridor costs, the organization or sponsor may owe the government money if, for example, prepayments exceed adjusted allowable risk corridor costs. In this case, failure to provide information could result in a shortfall to the government, since the entity would not have the information necessary for the Secretary to establish the proper amount owed. Although we have not proposed regulations on this issue, some of the remedies we are considering for the final rule are: (1) Assume that the sponsor's or organization's adjusted allowable risk corridor costs are 50% of the target amount; (2) assume that the sponsor's or organization's adjusted allowable risk corridor costs are the same percentage of the target amount as the mean (or median) percentage achieved by all PDPs or MA–PDs whose costs are lower than the target amount; (3) assume that the sponsor's or organization's adjusted allowable risk corridor costs are the same percentage of the target amount as the mean (or median) percentage achieved by all PDPs or MA–PDs (whose costs are both higher and lower than the target amount). We use a 50% threshold for option (a) because we believe this threshold would constitute a lower limit; and it would be unlikely for any organization or sponsor to have costs lower than 50% of their total payments. We request comments on these options, as well as proposals of other options that would allow us to recoup risk-sharing payments in the event a sponsor fails to provide us the adequate information necessary to determine appropriate risk-sharing payments.

Comment: Per the MMA rules, PDP's must submit year end utilization data for every individual enrolled in each region. CMS should be able to perform a match of PDP utilization against CMS enrollment files to determine if a PDP is reporting

utilization for all enrollees. While beneficiary expenditures that hit the risk corridors and reinsurance corridor will be known on a daily basis, beneficiaries who spend under the risk corridors will not be known until the end of the year. CMS will be unable to make an adjustment to the corridor for low spenders since they could have high utilization at the end of the year.

J. Coordination Under Part D Plans with Other Prescription Drug Coverage (Federal Register page 46696)

6. Coordination of Benefits with Other Providers of Prescription Drug Coverage (Federal Register page 46700)

— On rare occasions Part D plans would also be required to coordinate benefits with other Part D plans. In the event that a beneficiary disenrolled from one plan mid-year and enrolled in another, the two plans would be required to exchange information sufficient to allow the beneficiaries' claims to be processed as if there had been no break in enrollment. Specifically, the second plan would need to obtain the enrollee's claim data and adjust its claims processing system accumulators to reflect that a certain level of expenditures and out-of-pocket costs had already been incurred in order that the correct sequence of claims processing could be maintained. This is not to say that the second plan could claim the first plan's costs as their own allowable costs, but that their systems would process future claims as if the earlier costs had been incurred by the second plan. We solicit comments on any other issues that may be involved in coordination of benefits between Part D plans.

We solicit comment on how we can ensure that wrap-around coverage offered by SPAPs and other insurers does not undermine or eliminate the cost management tools established by Part D plans. We also request comment on the most effective way to administer this provision without creating undue administrative burden on either Part D plans or the SPAPs and other insurers that might choose to provide wrap-around coverage for eligible individuals.

Comment: Under the proposed rule, in order for a State program to qualify as a SPAP for purposes of Medicare Part D, the State program must satisfy the criteria set forth at 42 C.F.R. § 423.464(e)(1).

States often use SPAPs to cover significantly varying populations (the regulations also encourage the creation of new SPAPs as a means of facilitating "wrap-around" coverage). For example, the needs of a very low-income beneficiary may be significantly different than the needs of a non-Medicare, non-Medicaid individual who is at 200% of the federal poverty level ("FPL"). States must take such differences into account when designing SPAP programs. As a result, some States may have established or may develop SPAP programs with different "components" that offer significantly different benefits to different populations.

First Health Services believes that the proposed regulations should be amended to clarify that an SPAP may have both "qualifying" and "non-qualifying" components for purposes of meeting the Medicare Part D definition of an SPAP. For example, a State program may have a component dedicated to providing supplemental care to dual-eligibles, a separate component for coverage of individuals between 135% and 150% of the FPL, and a component for individuals above 150% of the FPL. These components might be operated separately, with different enrollment mechanisms and rules. If one component does not meet one of the criteria set forth at 42 C.F.R. § 423.464(e)(1), this should not disqualify the remaining components that meet the definition of an SPAP for purposes of Medicare Part D.

There is precedent for such a model in the concept of a "hybrid entity" under regulations implementing the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). See 45 C.F.R. § 164.103. Under HIPAA, a single entity may designate both "covered" and "non-covered" components, so that the entire entity is not inappropriately and unfairly constrained by the requirements of the HIPAA regulations. We believe a similar model should be developed under the Part D regulations to accommodate the varying needs of SPAPs. SPAP's would treat each PDP equally in providing wrap around services.

a. Coordination with SPAPs

— We do not know how SPAPs will actually choose to coordinate with Medicare drug plans, and we welcome comment in this regard—particularly from States. We would like to better understand what SPAPs plan to do in 2006 relative to Part D interaction (such as in payment of premiums or claim-specific wrap-around), and how Medicare can assist State preferences in this regard. Our goal is to make the coordination of benefits process as functional for the beneficiary, pharmacy, and States as possible.

We assume that some SPAPS will pay Part D plans' premiums on behalf of enrollees. For SPAPs that choose to wrap-around coverage rather than paying premiums, we propose to include SPAP information in a coordination of benefits system described below. In this way, pharmacies will know that a claim should be sent to the SPAP following adjudication by the Part D plan.

We request comment on this proposed approach, including the feasibility of the approach for SPAPs and the ease of administration for pharmacies. We also request comment on whether or not SPAPs that choose to coordinate benefits on a wrap-around basis should be required to provide feedback on how much of the remainder of the claim they have actually paid. Since SPAP payments count as true out-of-pocket spending toward catastrophic coverage, the Part D plans could simply assume that any amounts not paid by the Part D plan and sent to an SPAP for reimbursement would count toward calculating TrOOP. We are concerned that we may need information from SPAPs to determine more precisely the SPAP contribution or payment. But we are also mindful of systems implications for States and would appreciate comments in this regard, particularly from SPAPs.

Comment: In issuing its proposed regulations, CMS has asked for commentary on the coordination between SPAPs and PDPs and suggestions of additional areas in which such coordination would be beneficial for the individuals to be served under Medicare Part D. First Health Services believes that effective coordination between the SPAPs and PDPs will be central to ensuring that uninsured and low-income individuals receive the assistance they need from both State programs and Medicare Part D, and urges CMS to more explicitly authorize and facilitate such coordination in the key area of establishing formularies.

Continuity of pharmaceutical treatment can be of great importance to effective disease management and appropriate healthcare. As the proposed regulations themselves seem to acknowledge, PDP formularies must be developed with appropriate consideration of the point that – especially for older individuals – it is often therapeutically counter-productive, or even dangerous, to abruptly change medications. Accordingly, we believe that one area in which coordination between SPAPs and PDPs is especially important and should be expressly encouraged by the Part D rules is that of formulary development. It must be anticipated that a large number of individuals will be transferring from state pharmaceutical assistance to Part D coverage through a PDP, with the likelihood that the SPAP will prospectively be providing those individuals with "wrap-around" benefits. In such cases, PDP development of formularies that are different from the formularies offered by the SPAPs serving the same beneficiaries could create a situation that would be not only confusing but potentially highly detrimental to beneficiaries' care.

To ameliorate these problems, First Health Services urges the Secretary to revise the regulatory provisions with respect to formulary development in two ways. First, the regulations should make clear that formulary development is one area in which SPAPs and PDPs are encouraged to closely coordinate their activities. Second, we strongly urge the Secretary to include in the regulations a provision that would permit a PDP to be deemed in compliance with the formulary requirements under § 423.120(b)(1) and (b)(2), upon appropriate certification by the PDP, and an SPAP with which it is coordinating on benefits issues, that the PDP is adopting the SPAPs formulary and that the SPAP's formulary substantially comports with the requirements of § 423.120(b)(1) and (b)(2). Such a regulatory change would provide PDPs with the flexibility that will be required in order to fully coordinate with an SPAP regarding formulary composition, thereby ensuring a smooth transition for beneficiaries whose primary drug coverage is transferred from an SPAP to a PDP.

Sub Part K. Proposed Application Procedures and Contracts With PDP Sponsors (Federal Register page 46707.

6. General Provisions

— Section 1860D–4(b)(1)(A) of the Act assures pharmacy access by requiring a PDP sponsor to permit the participation of any pharmacy that meets the terms and conditions under the plan. Based on this requirement, we are considering adding the following language to the contract provisions: The PDP sponsor would agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any

willing pharmacy may access the standard contract and participate as a network pharmacy. We are interested in public comment on the inclusion of such a provision.

Comment: PDP's will create a pharmacy network within each region that will meet the TRICARE standards as required by the MMA. PDP's will welcome all interested pharmacies, however the pharmacy must agree to provisions of the PDP's contract. CMS should not become involved in contracting issues between PDP's and pharmacies.

M. Alternatives Considered (Federal Register page 46801)

1. Designation of Regions

— The MMA requires that we establish between 10 to 50 PDP regions within the 50 States and District of Columbia and at least one PDP Region covering the territories. These regions will define PDP service areas. PDPs that provide service in a particular region must cover that region entirely. PDPs can submit bids to provide services in anywhere from one to all regions.

The MMA stipulates that, to the extent practicable, PDP regions must be consistent with MA regions. However, if we determine that access to Part D benefits would be improved by establishing PDP regions that are different than MA regions, we may do so. As discussed in the preamble, we anticipate designating PDP and MA regions before January 1, 2005. The designation of regions will be made after the market study required by the MMA and the opportunity for public discussion and comment on this study.

In designating PDP regions, our primary objective will be to ensure that all beneficiaries have reliable access to PDP plans at the lowest possible cost. The law requires that beneficiaries have a choice of enrolling in at least 2 qualifying plans, at least one of which is a PDP. If it is not possible to achieve that with PDP plans undertaking the standard level of risk, the law makes provision for limited risk PDPs, and in cases where that does not occur a fallback plan that is paid based on cost.

For several reasons, we believe it is beneficial to have several PDP plans operating in a region. Most importantly, more plans means greater beneficiary ability to obtain coverage that meets their needs and greater competitive pressure to provide high quality and low costs. We also believe that PDPs that assume some financial risk, as opposed to a fallback plan that is paid based on cost, are likely to negotiate larger price concessions for beneficiaries. In addition, more competition for enrollees between PDPs, as well as MA–PDs, is likely to generate higher quality service for beneficiaries.

Given the goal of providing beneficiary access to risk-bearing PDP plans in as many areas as possible, an important question is what type of regional configuration, or method of configuring regions, has the greatest likelihood of achieving this. One of the principal questions is whether regions should be comprised of the largest possible number (the 50 States, or a close approximation), or a smaller number of regions covering much larger geographic areas. Designating a smaller number of regions that cover large geographic areas might be desirable in the sense that areas that might be less likely to attract market interest could be grouped with other more sought after areas. Large regions might also offer PDPs a larger potential enrollee market that would provide more leverage in negotiating rebates and discounts with manufacturers. On the other hand, regions of too large a size could deter participation if there are concerns by PDPs about providing uniform benefits and bearing financial risk across large and possibly diverse health care markets. In addition, large regions may make it more difficult for small organizations to participate as PDPs, although there is nothing to preclude small organizations from forming joint ventures to participate.

We recognize that there are a number of other factors that would affect any decision on the designation of regions, including State licensure issues for insurers and size and capital requirements for plans, as well as other potential barriers to initial or subsequent market entry; the number of competitors that are likely to operate in an area; and the goal of initiating and sustaining competition. We seek public comment on the various factors that may influence potential PDP plans' participation decisions and on how we can design regions in such a way to best ensure access to PDP plans. Another issue to be considered in designating PDP regions is whether they should be the same as Medicare Advantage (MA) regions. The statute stipulates that to the extent practicable, PDP and MA regions should be the same. However, because of the nature of health plan markets for physician and provider services, as opposed to the kind of product that PDPs will be offering and the uncertainty related to configuring insurance pools for risk-based drug only products, we believe potentially it may not be feasible to have the same regional configurations for each of these programs. For example, as shown in the regional market entry for the Medicare drug discount card, there are States in which there are no entrants by regional based drug card programs, yet these are markets in which there are MA plans. Also, there were States in which there was market entry by regional card programs but in which no MA plans participate. This might suggest that different regions may be appropriate for PDPs and MA plans. However, as noted previously, it is uncertain the extent to which experience with market entry by Medicare-approved discount card sponsors foreshadows what might occur under the Medicare drug benefit. We welcome comments on issues that should be considered in determining whether or not PDP and MA regions should be the same.

Comment: First Health Services believes that the establishment of PDP regions consistent with MA regions (as described in proposed § 422.55) is of far less importance than establishing PDP regions that are defined by individual State boundaries. It is critical to a number of operational aspects of Part D benefits administration that each State should be a separate PDP region. As the Proposed Rule seemingly acknowledges, existing SPAPs will play a critical role in coordinating benefits with the PDPs for the most vulnerable populations to be

served under the Part D program, as well as in providing "wrap-around" coverage for beneficiaries within these populations. The administrative complexities and burden of effectuating these goals will be enormously – and unnecessarily – increased to the extent that the boundaries of PDP regions are not consonant with the State boundaries defining the relevant SPAP service areas.

For example, it will be difficult for a PDP sponsor to effectively tailor its benefits and formulary so as best to serve individuals transitioning from an SPAP to a PDP, if the PDP must coordinate its program and benefits with multiple SPAPs that have differing formularies and benefit structures in place. Similarly, other aspects of the establishment and operations of PDPs, (e.g., compliance with State licensure requirements under § 423.401(a)(1)) would be rendered substantially more complex if PDP regions were to be established so as to encompass service areas in more than one State.

First Health Services also believes that creating a separate PDP service area for each State will promote beneficial competition between potential PDP sponsors. In fact, the establishment of large, multi-State regions would be anti-competitive because only a small number of potential, corporate PDP sponsors would be of sufficient size to be able to bid for such large, multi-State service areas. However, if separate PDP services areas are designated for smaller States, a greater range of potential PDP sponsors will realistically be able to bid on a service area contract and offer services.

First Health Services therefore urges CMS to amend § 423.112(b)(2) to clarify that the boundaries of MA regions will not be adopted to determine PDP regions except where such MA regions are defined by individual State boundaries. Such an amendment fully complies with the statutory language authorizing the Secretary to establish PDP regions which differ from MA regions if the establishment of such different regions "would improve access to benefits under this part." *See* Section 1860D-11(a)(2) of the Act. Coordinating the efforts of the PDPs and the SPAPs, and increasing competition between PDPs, will ultimately improve beneficiary access to Part D benefits.

4. Administration of Subsidy Program (§ 423.800)

— We would be establishing a process to notify the PDP sponsor or MA organization that an individual is both eligible for the subsidy and the amount of the subsidy. Because CMS has not yet developed such a process, comments are welcome concerning notification to the PDP sponsor or MA organization that an individual is eligible for a subsidy and the amount of the subsidy. Similarly, we request comments on the proposed requirement that the PDP sponsor or MA organization notify CMS that premiums or cost-sharing have been reduced and the amount of the reduction. We are also considering the process for reimbursing the sponsor or organization for the amount of the premium or cost-sharing reductions. Any individually identifiable information must be kept confidential. Finally, we are requesting comments on how to best reimburse subsidy

eligible individuals with respect to out-of-pocket costs relating to excess premiums and cost-sharing incurred before the date the individual was notified of subsidy eligibility but after the effective date the individual became subsidy eligible.

Comment: PDP's must be notified upon enrollment into the Part D program of their eligibility determination for LIS. This notification is critical to ensure proper access to the beneficiary's medications. CMS should provide a daily tape match to the PDP that provides the LIS identifier. This would be similar to the process used in the Medicare drug discount card program for persons eligible for the Transitional Assistance benefit.

CMS-4068-P-1298

Submitter : Ms. Liz Savage **Date & Time:** 10/04/2004 09:10:20

Organization : The Arc of the United States

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter from The Arc of the United States on the Medicare Prescription Drug Benefit

CMS-4068-P-1298-Attach-1.doc

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS – 4068 – P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: Comments to the "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632, CMS File Code CMS-4068-P

To Whom It May Concern:

The Consortium for Citizens with Disabilities (CCD) submits the following comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit." CCD is a Washington-based coalition of national disability organizations that advocates on behalf of the 54 million people with disabilities and chronic conditions in the United States.

We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions to insure that they will have the following: 1) Adequate information and assistance in navigating the enrollment and plan selection process; 2) Access to an affordable benefit that provides the drugs they need; and, 3) Access to an exceptions and appeals system that permits them to easily resolve unfavorable plan decisions in a timely manner.

Many of the CCD organizations worked with the Medicare Consumers Working Group, a broad coalition of advocates for Medicare beneficiaries, who submitted comprehensive comments on the proposed rule. CCD believes that significant revisions in the proposed rule are needed in order to ensure that people with disabilities have access to a quality prescription drug benefit and to ensure that full benefit dual-eligible beneficiaries ("dual eligibles") are not disadvantaged further by inadequate access to needed care. However, rather than duplicating the Medicare Consumers Working Group's extensive effort and detailed comments, CCD is submitting comments on issues we have identified as priorities

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for Medicare beneficiaries with disabilities. We recommend that CMS take the following steps to protect the health of people with disabilities and chronic conditions:

- Delay the implementation of the Part D program for dual-eligibles
- Expand outreach to Medicare beneficiaries with disabilities
- Designate special populations who will receive affordable access to an alternative formulary
- Impose reasonable limits on cost containment tools
- Strengthen and improve the inadequate and unworkable exceptions and appeals processes
- Require plans to dispense a temporary supply of drugs in emergencies

CCD believes that in many ways the Preamble provides much better guidance than the proposed rule itself and that the specificity in the Preamble should be reviewed by CMS and included in any final rule. On the other hand, we are concerned that there are critical gaps in information in the Preamble that also should be expanded upon. This is an extremely complex law with life and death implications for people with disabilities and chronic conditions. Therefore we suggest that CMS support the delay of implementation of the law for dual-eligibles and publish a second NPRM that reflects the input CMS receives on these proposed rules.

SUBPART B—ELIGIBILITY AND ENROLLMENT

A successful implementation of the MMA will require strong regulatory protections to ensure that people with disabilities are adequately informed that they must enroll in the Part D program and select a private prescription drug plan. In addition, for many people with disabilities, Medicaid prescription drug coverage will end—dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) must be clearly informed of the need to take action to prevent interruptions in access to prescription drugs.

The final rule must ensure that the enrollment process takes into account the unique needs of people with disabilities and recognizes the exceptional challenges of appropriately educating, screening, and enrolling people with disabilities.

423.34(d)(1), Temporarily Extend Medicaid FFP for Full Benefit Dual Eligibles

CCD is deeply troubled by the very real possibility that CMS will not be able to implement the MMA under the current timeframe in a way that adequately responds to the needs of people with disabilities and that ensures that access to prescription drugs will not be interrupted for dual eligibles for whom drug coverage will transfer from Medicaid to a private Medicare Part D plan. Therefore, in the strongest possible terms, we request that CMS immediately indicate its support for legislation that would delay the implementation of the MMA for dual eligibles.

Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006.

CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit starting on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the likelihood that not all 6.4 million dual-eligibles will be identified, educated, and enrolled in six weeks (from November 15, 2005, the beginning of the enrollment period to January 1, 2006), we recommend that the transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. The statute requires auto-enrollment on a random basis for all dual eligibles not enrolled on January 1, 2006. CCD has grave concerns regarding how this process might occur for the following reasons:

- It is very likely that many, if not a majority, of dual eligibles will not be able to enroll by January 1, 2006. Existing caseworkers in non-profits, government offices, or SPAPs will not have sufficient time with all 6.4 million dual eligible beneficiaries to educate them on the myriad choices, finding new providers, counseling them on formularies, or shepherding them through a complex enrollment process.

- Assigning dual eligibles on a random basis will—by statute—steer dual eligible beneficiaries into the lowest-cost plan. As a result of being the lowest cost plan, beneficiaries will have significantly restricted access to medications currently being administered to dual eligible beneficiaries.

- Because many dual eligibles will be enrolled in plans not tailored specifically to their unique needs, many beneficiaries will be forced—within a short span of time—to switch critical medications, find a new network pharmacy, and, at worst, go without medications simply because they did not receive enrollment materials in time.

A delay in implementation is critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. The Congress is kidding itself to think that in 6 weeks this complex population will independently enroll in a new plan. Without a doubt, if the current implementation schedule occurs on time, ***some dual eligibles will go to the pharmacy in January 2006 and not come home with needed medication***.

We recognize that this may require a legislative change and hope that ***CMS will actively support such legislation***.

423.36(c)(4), Special Enrollment Periods and Dual Eligibles

The selection of an appropriate prescription drug plan for people with disabilities will be especially challenging given their extensive and complex needs. Moreover, individuals may find that despite their best efforts to evaluate their private plan options, they have selected a plan that does not meet their needs or, their needs may change. For these reasons, we support granting dual eligibles special enrollment periods.

It is critical that dual eligibles receive notice explaining their right to a special enrollment period when they enroll in a plan, and every time their PDP changes its plan in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

423.44(d)(2), Disenrollment for Disruptive or Threatening Behavior

CCD is very concerned that the proposed rules would allow prescription drug plans to disenroll beneficiaries if their behavior is "disruptive, unruly, abusive, uncooperative or threatening." These provisions create great potential for discrimination against individuals with mental illness and cognitive disabilities.

The proposed provisions will be used purposefully to discriminate against persons with mental illness or other disabilities or will result in discrimination as an indirect consequence of plans not making adequate accommodations for individuals with disabilities, e.g., by training plan personnel on the special needs of these individuals and providing simplified processes for them to use to access the medications they need. Therefore, plans must be required to develop mechanisms for accommodating the needs of beneficiaries with these disabilities, and CMS must provide safeguards to ensure that these individuals do not lose access to drug coverage. The provisions to allow involuntary disenrollment for disruptive behavior must not be included in the final rule.

Additionally, CCD particularly urges CMS not to include the proposed expedited disenrollment process in the final rule. This process is offensive and unnecessary - and could lead to abuse by private plans that do not have the cultural competence needed to serve some people with disabilities or who wish to avoid potentially high cost individuals who have significant mental health needs or other types of disabilities.

Alternatively, CMS must provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and must waive the late enrollment penalty for these individuals. Individuals most likely to be disenrolled for disruptive behavior do not have the resources to pay for needed medications out of pocket and would suffer great hardship from losing drug coverage for an extended period.

Section 423.46, Late Enrollment Penalty

CCD urges CMS to delay implementation of a late enrollee penalty for all enrollees for two years. The drug benefit is a new and particularly complex program, especially for many people with disabilities. In our view, many beneficiaries with disabilities will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. During the initial implementation process, people should not be penalized because of the complexity of the program.

After the first two years, CMS should require plans to allow individuals with disabilities a waiver or grace period if they miss an enrollment deadline. These individuals face additional challenges and may need additional time to select a plan and enroll. Furthermore, the rationale for imposing late penalties – i.e., to discourage healthier beneficiaries from waiting to enroll until later – is less likely to apply to people with disabilities who are likely to require on-going treatment for one or more conditions or illnesses.

In addition, after the first two years, implementation of the late enrollment penalty should be delayed for individuals eligible for the low-income subsidy. Again, individuals may not understand that they have to apply separately for the subsidy and a drug plan, and may think application for the subsidy is sufficient. CCD also recommends that the final rule allow enrollees to appeal late enrollment penalties.

Section 423.48, Information about Part D

CCD believes that people with disabilities must have access to information in order to make informed judgments about private plan options. The final rule (rather than guidance) should include binding and enforceable standards defining the information plans must provide to beneficiaries and how they must make this information available. CMS has important obligations to ensure that information is accessible to people with various types of disabilities and the proposed rule is inadequate in this regard.

CMS must require plans to make information available in accessible formats for people who are blind or have low-vision. Materials must also be available in "plain English" for individuals with cognitive disabilities or low-literacy. On request, plans must be required to provide information in Braille, large print, audio-tape or computer disc. In addition, CMS should require that PDPs' Internet web sites are accessible for individuals with vision impairments.

Information should also be provided in languages other than English to reflect the languages spoken in a plan's service area. This should include adequate information about drug plan options and should be provided annually, in writing, and include details about the plan benefit structure, cost-sharing and tiers, formulary, pharmacy network, and the appeals and exception processes.

Need for Targeted Outreach to Beneficiaries with Disabilities

Targeted and hands-on outreach to Medicare beneficiaries with disabilities, especially those with low-incomes, is vitally important in the enrollment process. We strongly urge CMS to develop a specific plan for facilitating enrollment of beneficiaries with disabilities in each region that incorporates collaborative partnerships with state and local agencies and disability advocacy organizations.

The State Health Insurance Assistance Programs (SHIPs) are funded by CMS and are charged with being the local one-stop shop for all Medicare beneficiaries. CCD research on SHIPs finds that while they are well intentioned, they often do not understand the unique needs of individuals with disabilities; may not be physically accessible; and may not have information available in accessible format. We strongly recommend that the SHIPs mandate be clarified to ensure that they address the needs of individuals with disabilities, including non-elderly individuals. This could greatly improve education and outreach to this population.

SUBPART C- BENEFITS AND BENEFICIARY PROTECTIONS

No section of the proposed rule is more important to ensuring that the Part D program provides a prescription drug benefit that will meet the diverse needs of people with disabilities than subpart C. CCD is deeply concerned that the proposed rule fails to meet even minimal standards for ensuring that people with disabilities will be able to access Part D drug coverage that meets their needs.

Definition of "Long-Term Care Facility" to Explicitly Include ICF/MRs and Assisted Living Facilities

For people with disabilities residing in residential facilities, including intermediate care facilities for persons with mental retardation and related conditions (ICF/MRs) and assisted living facilities, it is necessary that Part D prescription drug coverage is compatible with the manner in which residential facilities deliver prescription drugs. The final rule must ensure that persons with disabilities residing in residential living facilities are not subject to additional cost-sharing, or out-of-network cost-sharing if they access prescription drugs through a long-term care (LTC) pharmacy.

For this reason, we recommend that the final rule include a definition of "long-term care facility" that explicitly includes ICF/MRs and assisted living facilities. We believe that many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

423.104(e)(2)(ii), Establishing Limits on Tiered Copayments

CCD strongly opposes the provision in the proposed rule that permits Part D plans to "apply tiered co-payments without limit."

The final rule must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs. Permitting unlimited cost-sharing tiers could allow a Part D plan to effectively bar access to clinically necessary covered Part D drugs because cost-sharing is unaffordable and the exceptions process does not include adequate safeguards or standards to ensure a fair review of an individual's request for an exception to a Part D plan's non-preferred cost-sharing.

Moreover, allowing plans unlimited flexibility in establishing cost-sharing tiers increases their opportunity to discriminate against people who need costly medications or who need multiple medications. We also believe that permitting multiple cost-sharing tiers will greatly complicate the ability of CMS to determine actuarial equivalence and to determine that the design of a plan does not substantially discourage enrollment by certain eligible Part D individuals under the plan.

Section 423.120, Access to Covered Part D Drugs

Balancing Convenient Access with Appropriate Payment for Long-Term Care Pharmacies

CCD believes that CMS must propose a way to ensure that plan enrollees residing in long-term care facilities must have access to the LTC pharmacy in the facility where they reside. We could support one of two approaches for achieving an appropriate balance of convenient access with appropriate payment.

The first option is for the final rule to require PDPs to contract with all LTC pharmacies. Alternatively, the final rule could require PDPs to make available a standard contract to all LTC pharmacies. However, plan enrollees residing in facilities where the LTC pharmacy has elected not to contract with a prescription drug plan must be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy.

Further, we believe that there are overlapping responsibilities for the delivery of services between LTC facilities and prescription drug plans. To the extent that prescription drug plans are responsible for coordination and medication management, the final rule should encourage plans to contract with LTC pharmacies to provide these services to the plan's enrollees in long-term care facilities.

1860D-11(e)(2)(D) Authority to Review Plan Designs to Ensure that They Do Not Substantially Discourage Enrollment by Certain Part D Eligible Individuals

CCD is very concerned that plans will discourage enrollment of people with complex medical needs who will need access to a wide variety of medications. CMS must take advantage of every opportunity to ensure this does not happen.

We urge CMS to use the authority provided under section 1860D-11(e)(2)(D) to review plan designs, as part of the bid negotiation process, to ensure that they are not likely to substantially discourage enrollment by certain Part D eligible individuals.

CMS needs to analyze formularies, cost-sharing tiers and cost-sharing levels, and how cost-sharing (including both tiers and levels) is applied to assure that people with the most costly prescriptions are not required to pay a greater percentage of the cost of those drugs.

CMS also needs to assure that a variety of drugs are included in a formulary at the preferred cost-sharing tier to treat chronic conditions and conditions that require more costly treatments. Furthermore, as recommended previously, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through high cost-sharing for out-of-network access.

423.120(b), Formulary Requirements

CCD has many concerns related to formulary requirements and urges CMS to release a final rule that strengthens the consumer protection requirements and requires special treatment for specific populations.

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must be protected from tiered cost-sharing or burdensome prior authorization procedures that could create insurmountable access barriers.

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing bed rest, unnecessary hospitalizations and even death, on the other. Often, people with disabilities need access to the newest medications, because they have fewer side effects and may represent a better treatment option than older less expensive drugs.

Medicare beneficiaries with disabilities also require access to a broad range of medications. For example, people with spinal cord injuries or diseases of the spinal cord must have access to a broad range of antibiotics. Bacterial infection is a leading cause of hospitalization and death for these individuals. Because bacterial resistance to antibiotics is currently a very serious and growing issue CMS must ensure broad and timely access to a wide variety of

antibiotic medications. Bacterial resistance coupled with the common problem associated with individual beneficiary allergies make broad antibiotic access a matter of life and death for this population and the elderly.

Many individuals have multiple disabilities and health conditions making drug interactions a common problem. Frequently, extended release versions of medications are needed to effectively manage these serious and complex medical conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects, making it more important for the doctor to be able to prescribe the best medication for the individual. Often that process takes time since many people with significant disabilities must try multiple medications and only after much experimentation find the medication that is most effective for their circumstance.

The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury or debilitating side effects, as well as hospitalization or other types of costly medical interventions. It can also impact a person's decisions about work. The Ticket to Work and Work Incentives Improvement Act (TTWWIIA) expanded options for states to cover working people with disabilities under their Medicaid programs. Many of these individuals would already be Title II/Medicare eligible. Because of the state buy-in they have been able to access prescription drugs through Medicaid. If the Medicare formularies are limited for people with disabilities, an important purpose of TTWWIIA would be thwarted.

CCD recommends that the final rule provide for alternative, flexible formularies for special populations that would include coverage for all FDA-approved covered Part D drugs. Further, because of the clinical importance of providing access to the specific drugs prescribed, drugs prescribed to these defined populations must be made available at the preferred level of cost-sharing for each drug. We recommend that this treatment apply to the following overlapping special populations:

- **Dual Eligibles:** In enacting the MMA, Congress and the Administration both promised that dual eligibles (persons eligible both for Medicare and Medicaid) would be better off when coverage for prescription drugs is transitioned from Medicaid to Medicare Part D coverage. Historically, the Medicaid prescription drug benefit has been closely tailored to the poor and generally sicker population it serves, providing beneficiaries with a range of drugs that they need with little or no co-payment. Under federal law, states that elect to provide prescription drugs in their Medicaid programs must cover all FDA-approved drugs from every manufacturer that has entered into an agreement with the Secretary of Health and Human Services to pay rebates to states for the products they purchase.

  Dual eligibles include people with disabilities and other serious conditions who need a wide variety of prescription drugs. Medicare prescription drug plans, as programs serving dual eligibles, must be able to respond to a range of disabilities and conditions, including physical impairments and limitations like blindness and spinal cord injury, debilitating psychiatric conditions, and other serious and disabling conditions such as

cancer, cerebral palsy, cystic fibrosis, Down syndrome, mental retardation, Parkinson's disease, multiple sclerosis, autism, and HIV/AIDS. If dual eligibles are not to be worse off when Part D prescription drug coverage begins, then they must have continued access to an alternative and flexible formulary that permits treating physicians to prescribe the full range of FDA-approved medications.

- **Institutionalized Populations:** Many, but not all, Medicare beneficiaries residing in nursing facilities and other residential facilities are dual eligibles. The same rationale provided for dual eligibles applies to providing institutionalized individuals access to flexible formularies on the basis of their complex and multiple prescription drug needs. Moreover, although we recommend that any alternative formulary include access to all FDA-approved medications, should the final rule permit a more restrictive alternative formulary, it must ensure that all drugs included on the formulary of participating LTC pharmacies are included on the plan's formulary, and drugs that are preferred by the LTC pharmacies' formularies must be treated by the plan as a preferred drug.

  Institutionalized individuals have limited capacity to pay cost-sharing for non-preferred drugs or to purchase drugs for which coverage has been denied. It is imperative that any alternative formulary provides strong protections that prevent individuals from being charged cost-sharing. For dual eligibles residing in institutions, a condition of eligibility requires them to pledge all, but a nominal personal needs allowance, to the cost of their care. For non-dual eligibles, the high cost of nursing home coverage leaves few remaining resources to pay non-preferred cost-sharing or to purchase drugs for which coverage has been denied.

- **Persons with Life-Threatening Conditions**: These are individuals with a diverse range, but limited number of conditions in which the absence of effective treatment would be life-threatening.

These individuals must have unrestricted and affordable access to the full range of available treatments. CCD believes that the MMA intended to ensure that beneficiaries will have access to all needed medications, including newly approved medications. Provisions in the proposed rule are inadequate for persons with life-threatening conditions for whom access to life-saving medications cannot be weighed against the financial interests of for-profit Part D plans. Therefore, these individuals must have immediate access to all FDA-approved medications.

- **Persons with Pharmacologically Complex Conditions:** Medications to treat many complex conditions are not generally interchangeable, including those with the same mechanism of action, and have fundamental differences that render them pharmacologically unique.

  In these circumstances, it is inappropriate to permit private plan formulary and cost-sharing policies to drive utilization to specific preferred drugs within a class. CCD recommends that the final rule require the Secretary to seek input from affected groups

and the general public and publish annually a list of conditions for which pharmaceutical management is complex and which have access to an affordable and flexible alternative formulary. This category should encompass.

- Persons with conditions that are recognized for their pharmacological complexity must include, at a minimum, conditions such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS;

- People who require multiple medications to treat many conditions—where drug-to-drug interactions are a critical challenge and where certain formulations might be needed to support adherence to treatment; and,

- Persons taking drugs with a narrow therapeutic index. These drugs are clinically effective and safe only at a narrow dosage range, and generally require blood level monitoring and highly individualized dosing requirements. To allow automatic substitution without physician approval can be deadly.

423.120(b)(1), Development and Revision by Pharmacy and Therapeutics (P&T) Committee

CCD strongly recommends that the final rule ensures that P&T committee decisions are binding on plans.

P&T committees can provide important checks on the profit-seeking motives of private drug plans by bringing research findings and clinical experiences to bear on decisions that will restrict access to certain medications. P&T committees must be empowered to make policy decisions regarding formulary tiers and any clinical programs to encourage the use of preferred medications, including formulary tiers and any clinical programs to encourage the use of preferred medications including prior authorization, fail first and step therapy.

In order to fulfill these critical functions the P&T committees must be charged with a strong mission to promote and protect the health of the beneficiaries. In all cases, the P&T committee should be responsible for ensuring that adequate access is provided for the most clinically efficacious drugs in the preferred tier for all classes of covered drugs. The final regulations should require a majority of the members to be independent and free of conflicts.

The final rule must require P&T committees to have formalized contractual relationships to advise the P&T committee in decision making with respect to areas where the P&T committee does not have adequate clinical expertise. At a minimum, this must include current clinical expertise and current experience in the following areas of medicine: geriatric medicine, oncology, cardiology, neurology, infectious disease, mental illness, and rare disorders.

The final rule should also require P&T committees to do the following:

- Hold public hearings and receive input from the public prior to the adoption of or revision to plan formularies.
- Specify that meetings of the P&T committee should be open to the public and occur at least quarterly.

In addition, plans should be required to seek input in the P&T committee process from affected enrollee populations, including elderly populations, and a diverse range of organizations representing people with disabilities.

Ensuring the Adequacy of the USP Model Guidelines

We do not support the CMS position that the USP model guidelines should not be required to include classes of drugs if there is no FDA approved drug with an on-label indication for each class, even though there are FDA-approved drugs with commonly accepted off-label uses that would fall within a class.

Further, we do not believe it is appropriate for physicians to be given the new burden to "document and justify off-label use in their Part D enrollees' clinical records."

CCD has written USP urging significant changes to the model guidelines to ensure that individuals have access to the medication they require. We are very concerned that in many cases two drugs per class will not provide a sufficient level of access to ensure a quality prescription drug benefit for individuals with disabilities. CMS must ensure that the model guidelines do not create access barriers to clinically appropriate off-label drugs or to newer, more effective medications within the classes.

We were also significantly concerned that the model guidelines did not have classes for the medications used to treat serious long term conditions like multiple sclerosis and that the classes for psychiatric medications and the anti-convulsants require significant revisions.

Standards for determining PDP/MA Formulary Discrimination

We strongly believe that any review standards developed by CMS must be published as legally enforceable regulations and not as guidelines. We urge CMS to develop criteria and standards that do not allow plans to discourage enrollment by requiring higher levels of cost sharing on drugs that disproportionately affect specific groups of beneficiaries. CMS needs to develop standards that can assess whether the formulary is directing utilization away from efficacious treatments and commonly recognized treatment protocols.

Providing a quality drug benefit to individuals with disabilities will require access to a broad range of medications including many of the newer drugs with fewer side effects. For example, a formulary that only included two anti-convulsants would clearly be discriminatory to people with seizures since epilepsy medications are not interchangeable. Different drugs control different types of seizures and the response to the medication is very

individualized. No one or two products of currently available anticonvulsants will be successful for all people with seizures. Access to the medication an individual requires to control their seizures can be a matter of life and death for people with epilepsy.

CMS must also ensure that the formularies do not exclude whole classes of drugs such as immunomodulating drug therapies used to treat multiple sclerosis. This is one of CCD's significant concerns with the USP model guidelines and must be addressed in order to avoid discrimination toward the people who rely on these medications.

Notification Requirements for Formulary Change

CCD believes that the proposed rule provides inadequate notification provisions regarding formulary changes. They are inadequate both for effectively notifying and protecting beneficiaries.

We recommend that if the final rule limits the notice requirements to persons directly affected by the change, then plans must be required to provide notice in writing, mailed directly to beneficiary, 90 days prior to the change, and the notice must inform the beneficiary of their right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary.

423.128 (d), Access to Call Centers

We believe that it is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center.

The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program. This is a critical requirement that must be included in the final rule.

423.128(e), Required Information in the Explanation of Benefits

We support the inclusion in the final rule of provisions in the proposed rule regarding elements of the explanation of benefits. These elements, however, must be supplemented by the following:

- **Appeals Rights and Processes:** Information about relevant requirements for accessing the exceptions process, the grievance process, and the appeals process.

- **Access for all Beneficiaries to Formulary Information:** Plans should be required to provide information to all Part D eligible individuals, and not just plan enrollees, about the plan formulary. (See our comments in Subpart B, Section 423.48, Information about Part D.)

- **Including Formulary in Explanation of Benefits**: While we are supportive of the provision in the proposed rule that requires plans to make available access to the plan's formulary, in isolation, this is insufficient. Beneficiaries need precise and detailed information about the formulary both to make an informed choice about enrollment and then to minimize their out-of-pocket costs once enrolled in a plan. Simply giving beneficiaries a description of how they can obtain information about the formulary is insufficient to further the goals of the statute. Plan descriptions should include a detailed formulary, listing not only all the drugs but the tier and amount of co-payment upon which each drug is placed, especially if plans will be allowed to require beneficiaries to pay 100% of the cost of certain formulary drugs.

- **Plan terminations:** 423.128(c)(iii) requires plans to tell all Part D eligible individuals that the part D plan has the right to terminate or not renew its contract, but only if the individuals request this information. Information about the potential for contract termination needs to be included in all plan descriptions and in all marketing materials, and not just if requested by an enrollee or Part D eligible individual.

  Based upon experience with the Medicare+Choice market, the drug plan market will experience volatility that results in adverse consequences to many beneficiaries. The Medicare+Choice model summary of benefits requires this information to be in the summary of benefits and in the evidence of coverage; the same rule should apply for Part D.

SUBPART D – COST CONTROL AND QUALITY IMPROVEMENTS REQUIREMENTS FOR PRESCRIPTION DRUG BENEFIT PLANS

Section 423.150, Scope

The need to limit and prohibit unacceptable cost containment strategies—CCD has serious concerns that the proposed rule contains no restrictions on the ability of plans to use cost-containment tools such as dispensing limits, or prior authorization.

Indeed, the preamble to the proposed rule appears to specifically encourage plans to use such cost management tools, without constraint, to limit the scope of the prescription drug benefit. We believe that this is completely inappropriate, and inconsistent with commitments made by CMS to the Congress and the public.

We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration, and scope of coverage for covered Part D drugs. Specifically, the final rule must prohibit plans from limiting access to covered Part D drugs through limits on the number of drugs that can be dispensed within a month, limiting the number of refills an individual can obtain for a specific drug, or by placing dollar limits on the amount of the prescription drug benefit. For example, research in the mental health field has demonstrated that fewer than six mental health medications per month seriously risks patient health.

CCD also strongly recommends that the final rule explicitly prohibit plans from requiring therapeutic substitution. While the MMA authorizes the use of formularies which could lead prescribers' practices to alter their practice in order to comply with standard Part D plan preferences for covered drugs within a class, we believe that the ultimate authority to decide which specific drug a Medicare beneficiary will receive must reside with the treating physician. Therefore, to protect patient safety and health, the final rule must prohibit plans from requiring or encouraging pharmacists to engage in therapeutic substitution without the advance knowledge and written concurrence of the treating physician. We are encouraged that the preamble to the proposed rule indicates that therapeutic substitution will be prohibited without the prescriber's approval, this prohibition must appear in the text of the final rule.

Further, the use of prior authorization has become a common practice in the private sector and Medicaid. For many Medicare beneficiary populations, the manner in which prior authorization and fail first (or step therapy) systems have been implemented in these other contexts has been clearly unworkable both from the perspective of beneficiaries and treating physicians. Prior authorization can delay necessary and appropriate treatment putting at risk the health and safety of individuals who depend on medications for the management of their conditions.

Prior authorization is particularly burdensome to people in group home settings and institutions where often there may not be a well-informed and aggressive advocate or health care professional to ensure that residents with disabilities get the medication they need.

The final rule must establish clear standards and requirements for Part D plans that elect to adopt prior authorization and fail first policies. In particular, the final rule must require plans to ensure that any system of prior authorization is easily accessible to beneficiaries and physicians, and must impose negligible burdens with respect to time needed to complete the prior authorization process, expense, and information documentation.

Most state Medicaid programs exempt certain types of prescription drugs from prior authorization/fail first policies because of the complexity of the underlying condition, the recognized need for physicians to have broad prescribing flexibility, and the grave clinical consequences that could result if necessary access to prescription drugs is denied. Medicaid experience also shows that when certain populations are not exempted from prior authorization, significant problems arise. We propose that the final rule require the Secretary to consult with the public and publish annually a list of conditions which will be exempted from prior authorization/fail first policies, and should include conditions such as mental

illness, epilepsy, HIV/AIDS, multiple sclerosis and cancer, that are widely acknowledged for the difficulty and complexity of pharmaceutical management.

Further, ***we strongly recommend that when prior authorization is imposed, whenever the prior authorization process has not been completed within 24 hours of the time that a prescription was first presented at a pharmacy, plans must be required to dispense a temporary supply of the prescribed drug pending the completion of the prior authorization process***, including any time needed to receive an exception process and appeal decision. The final rule must also provide for exigent circumstances when an emergency temporary supply of a prescription drug must be dispensed immediately, without allowing for a 24 hour prior authorization period.

Requiring beneficiaries who have been stabilized on a particular psychiatric or anti-convulsant medication to switch to another medication can be very dangerous for the beneficiary and is not fiscally prudent. It is very difficult to determine which medication will work best for an individual and most have to try many different kinds of medications. Moreover some of these medications stay in the system for a long time (e.g., up to six weeks) and modifications of drug therapy must be done very carefully to avoid dangerous drug interactions. Each failed trial results in suffering and possible worsening of a person's condition.

We recommend that the final rule require plans when enrolling new enrollees to continue for at least six month any prescription drug regimen for all individuals who have been stabilized on a course of treatment. Moreover, the plan must provide an organization determination within the first month of enrollment for all covered Part D drugs that are part of the treatment regimen and notify, in writing, the beneficiary whether each drug in the regimen is covered and the beneficiary's cost-sharing requirement. Should the plan determine that any drugs in the regimen are not covered, all individuals stabilized on a treatment regimen should be automatically eligible for an exception request, and plans should be prohibited from discontinuing access to all drugs in the regimen pending final resolution of the appeals process.

Cost management tools subject to P&T Committees—In response to a question in the preamble of the proposed rule, we strongly recommend that P&T committees should approve and oversee implementation of utilization management activities of health plans offering the Medicare drug benefit. These committees should be empowered to make policy decisions and be charged with a mission to promote and protect the health of beneficiaries. In overseeing utilization management activities, P&T committees must be empowered to ensure that beneficiaries have access to a variety of drugs that reflect current utilization patterns and current research and that take into account the efficacy and side effects of medications in each therapeutic class and the complex needs of an ethnically diverse, elderly, co-morbid, and medically complex population.

SUBPART M—GRIEVANCES, COVERAGE DETERMINATIONS, AND APPEALS

Many people with disabilities who are dually-eligible for Medicaid and Medicare have cognitive or mental disabilities which make it more difficult for them to navigate a cumbersome and multi-step appeals process. The final rule must ensure that these individuals who currently receive their prescription drugs through Medicaid are not harmed by the enactment of the MMA. Additionally, for many individuals with a variety of physical and mental disabilities, access to appropriate medication is one of the major factors which allow them to live full and more independent lives in their communities. CMS must ensure that the final rule is consistent with the principles and goals of the President's New Freedom Initiative to ensure that all people with disabilities have the opportunity to live in the community where they belong.

The proposed rule fails to meet the requirements of the Due Process Clause of the Fifth Amendment to the Constitution.

CCD believes that the proposed rule fails to meet Constitutional due process requirements and fails to satisfy the requirements of the statute. As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid beneficiaries, whose prescription requests are not being honored, receive a 72-hour supply of medications pending the initial coverage request. They are entitled to notice and face-to-face hearings, pending an appeal if their request is denied and they file their appeal within a specified time frame. Currently, all state Medicaid appeals processes are completed more expeditiously than Medicare appeals. Based on this fact and on the fact that the majority of people with disabilities who are dually-eligible for Medicaid and Medicare, have major health care needs, CCD believes it is completely inappropriate for the proposed rule to expose these individuals to a weakened due process system.

The appeals process as described in Subpart M does not accord dually-eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights; with an adequate opportunity to a face-to-face hearing; with an adequate opportunity to have access to care/prescription drugs pending resolution of the appeal; or with a timely process for resolving disputes. While CCD recognizes that the most efficient means of protecting enrollees – which would be to amend the MMA to provide for an appeals process similar to Medicaid -- is beyond the authority of CMS, CCD does believe that CMS can take steps in the final regulations to improve notice and the opportunity for speedy review.

Sections 1860D-4(f), (g), and (h) require that sponsors of Part D plans establish grievance, coverage determination and reconsideration, and appeals processes in accordance with Section 1852 (f) & (g) of the Social Security Act. In addition, CMS – in the settlement of *Grijalva v. Shalala* and in the Medicare Plus Choice program – already has established the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review. CCD strongly

recommends that CMS incorporate a similar fast-track process for Part D, which would be more in keeping with due process requirements.

Require plans to have an expedited appeals and exceptions process and to dispense a temporary supply of drugs pending the resolution of an exception request or an appeal.

The proposed system does not ensure that beneficiaries' rights are protected and does not guarantee that beneficiaries have access to needed medications. This is a major cause for concern for the CCD. For millions of individuals with disabilities such as epilepsy, mental illness, HIV, Multiple Sclerosis, and spinal cord injuries -- treatment interruptions can lead to serious short-term and long-term problems. For this reason, the CCD strongly recommends that the final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

For people with HIV/AIDS, even temporary interruptions in treatment can spur the development of drug resistant strains of HIV that have broad implications for the public health, and seriously compromise the likelihood that an individual will continue to benefit from their current drug regimen and jeopardize treatment success with any of the available anti-HIV medications. Fifty to seventy percent of people living with AIDS develop drug resistance. Failure to prevent treatment interpretations by supplying a temporary drug supply will contribute to this statistic.

Many people with epilepsy depend on specific medication to control their seizures. A disruption in their medication regimen can cause breakthrough seizures, the consequences of which can be very severe and can include loss of driving privileges, absence from work and hospitalization. Access to a temporary supply of drugs is also critical for people with physical disabilities such as spinal cord injury (SCI). Urinary tract infections, a common secondary condition of SCI, can worsen quickly and result in kidney infections which can lead to autonomic dysreflexia, a life threatening condition.

For many people with mental illness, access to the one specific medication or the critical combination of specific drugs, is what helps them maintain their mental and physical health as well as their independence and the ability to live a full life in the community. Treatment interruptions for these individuals are just as dangerous to them as is a treatment interruption to a person with a physical disability such as epilepsy.

CCD concerns related to treatment interruptions are heightened due to the absence of any adequate protections to ensure that individuals can receive a timely resolution of an appeal. We are also extremely concerned about the lengthy period of time that is allowed to pass before an individual has access to a fair and independent review of their appeal by an independent decision maker at the Administrative Law Judge (ALJ) level. CCD recognizes that the expedited time-frames and the general 72-hour standard are a significant improvement over the standard time-frame of 14 days to make a determination and 30 days for a reconsideration. Nonetheless, from the perspective of individuals with serious and complex health conditions and disabilities, 72 hours is an unacceptable delay.

CCD strongly recommends that the final rule clearly specify that all disputes relating to coverage of Part D drugs for people with disabilities automatically qualify for an expedited decision (for all types of requests including a request for an exception, a grievance, and all level of the appeals). Moreover, we strongly recommend that the final rule clearly require plans to dispense a temporary supply of the drug in dispute pending the final outcome of an appeal.

Strengthen and improve the inadequate and unworkable exceptions and appeals processes by establishing clear standards; expediting decisions; minimizing evidence burdens on physicians; and ensuring that drugs provided through the exceptions process are made available at the "preferred drug" level of cost-sharing.

CCD is also concerned that the appeals processes outlined in the proposed rule are overly complex, drawn-out, and inaccessible to beneficiaries with disabilities. We are specifically concerned about the impact of such a burdensome process on individuals with cognitive and mental disabilities. We strongly recommend that CMS establish a simpler process that places a priority on ensuring ease of access and rapid results for beneficiaries and their doctors. We also strongly recommend that the final rule include a truly expedited exceptions process for individuals with immediate needs. Under the proposed rule, there are too many levels of internal drug plan appeals that a beneficiary must navigate before receiving a truly independent review by an administrative law judge (ALJ) and the timeframes for plan decisions are unreasonably long.

CCD believes that the provisions in the MMA that call for the creation of an exceptions process are a critical consumer protection that -- if properly crafted through enforceable regulations -- could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. However, as structured in the proposed rule, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and appeals process.

CCD is particularly concerned that the proposed rule would require treating physicians to assert that an exceptions request is based on both clinical experience and scientific evidence. This is an inappropriate standard that most doctors could not meet because scientific experience is not always available to support the knowledge which they acquire through clinical experience treating people with a range of disabilities – from HIV to mental illness – to epilepsy – to cerebral palsy – to spinal cord injury – to MS. CCD recommends that this requirement be eliminated from the final rule.

CCD recommends that CMS revamp the exceptions process to:

1. Establish clear standards by which prescription drug plans must evaluate all exceptions requests;
2. Minimize the time and evidence burdens on treating physicians; and

3. Ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

SUBPART P –PREMIUMS AND COST SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

432.772, Definitions

Institutionalized individual: The definition should include those individuals eligible for home and community based services under a Medicaid waiver (see, e.g., definition of "institutionalized spouse" at 42 U.S.C. § 1396r-5(h)(1)(A)), since those individuals must meet the acuity standards for Medicaid coverage in a nursing facility, and should include individuals in ICF/MRs and individuals in any institution in which they are entitled to a personal needs allowance.

423.782(a)(2)(iii), Dual eligible beneficiaries must not be denied medications for failure to pay co-payments.

Dual eligible beneficiaries will be required to pay $1 for generic drugs and $3 for brand-name drugs under Medicare Part D. Currently under Medicaid statute, an individual cannot be denied a medication for failure to pay a co-payment. Many people with disabilities depend on multiple medications including brand name medications. Even minimal co-payments will create a financial burden for individuals who will be left to choose between paying for medications and meeting other needs, like food and housing.

CCD strongly recommends that in the final rule dual eligibles must maintain the protection that they currently have under Medicaid and not be denied a drug for failure to pay cost sharing.

423.782(a)(iv) and §423.782(b)(2), Low-income individuals should not be denied medications for failure to pay co-payments.

Low-income Medicare beneficiaries between 100% and 150% of the FPL face considerable cost-sharing requirements in the proposed regulations that could prevent them from filling necessary prescriptions. Studies have demonstrated that even minimal levels of cost sharing restrict access to necessary medical care for individuals with low incomes. Individuals between 100% and 135% of FPL must pay $2 for generics and $5 for brand-name drugs. Those between 135% and 150% are required to pay a 15% co-insurance for their drugs. For individuals who require expensive treatments or multiple medications, this requirement will

impose an enormous financial burden on thousands of individuals who will be unable to pay out-of-pocket for these medications. Beneficiaries eligible for the full or partial low-income subsidy should not be denied a prescription for failure to pay a co-payment or other co-insurance.

CCD appreciates the opportunity to comment on these critical regulations which will have a profound impact on America's 13 million Medicare beneficiaries with disabilities.

For more information contact the CCD Health Task Force Co-Chairs: Kirsten Beronio (National Mental Health Association) 202-675-8413, Liz Savage (The Arc and United Cerebral Palsy) 202-783-2229, Kathy McGinley (National Association of Protection and Advocacy Systems) 202-408-9514), and Peter Thomas (American Medical Rehabilitation Providers Association) 202-466-6550.

On behalf of:

American Association on Mental Retardation
American Association of People with Disabilities
American Congress of Community Supports and Employment Services
American Congress of Rehabilitation Medicine
American Council of the Blind
American Diabetes Association
American Foundation for the Blind
American Medical Rehabilitation Providers Association
American Network of Community Options and Resources
American Therapeutic Recreation Association
APSE: The Network on Employment
Association of Academic Physiatrists
Association of University Centers on Disabilities
Bazelon Center for Mental Health Law
Center on Disability Issues and the Health Professions
Easter Seals
Epilepsy Foundation
Family Voices
Helen Keller National Center
Learning Disabilities Association of America
Lutheran Services in America
National Association for the Advancement of Orthotics and Prosthetics
National Association of County Behavioral Health Directors
National Association of Protection and Advocacy Systems
National Coalition on Deaf-Blindness
National Mental Health Association
National Multiple Sclerosis Society
National Association for the Advancement of Orthotics and Prosthetics
National Association of Councils on Developmental Disabilities

National Association of Social Workers
National Fragile X Foundation
National Law Center on Homelessness & Poverty
National Organization of Social Security Claimants' Representatives
National Respite Coalition
Paralyzed Veterans of America
Spina Bifida Association of America
TASH
The Arc of the United States
Title II Community AIDS National Network
United Cerebral Palsy
United Spinal Association
Volunteers of America
World Institute on Disability

Submitter : Mr. Thomas Arnold **Date & Time:** 10/04/2004 09:10:57

Organization : Agency for Health Care Administration

Category : State Government

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Definition of Long Term Care Facility

CMS is requesting comments regarding the definition of long-term care facilities. In section 423.100 of the proposed rule, long-term care facility is interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act; or a nursing facility as defined in section 1919(a) of the Act. The definition is limited to these two types because it is CMS? understanding that those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies. The definition does not include other long-term care facilities such as those for the developmentally disabled or mental health centers.

CMS expresses particular interest in whether other facilities such as intermediate care facilities for mentally retarded or related conditions (ICF/MRs), described in section 440.150 of the proposed rule, should be included explicitly in this definition. Many of these individuals are covered by both Medicare and Medicaid and will need continued access to drugs under Part D. We encourage CMS to consider ICF/MRs and other types of facilities that contract with long-term care pharmacies exclusively, in a manner similar to SNFs and other nursing facilities, in its definition of long-term care facilities.

Formularies

We applaud the intent to level the playing field with respect to mail order and community pharmacies by allowing 90-day supplies to be dispensed by both entities.

As provided under section 1860D-4-(b)(3)(c)(ii) of the Act, CMS has requested that the U.S. Pharmacopoeia (USP) develop a model set of guidelines that consist of a list of drug categories and classes that may be used by PDP sponsors and MA organizations to develop formularies for their qualified prescription drug coverage, including their therapeutic categories and classes. CMS expects that the model categories and classes developed by USP will be defined so that each includes at least two drugs approved by the FDA for the indications in the category or class. That is, no category or class would be created for which there is no FDA-approved drug, thus avoiding having to include a drug based on its off-label indication. It is likely, in some cases, that only two drugs will be included in a class. We believe that any established formulary exception criteria must be flexible enough to take into account the actual circumstances of particular recipients. MA-PDs and PDPs should be required to be flexible to accommodate individual recipients.

We would like to note that the AHSP therapeutic classification system is out of date for a number of therapeutic classes and needs to be updated. In addition, the requirement prohibiting any PD or MA PD from changing its therapeutic classification for a drug more than one time per year at the beginning of the plan year does not reflect the rapid changes in the pharmacologic knowledge base and therapeutic uses of many drugs.

Also, the prohibition against changing the cost-sharing tier of co-payment for specific drugs without providing 30-day advance notice to prescribers, pharmacies and enrollees may be counter-productive unless this notice can be made electronically. If mailed notices are required, the costs associated could easily exceed savings to the plan or to enrollees for many products. It is unclear whether the regulations anticipate web-posting as satisfactory notice or whether direct mailing would be required. The regulations may be contradictory in view of the ?at least weekly? update requirement in the following section, 423.128

We agree with the requirement that plans include cost utilization management, medication therapy management programs (MTMP) and fraud and abuse control programs. We feel the regulations should provide more guidance to plans in the structure and reimbursement for MTMPs and we applaud the effort to encourage electronic prescribing by

ELIGIBILITY, ELECTION, AND ENROLLMENT

The Florida Agency for Health Care Administration (AHCA) respectfully submits the following comments about the proposed rule on the Medicare

program and the Medicare prescription drug benefit. AHCA administers Florida's $14 billion Medicaid program and serves more than 2.2 million recipients annually. Nearly 460,000 of the state?s Medicaid recipients are also eligible for Medicare and account for more than $1 billion of the state?s prescription drug budget. This includes spending for approximately 55,000 recipients enrolled in the Silver SaveRx program, Florida?s Pharmacy Plus Program.

Florida?s dual eligibles, like seniors across the country, are expected to take advantage of the opportunity to gain coverage under the new Medicare Part D benefit. We applaud CMS for its efforts in addressing many of the issues that states and recipients will face when the benefit is implemented.

Enrollment

In accordance with Section 1860D-1(b)(1) of the MMA, CMS has proposed rules related to enrollment of Part D eligibles in prescription drug plans. Specifically, the rule proposes an enrollment process by which the state may randomly enroll full dual-eligible individuals who fail to select and enroll in a PDP or a MA-PD plan by a specified date. The process as proposed raises significant concerns and questions.

For full dual eligibles, the time frame allowed for initial enrollment runs from November 2005, through May 2006. This provision can be interpreted to mean that any individual who does not select a plan will be enrolled randomly in May 2006. There are several reasons why a recipient may fail to enroll in a PDP or MA-PD in a timely manner. One possibility is apprehension about relinquishing the familiar benefits available under Medicaid; another is uncertainty about subsidies, program design, and plan availability. Nonetheless, this interpretation, fails to consider the possible lapse in coverage a recipient could face between January 1, 2006, and the date on which he/she actively enrolls in a plan or is automatically enrolled in May. We understand that federal matching funds would no longer be available to state Medicaid agencies for this population after January 1, 2006; however, we are certain it is your intent to ensure that seniors have prescription coverage during this six-month period.

As an alternative we suggest allowing for a delay in enrollment or establishing a phased-in enrollment process for this population, during which time the states could continue to receive federal matching funds for providing prescription drug coverage. This would allow time for adequate outreach and education to ensure that recipients understand the program and the options available to them. Furthermore, it would help ensure that beneficiaries would not lose coverage for any period.

CMS is also seeking input on the appropriate entity to perform automatic and random enrollment functions. These functions include enrollment during initial and special enrollment periods, as well as tracking premium subsidy qualifications. Options include having enrollment conducted by CMS, the state, or a contracted entity. As a condition of state performance, CMS requires proper and efficient administration of the state plan. In the preamble, CMS recognizes that states will need accurate and timely Part D data to perform enrollment functions. We recommend that states have the option of performing automatic and random enrollment functions. CMS should also consider giving the states that choose to perform those functions full federal participation match rather than the administrative match.

Issues 11-20

SPECIAL RULES FOR STATES

Phased Down State Contribution

Under the proposed rule, states are required to contribute to the cost of the Medicare Part D drug benefit. The phased down state contribution is based on expenditures for covered Part D drugs during calendar year 2003 and adjusted by a growth factor in subsequent years. The growth factor will be based on increases in per capita expenditures for Part D drugs for Part D eligible individuals.

We have questions about the methodology with respect to values used in the base year. Specifically, the PDSC calculation includes rebates earned in the base year but collected in subsequent years. We would like clarification as to how CMS intends to account for rebates earned but not collected.

Moreover, we believe that states should be allowed to appeal CMS calculations of the PDSC amount. The preamble and other information suggest that CMS will attempt to arrive at a number that the state and CMS will agree on. This process is not spelled out, and we believe it should include an opportunity for states to dispute calculations that would result in a higher contribution.

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FLORIDA MEDICAID

JEB BUSH, GOVERNOR

ALAN LEVINE, SECRETARY

October 4, 2004

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: CMS Proposed Rule – 4068 – P

Dear Dr. McClellan:

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Section 423.279 addresses potential geographic adjustments to the national average monthly bid amount. This section requires that any adjustment CMS applies be budget-neutral to CMS; in addition, any increase for one region will affect one or more other regions. As a result, we would expect this issue to be highly controversial. We suggest deleting this provision from the final rule.

In section 423.336, Risk Sharing Arrangements, the description of risk corridors and first and second threshold lower and upper limits is difficult for all but trained actuaries. Examples of these calculations similar to that used to calculate the states' phased-down contribution will help to eliminate confusion on this issue.

Section 423.782 describes cost sharing subsidies and cost sharing responsibilities. Because beneficiaries are increasingly involved in choice of therapies as a result of direct-to-consumer advertising by drug manufacturers, the regulations should require that plans provide clear tabular explanations of cost sharing responsibilities by product included on their formularies and the alternative products available in that therapeutic class.

We appreciate the opportunity to submit comment on this proposed rule and look forward to working with CMS to implement this important benefit. Should you have any questions, please contact me directly at 850-413-9660.

Sincerely,

Thomas W. Arnold
Deputy Secretary for Medicaid

Submitter : Mrs. Mary Thompson **Date & Time:** 10/04/2004 09:10:24

Organization : YKHC

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-4068-P-1300-Attach-1.doc

YUKON-KUSKOKWIM HEALTH CORPORATION

Mary I. Thompson, Dir. of Revenue Mgmt.
P.O. Box 3427 • Bethel, Alaska 99559
(907) 543-6216 • fax: (907) 543-6926

Financial Services Division
Patient Financial Services

October 3, 2004

CMS

RE: Comments on the Treatment of American Indians and Alaska Natives and Reimbursement to Tribal, Indian Health Service and Urban Indian Programs Under August 3, 2004 Proposed Rules for 42 CFR Parts 417 and 422, The Medicare Advantage Program

File Code CMS-4069-P

Dear Administrator:

The **Yukon-Kuskokwim Health Corporation (YKHC)** is concerned about the impact of the proposed regulations for Medicare Part C. The proposed regulations for the Medicare Advantage (MA) program published on August 3, 2004, do not mention American Indians, Alaska Natives, tribes, tribal organizations, tribal health services or the Indian Health Service.

The preamble to the regulations provides an analysis of the effects on small entities under the Regulatory Flexibility Act (RFA). The RFA analysis states: "We welcome comments on this approach and on whether we have missed some important category of effect or impact." We would like to state emphatically that you have missed an important category of effect and impact by omitting consideration of Tribal governments and Indian health care facilities.

The National Indian Health Board (NIHB) has submitted comments on the Part C regulations and YKHC endorses those comments.

Furthermore, we urge you to consult with Tribes to identify issues and workable solutions when new programs are being designed by the Centers for Medicare and Medicaid Services.

Sincerely yours,

Mary I. Thompson

Director of Revenue Management

FOR YOUR REVIEW, THESE ARE THE COMMENTS NIHB WILL SUBMIT TO CMS.

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Comments on the Treatment of American Indians and Alaska Natives and Reimbursement to Tribal, Indian Health Service and Urban Indian Programs Under August 3, 2004 Proposed Rules for 42 CFR Parts 417 and 422, The Medicare Advantage Program

File Code CMS-4069-P

Dear Administrator:

The National Indian Health Board (NIHB) is deeply concerned about the impact of August 3, 2004, proposed Medicare Modernization Act (MMA) rules regarding the **Medicare Advantage** program on American Indians and Alaska Natives (AI/AN) as well as the Indian Health Service, Tribal and urban (I/T/U) health programs that serve them. These comments and recommendations are submitted to the Centers for Medicare and Medicaid Services (CMS) with the very serious concerns of Tribes across the nation.

INTRODUCTORY STATEMENT REGARDING INDIAN HEALTH SYSTEM

These comments address the implications of the proposed rules on the Indian health care delivery system and the changes that must be made to prevent Part C implementation from destabilizing the system responsible for providing health care to the approximately 1.3 million American Indians and Alaska Natives (AI/AN) served by the IHS system. In the form proposed by CMS, the rules will put in jeopardy significant revenues the Indian health system now collects from Medicaid for "dual eligibles". Since the loss of revenue to Indian health was **not** Congress's objective in enacting the Part C benefit, the rules must be revised in several respects to protect the Indian health system from what could be substantial harm. Furthermore, to enable voluntary enrollment by AI/AN in Part C requires substantial modifications to the proposed rules.

We ask that all CMS staff charged with reviewing comments and revising the proposed regulations be supplied with a copy of this introductory statement regarding the Indian health care system. Compliance with the dictates of notice and comment rulemaking requires that all relevant information supplied by commenters must be taken into account. Full consideration of the comments we offer on individual regulations can only be accomplished by a thorough understanding of the unique nature of the Indian health care system, and the responsibility of our steward, the Secretary of Health and Human Services, to assure that inauguration of Medicare Part C does not result in inadvertent and unintended harm to that system.

The regulations governing the Part C must be revised to achieve the following goals:

- Encourage MA enrollment by AI/AN by removing financial barriers and allowing AI/AN to voluntarily participate in Medicare Advantage plans, without financial penalty because of location of residence, selection of a plan that includes I/T/U, or use of I/T/U.

- Ensure that I/T/U, under all conditions, are held harmless financially and are fully reimbursed for covered services provided to AI/AN who enroll in a Medicare Advantage plan.

- Allow I/T/U the flexibility to sponsor AI/AN in Medicare Advantage plans, under a special group payer arrangement.

- Allow, in the future, the development of an AI/AN special Medicare Advantage plan that includes the active participation of Tribes in its design and implementation.

- Explicitly exempt AI/AN dual eligibles from mandatory participation in a State Title XIX MA or MA-PD Plan.

In order to fully comprehend the potential adverse impact Part C implementation will have on the Indian health care system -- particularly with regard to the dual eligibles it serves -- one must have an understanding of the way health care services are delivered to AI/ANs and the current state of Indian health. These considerations must be kept in mind as CMS reviews these comments in order to promulgate regulations that assure the inauguration of the Part C or Medicare Advantage (MA) program does not have negative consequences on the Indian health system by reducing the level of reimbursements from Medicaid or Medicare on which the system has come to rely.

Indian Health Care System and Indian Health Disparities

Overview. The Indian health care system does not operate simply as an extension of the mainstream health system in the United States. To the contrary, the Federal government has built a system that is designed specifically to serve American Indian and Alaska Native people in the context in which they live -- remote, sparsely-populated and, in many cases, poverty-stricken areas where the Indian health system is the only source of health care. Integral to that system are considerations of tribal cultures and traditions, and the need for culturally competent and sensitive care.

U.S. Trust Responsibility for Indian Health. The United States has a trust responsibility to provide health care to AI/ANs pursuant to federal laws and treaties with Indian Tribes.[1] Pursuant to statutory directive,[2] this responsibility is carried out by the Secretary of Health and Human Services, primarily through the Indian Health Service (IHS) with annual appropriations supplied by Congress. The IHS-funded health system follows the public health model in that it addresses the need for both medical care and preventive care. In order to perform this broad mission, the IHS funds a wide variety of efforts including: direct medical care (through hospitals, clinics, and Alaska Native Village health stations); pharmacy operations; an extensive (but underfunded) Contract Health Services program through which specialty care IHS cannot supply directly is purchased from public and private providers; health education and disease prevention programs; dental, mental health, community health and substance abuse prevention and treatment; operation and maintenance of hospital and clinic facilities in more than 30 states; and construction and maintenance of sanitation facilities in Indian communities.

Health Disparities. AI/ANs have a higher rate of disease and illness than the general population and consequently require more medications and incur higher prescription drug costs than most Americans. A recent in-depth study of Indian health status performed by the staff of the U.S. Commission on Civil Rights[3] reveals a number of alarming statistics such as:

- AI/ANs have the highest prevalence of Type II diabetes *in the world*, are 2.6 times more likely to be diagnosed with the disease than non-Hispanic whites, and are 420% more likely to die from the disease.
- The cardiovascular disease rate among AI/ANs is two times greater than the general population.
- AI/ANs are 770% more likely to die from alcoholism.
- Tuberculosis deaths are 650% higher among AI/ANs than the general population.
- AI/AN life expectancy is 71 years, five years less than the general U.S. population.

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[1] *See, e.g.,* 25 U.S.C. § 1601.
[2] 42 U.S.C. § 2001.
[3] U.S. Commission on Civil Rights, *Broken Promises: Evaluating the Native American Health Care System*, July 2, 2004 (staff draft).

- The ratio of cancer deaths to new cancer cases is higher for Native Americans than the ratios for all other races, even though incidence rates are lower.
- The Indian suicide rate is 190 percent of the rate of the general population.

Composition of the Indian Health Care System. Operationally, health services to AI/ANs are delivered through the following entities:

- The Indian Health Service directly operates hospitals and clinics throughout Indian Country that are staffed by federal employees.
- Indian Tribes and tribal organizations may elect to assume management and control over IHS programs at the local tribal level through authority of the Indian Self-Determination and Education Assistance Act. At present, over one-half of the IHS budget is distributed to ISDEAA tribal programs.
- In 34 cities, urban Indian organizations operate limited health programs (largely referral services) for Indian people living in urban areas through grants authorized by the Indian Health Care Improvement Act.

Funding Sources. Indian health programs are supported primarily from annual federal appropriations to the Indian Health Service. Regardless of the operational form, all Indian health programs are severely underfunded. In a 2003 report[4], the U.S. Commission on Civil Rights found that the per-capita amount spent by the Indian Health Service for medical care was nearly 50% lower than spending for federal prisoner medical care and only slightly more than one-third of the average spending for the U.S. population as a whole. The Veterans Administration spends nearly three times as much for its medical programs as the Indian Health Service.

In an effort to improve the level of funding for Indian health programs, Congress, in 1976, made IHS/tribal hospitals eligible for Medicare Part A reimbursements, and enabled hospitals and clinics to collect Medicaid reimbursements, either as IHS facilities or as FQHCs. It was not until the 2000 BIPA that IHS facilities were authorized to collect for some Medicare Part B services. With enactment of the MMA, Congress authorized these facilities to collect for remaining Part B services for a five-year period.

Pursuant to Federal law, the cost of Medicaid-covered services, including pharmacy services, provided by I/T/Us to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. If coverage for dual eligibles changes from Medicaid to Medicare, the Federal government must assure that the reimbursement of services for Indian dual eligibles continues without interruption and without reduction to I/T/U.

Indian health programs have become critically reliant on the third-party revenues, especially those supplied by Medicare and Medicaid. According to the IHS, Medicare, Medicaid and other third party collections can represent up to 50% of operating budgets at some facilities.

Scope of Services. The compliment of health services provided at a single site or by a Tribe varies from a single health station, common in Alaska, to comprehensive in and outpatient hospital services. Other health services provided directly by or through Indian health programs can include medical, dental, mental health, chemical dependency treatment, ambulance, pharmacy, home health, hospice, dialysis, public health and traditional healing.

The diversity of services provided through Indian health programs, and the generally limited size of the population they serve makes comprehensive contracting with private plans an expensive and challenging task.

Pharmacy Services for Dual Eligibles and Impact of Part D

[4] U.S. Commission on Civil Rights, *A Quiet Crisis: Federal Funding and Unmet Needs in Indian Country*, July 2003.

Because most Indian health facilities are located in remote areas far distant from the mainstream health system, they must also operate pharmacies so their patients can access needed medications. IHS, Tribes, and urban Indian organizations operate 235 pharmacies throughout Indian Country. IHS and Tribes dispense pharmaceuticals to their Indian beneficiaries without charge, as is the case for all health services they offer.

A sizeable portion of the patient base for I/T/U pharmacies consists of dual eligibles. IHS estimates that there are between 25,963[5] and 30,544[6] individuals in the IHS patient database who are receiving both Medicare and Medicaid. Since this database does not include information from some tribally-operated facilities (those who do not use the IHS computerized data system) nor information about Indians served by urban Indian clinics, the number of dual eligibles system-wide is even greater than the IHS database reveals.

While there is no comprehensive data on the per-capita drug costs for dual eligibles in the Indian health system, we have been able to make some rough estimates by examining average state per-capita spending for this population. In 2002, the average per-capita spending for dual eligibles was $918.[7] We believe this is a very conservative figure for Indian Country, in view of the higher rates of illness that have expensive drugs associated with their treatment, including diabetes and mental illness. Furthermore, the IHS calculates that the cost of pharmaceuticals has increased by 17.6 percent per year between FY 2000 and FY 2003. This includes the cost of new drugs, increases in drug costs and population growth. Thus, if we trend the average out to the year 2006, the expected average per capita spending on drugs for dual eligibles would be $1,756.

Using these population and per-capita spending data, we estimate that the Medicaid recovery for dual eligible drug costs in the Indian health system ranges between **$23.8 million**[8] **and $53.6 million**.[9] It is vital that these revenues, so critical to the Indian health system, not be interrupted or reduced when dual eligibles are removed from the Medicaid for pharmacy services and placed into either an MA-PD or a Part D plan.

Part A and B Services for Dual Eligibles and the potential Impact of Medicare Advantage

As with Part D, the most serious concerns and most immediate reduction in Indian health program revenues are related to AI/AN who are dually eligible for Medicaid and Medicaid. If States are allowed to mandate enrollment of these individuals in special MA or MA-PD plans, the result will be disastrous for effected Tribes. Although a financial analysis has not been conducted, potential revenue loss to I/T/U on a per patient basis would far exceed losses estimated for Part D alone.

The Secretary of Health and Human Services, as the principal steward of Indian health, has a responsibility to assure that the MMA, which was intended to benefit *all* Medicare beneficiaries, does not produce the opposite result for *Indian* Medicare beneficiaries who use the Indian health care system. He can guard against such an outcome by exercising the broad authority granted to the Secretary to assure access to Part C for AI/AN. We believe that Congress recognized that access for Indian beneficiaries means the ability to utilize Part C benefits through I/T/U and that AI/AN should be able to enjoy voluntary participation in Medicare Advantage plans on a equal basis with all other Medicare beneficiaries.

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[5] This number represents 85 percent of the three-year total of active users.
[6] This is the number of active users, defined as at least one visit in the past three years.
[7] From Table 2, "Full" Dual Eligible Enrollment and Prescription Drug Spending, by State, 2002, in "The 'Clawback:' State Financing of Medicare Drug Coverage" by Andy Schneider, published by the Kaiser Commission on Medicaid and the Uninsured, June 2004.
[8] This low number was calculated using the 25,963 figure for dual eligibles in 2003 and the $918 per capita spending in 2002. It is probably unrealistically low for 2006 given the increase in aging population in Indian Country and the increase in drug prices.
[9] This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.

BACKGROUND FOR PART C ISSUES

There is a fundamental mismatch between the Indian health care system and the proposed rules to implement the MMA. The result of this flaw in the proposed regulations could result in a critical loss of revenue for the Indian health programs across the nation and will further contribute to an even greater disparity in health care between the AI/AN and the general population than already exists. In fact, the proposed rules for Part C make no mention of AI/AN or I/T/U at all. As written, it is unlikely that many AI/AN who receive health care through an I/T/U will be able to benefit from these important Medicare changes. If they do chose to participate in a Part C plan, it is unlikely that Indian health facilities will be able to obtain compensation for the services provided to those Medicare beneficiaries. Furthermore, to the extent that States require dual eligibles to enroll in Title XIX Medicare Advantage (MA) plans, I/T/U will experience significant reductions in revenue associated with these patients.

As sovereign nations and recognized governments, Tribes insist that HHS and CMS acknowledge the impact and financial burden MMA regulations have on Tribal governments and Indian people.

Appropriately including AI/AN and I/T/U in MMA proposed regulations for Medicare Advantage first requires the recognition of key elements of this fragile health system.

- AI/AN are a unique political group guaranteed health care through treaties.
- The federal government has failed to meet this obligation and currently funds Indian health programs at only about 50% of need.
- The Department of Health and Human Services has and continues to develop Tribal consultation policies which have not been used in the process of drafting or assessing the impact of the proposed MMA rules.
- AI/AN, especially those living on or near reservations, suffer from the highest levels of poverty and disease burden in the United States.
- I/T/U, as culturally appropriate providers, have achieved great success in promoting preventive services and improving the health of AI/AN but still face daunting challenges.
- The IHS and Tribally-operated facilities do not charge AI/AN individuals for the health services provided to them, but they do rely upon third party payments, including Medicare and Medicaid.
- Unlike other populations, AI/AN are often reluctant to enroll in Medicaid and Medicare because they understand health care to be a right, thus premiums, and other cost sharing significantly discourages their participation and acts as an insurmountable barrier to program enrollment.
- Unlike other health care providers, I/T/U cannot charge AI/AN patients and therefore beneficiary "cost sharing" merely results in significant and inappropriate reimbursement reductions.
- Many I/T/U facilities provide services in remote areas where the size of the population is insufficient to support a private health care delivery system and where the market forces key to the implementation of this legislation do not exist.
- Private health and prescription drug plans often do not want to contract with I/T/U for many reasons including the health status and small size of the AI/AN population, the special contracting requirements, and the high administrative costs associated with developing and maintaining new contractual relationships with numerous small clinics.
- Resources spent by I/T/U to implement MMA by providing staff time for training, outreach, education, enrollment assistance, contract negotiation, and redesigning IT and administrative systems to accommodate new contracts with Medicare Advantage plans, further reduce funding for the health care of AI/AN.
- The number of AI/AN in the United States who are enrolled in Medicare and who use I/T/U is estimated to be 103,000. Approximately half of this group are thought to be dually eligible for Medicaid. Even if 20% of the remaining AI/AN Medicare population enrolls in a MA or MA-PD plan, the number of Indian enrollees in any MA plan will likely be very small and will have minimal impact

on plans. However, because of the small and widely dispersed population, the per enrollee cost to plans (and I/T/U) to develop, negotiate, execute and implement contracts will be high.

- Although the impact of AI/AN enrollment in MA and MA-PD plans may seem insignificant to plans and CMS, the relative impact on individual Tribes could represent significant losses.

We hope CMS agrees that these regulations should minimize unintended consequences of MMA on I/T/U as well as promoting access to new Medicare options for AI/AN. There are two basic approaches to address Indian issues: 1) simple blanket policies requiring MA and MA-PD plans to pay I/T/U for covered services and limited exemptions for AI/AN; or, 2) numerous, extremely complex policies and exceptions to the proposed rules. **We challenge CMS to closely consider the issues presented here and assist in crafting language for the final rules that will "first do no harm" to Indian health programs and, second, step forward to actually improve access to Medicare for AI/AN and reimbursement for services provided to them by I/T/U**.

Options for AI/AN MMA Policy

Five policy decisions to alleviate well-documented problems I/T/U have experienced contracting with private plans would address a majority of concerns raised by the proposed rules:

1. Encourage MA enrollment by AI/AN by removing financial barriers and allowing AI/AN to voluntarily participate in Medicare Advantage plans, without financial penalty because of location of residence, selection of a plan that includes I/T/U, or use of I/T/U.
    - Waive AI/AN cost sharing for all plans.
    - If AI/AN dual eligibles are required to enroll in an MA or MA-PD plan, establish the default enrollment for AI/AN to an MA or MA-PD plan for which the network includes local I/T/U facilities, or pays fully for out of network services.
    - Allow unlimited plan switching to facilitate enrollment in plans with culturally sensitive I/T/U providers. Exempt AI/AN from "lock-in" or "lock-outs".
    - Exempt AI/AN from cost differentials associated with selection of a plan that includes culturally appropriate I/T/U provider or more robust networks

2. Ensure that I/T/U, under all conditions, are held harmless financially and are fully reimbursed for covered services provided to AI/AN who enroll in a Medicare Advantage plan. We see three basic options to implement this policy:
    a. Require all MA (and MA-PD) plans to recognize I/T/U as in-network providers and reimburse at IHS Medicaid rates (as paid under the original or traditional Medicare), even without contracts. We believe this would be the desired option of plans and CMS because the minimal administrative burden and simplicity of regulations would reduce the cost of implementation.[10]
    b. Require MA (and MA-PD) plans to recognize I/T/U as in-network providers, even without contracts, and reimburse at Plan's standard Medicare rates. CMS provides "wrap-around" reimbursement to hold I/T/U harmless for difference between plan reimbursement and IHS Medicaid rate.
    c. Require all MA (and MA-PD) plans to contract with all willing I/T/U under similar special contract provisions terms as those used for the special endorsed Prescription Drug Discount Card contracts and using IHS Medicare rates. Also exempt I/T/U from plan credentialing, risk

[10] Washington State Administrative Code provides a precedent and contains sample language for this provision. **WAC 284-43-200 Network adequacy.** (7) To provide adequate choice to covered persons who are American Indians, each health carrier shall maintain arrangements that ensure that American Indians who are covered persons have access to Indian health care services and facilities that are part of the Indian health system. Carriers shall ensure that such covered persons may obtain covered services from the Indian health system at no greater cost to the covered person than if the service were obtained from network providers and facilities. Carriers are not responsible for credentialing providers and facilities that are part of the Indian health system. Nothing in this subsection prohibits a carrier from limiting coverage to those health services that meet carrier standards for medical necessity, care management, and claims administration or from limiting payment to that amount payable if the health service were obtained from a network provider or facility.

sharing, and other contracting requirements that are conducted or prohibited by federal or tribal statute, rule or policy. These contract provisions are outlined under 422.112 and are similar to those recommended for Part D.

3. Allow I/T/U the flexibility to sponsor AI/AN in Medicare Advantage plans, under a special group payer arrangement.
    - Permit sponsorship of AI/AN with flexibility and adequate timelines to add and drop individuals
    - Require plans and CMS to send sponsors information normally sent to enrollees so sponsors can respond quickly
    - Add special plan disenrollment rule for sponsored AI/AN and require communication and problem resolution process between plan and sponsor prior to plan disenrollment of AI/AN

4. Allow, in the future, the development of an AI/AN special Medicare Advantage plan that includes the active participation of Tribes in its design and implementation.

5. Explicitly exempt AI/AN dual eligibles from mandatory participation in a State Title XIX MA or MA-PD Plan.
    - MMA should not reduce the funding currently going to support Indian health programs; however, the effect of mandatory AI/AN dual eligible enrollment would result in significant losses for effected I/T/U
    - Sec. 1932 [42 U.S.C. 1396u-2] exempts AI/AN from mandatory Medicaid managed care plan enrollment, in recognition of the many difficulties facing I/T/U in interfacing with private plans. For these same reasons, we believe AI/AN dual eligibles should not be required to enroll in MA or MA-PD plans.
    - Allow same options, or exemptions, for AI/AN as currently exists under state Medicaid plans.

Additional AI/AN policy issues that require changes in the proposed rules:

- Remedy potential reimbursement and Contract Health Services funding problems for I/T/U created by MSA without restricting as an option for AI/AN.

- Require consistency with Part D rules relative to AI/AN policy.

Recommended Revisions to August 3, 2004 Proposed Rules

Proposing specific section-by-section language changes to the proposed rules to accomplish the AI/AN policy objectives stated above would require time and resources beyond our current means. **We challenge CMS to come forward with comprehensive changes to the proposed rules that will appropriately allow access to MA for AI/AN and I/T/U as special populations and providers.** Listed here is a limited set of suggested revisions.

Subpart A – General Provisions

To enable an AI/AN specific MA or MA-PD plan in the future:

422.2 *Definitions*

Basic benefits add, “including covered services received through an Indian health service program.”

Special needs individuals add “American Indians and Alaska Natives (AI/AN) are exempt from mandatory enrollment in Title XIX plans but would qualify for optional enrollment in an AI/AN specialized MA plan.”

In establishing contracts with a national, statewide or regional MA or MAPD plans preference should be given to state licensed managed care organizations that are controlled by Indian Health Service funded Tribal and /or Urban Indian Health Programs which are funded to provide services in clients. This approach is the best means of assuring access to culturally competent and geographically proximal services to individual Indians.

To address the cost of implementation at the I/T/U level:

422.6 *Cost Sharing in Enrollment Related Costs*

We have commented to CMS on several occasions about the high cost to I/T/U for MMA implementation costs related to outreach, education and enrollment of AI/AN. We strongly encourage CMS to identify in this or another section the need for funding to support these activities be specifically directed to local I/T/U where the work is done and bearing the costs is most difficult. Unlike other Medicare populations, AI/AN are unlikely to enroll in MA plans without specific information from their I/T/U.

Subpart B – Eligibility, Election and Enrollment

To address potential intended loss of revenue to I/T/U:

422.52 *Eligibility to elect MA plan for special needs individual*

(b)(2) add, “except mandatory enrollment for AI/AN is prohibited.”

To discuss and address unique issues related to AI/AN Medicare MSA:

422.56 *Enrollment in an MA MSA plan*

(c) The enrollment of AI/AN in MSAs presents unique challenges. Tribes would like an opportunity to discuss this issue with CMS to ensure it is implemented in a way that will improve access to services.

To accommodate I/T/U group payer arrangements:

422.60 *Election process*

Require MA and MA-PD plans to accept AI/AN enrollment, even if CMS has allowed the plan to close due to capacity limits. Rationale: AI/AN could enroll in MA plans under a variety of circumstances, including a group sponsorship. Because the number of AI/AN is small and the number of culturally appropriate plans available will be very limited, CMS should require plans to enroll AI/AN at anytime.

422.62 *Election coverage under an MA plan*

We request that CMS add the following provisions in an appropriate place:

- AI/AN may switch MA or MA-PD plan at any time if local I/T/U is not reimbursed by plan as in-network provider at original (or traditional) Medicare rate
- AI/AN who are in a sponsorship program may, with the consent of the sponsor, switch plans at any time
- Sponsors may add AI/AN enrollees to an MA plan at anytime under the following conditions: relocation to sponsor service area; loss of alternative health insurance coverage; change in sponsorship policies.
- AI/AN sponsored in a group payer arrangement are exempted from “lock-ins” and “lock-outs”.

422.66 *Coordination of enrollment and disenrollment through MA organizations*

We request that CMS add the following provisions in an appropriate place:

- Establish a default enrollment process for AI/AN that uses a plan that reimburses local I/T/U at in-network rates
- Provide flexibility for switching plans under conditions AI/AN are likely to encounter

- Communicate directly with local I/T/U about patient enrollment/disenrollment

422.74 *Disenrollment by the MA organizations*

Add "Process for disenrolling an AI/AN under a sponsorship or group program must include direct communication with sponsor with adequate documentation of problem and steps taken to resolve as well as adequate timelines."

422.80 *Approval of marketing materials and election forms*

This language lists as prohibited marketing activities for MA Plans to *"Engage in any discriminatory activity, including targeted marketing to Medicare beneficiaries. . .and (iii) solicit Medicare beneficiaries door-to-door."* While the intent of this language is to prohibit aggressive enrollment practices that favor healthier individuals, the unintended consequence may be to limit the development of needed materials targeted to AI/AN. While MA Plan representative should be prohibited from soliciting business by going door-to-door, the outreach workers employed by tribal and IHS facilities should be encouraged to provide information about Medicare alternatives in the homes of AI/AN elderly. We ask that CMS clarify this issue.

Subpart C – Benefits and Beneficiary Protections

To address potential intended loss of revenue to I/T/U:

422.100 *General Requirements*

If not clearly addressed in another section, MA and MA-PD plans should be required to reimburse I/T/U at the original Medicare rate under all circumstances when the I/T/U provides a covered benefit.

To remove financial barriers for AI/AN enrollment:

422.101 (d) *Requirements relating to basic benefits special cost sharing rules*

Add (5) “Special rules for AI/AN. Covered services provided to AI/AN through I/T/U, including both direct care, contract health care and other payments, will be credited toward all AI/AN cost sharing including deductibles, copayments, coinsurance and catastrophic limits.”

To facilitate a special AI/AN MA or MA-PD plan and accommodate I/T/U group payer arrangements:

422.106 *Coordination of benefits with employer group health plans and Medicaid*

The discussion in the Federal Register states: *“Section 222(j)(2) of the MMA allows us to waive or modify requirements that hinder the design of, the offering of, or the enrollment in an MA plan offered by an employer, a labor organization. . .”* This type of waiver authority should also be used to create the flexibility to develop a national plan for AI/AN beneficiaries. We also ask CMS if this section could explicitly allow I/T/U or other entities to sponsor groups of AI/AN under a group plan. We assume this option to be exercised locally but could also envision a national AI/AN plan that would allow optional local sponsorship. We believe that few AI/AN who receive services through I/T/U will enroll in a MA plan on their own, therefore we ask CMS to develop an enabling option for I/T/U, or Tribes to enroll and pay for groups of AI/AN as sponsors.

As stressed above, we ask that dual eligible AI/AN be explicitly exempt from mandatory enrollment in MA or MA-PD plans.

To remove financial barriers for AI/AN enrollment:

422.111 *Disclosure requirements*

(e) *Changes to provider network* add “Changes to provider networks which affect AI/AN will provide cause for a AI/AN to switch to another plan at anytime without penalty.”

422.122 *Access to Services*

Access to services for AI/AN requires the inclusion of I/T/U. All MA and MA-PD plans, including private fee-for-service plans referenced under 422.114 (c), should be required to include Indian health facilities as in-network providers to achieve network adequacy (without requiring the I/T/U to serve individuals who are not IHS beneficiaries), and AI/AN beneficiaries should be exempted from higher cost sharing if they use I/T/U. There are several reasons for this recommendation including: 1) AI/AN should be able to seek care at I/T/U as culturally appropriate services; 2) AI/AN could not be charged any cost sharing by I/T/U thus differences in premium or copayments

would only serve to further reduce revenue to tribal and Indian health facilities; 3) many I/T/U may be unable to contract with desirable MA or MA-PD plans for reasons already documented by CMS.

To enable I/T/U contracting with Part C plans:

Add "(a)(1)() *Access to IHS, tribal and urban Indian programs.* In order to meet access standards a Medicare Advantage plan or MA-PD plan must agree to contract with any I/T/U in its plan service areas.

(i) Such contracts shall incorporate, within the text of the agreement or as an addendum, provisions:

A. Acknowledging the authority under which the I/T/U is providing services, the extent of available services and the limitation on charging co-pays or deductibles.
B. Stating that the terms of the contract may not change, reduce, expand, or alter the eligibility requirements for services at the I/T/U as determined by the MMA; Sec. 813 of the Indian Health Care Improvement Act, 25 U.S.C. §1680c; Part 136 of Title 42 of the Code of Federal Regulations; and the terms of the contract, compact or grant issued to Provider by the IHS for operation of a health program, including one or more pharmacies or dispensaries.
C. Referencing federal law and federal regulations applicable to Tribes and tribal organization, for example, the Indian Self-Determination and Education Assistance Act, 25 U.S.C. §450 *et seq*. and the Federal Tort Claims Act, 28 U.S.C. §2671-2680.
D. Recognizing that I/T/Us are non-taxable entities.
E. Clarifying that Tribes and tribal organizations are not required to carry private malpractice insurance in light of the Federal Tort Claims Act coverage afforded them.
F. Confirming that a MA plan may not impose state licensure requirements on IHS and tribal health programs that are not subject to such requirements.
G. Including confidentiality, dispute resolution, conflict of law, billing, and payment rate provisions.
H. Recognizing that an I/T/U formulary cannot be restricted to that of the MA-PD plan.
I. Declaring that the Agreement may not restrict access the I/T/U otherwise has to Federal Supply Schedule or 340b drugs.
J. Stating that the I/T/U shall not be required to impose co-payments or deductibles on its Indian beneficiaries.
K. Authorizing I/T/U to establish their own hours of service.
L. Eliminating risk sharing or other provisions that conflict with federal, IHS or tribal laws, rules or policies."

We support the provision for payments to *"essential hospitals"* and request that I/T hospitals be explicitly identified by adding to (c)(6) All hospitals operated by Tribes or the Indian Health Service will be considered essential under this provision."

Subpart F – Submission of Bids, Premiums, and Related Information and Plan Approval

To remove financial barriers for AI/AN enrollment and accommodate I/T/U group payer arrangements:

422.262 *Beneficiary Premiums*

AI/AN served by an I/T/U will most likely not elect to pay Part D premiums because these patients can access health care through the Indian Health Service (IHS) based on the Federal Government's obligation to Federally recognized Tribes. It is our interpretation that the payment options cited to implement 422.262, Beneficiary Premiums, includes the IHS and Tribes. (Preamble, page 46651, "the IHS may wish to pay for premiums to eliminate any barriers to Part D benefits"). We specifically ask CMS to remove barriers Tribes have encountered in paying Part B premiums for AI/AN under current CMS group payer rules (size of group and switching an individual from automatic deduction to group pay). Without these changes it is unlikely that AI/AN, who are entitled to health care without cost sharing, will enroll in MA plans.

Subpart G – Payments to Medicare Advantage Organizations

To discuss and address unique issues related to AI/AN Medicare MSA:

422.314 *Special rules for beneficiaries enrolled in MA MSA plans*

The enrollment of AI/AN in MSAs presents unique challenges. Tribes would like an opportunity to discuss this issue with CMS to ensure it is implemented in a way that will improve access to services.

To address potential intended loss of revenue to I/T/U:

422.316 *Special rules for payments to federally qualified health centers*

Add "Tribal FQHCs are not required to contract with MA or MA-PD plans as a condition for reimbursement. CMS will pay tribal FQHC at the same rate they would receive under original Medicare."

Conclusion

We understand that some of the MMA proposed rules related to point of service options and coverage of areas without adequate networks are intended to encourage the availability of MA and MA-PD plans in rural areas. However, because I/T/U operate in a diverse range of environments, the patient populations tend to be small and the array of possible local options is unknown, proposing complex policies to shoehorn in AI/AN seems ill advised. Our assessment of the negative impact on AI/AN and their access to MA plans is based on years of experience under implementation of State Medicaid managed care waivers. While the experience of Tribes and AI/AN under these private health plans was frequently

disastrous, a number of Indian policy models have emerged which can be adopted for MMA implementation. In fact, to acknowledge these problems, a July 17, 2001 “Dear State Medicaid Director” letter, was issued by CMS directing states to notify and communicate with Tribes during a waiver or renewal and inform Tribes of “the anticipated impact on Tribal members.” We encourage CMS to consult with Tribes in a similar manner, and although it has, by default, fallen on Tribes themselves to assess the impact of MMA proposed regulations, we expect CMS to seriously consider remedies for all of the issues raised in this letter.

Again we urge CMS to consider eliminating unnecessary administrative cost burdens to all involved (AI/AN, I/T/U, CMS, Tribes, Indian Health Service and MA plans) and adopt simple blanket policies for AI/AN and I/T/U that will promote access to these new benefits as well as guarantee Medicare reimbursements from the MA and MA-PD plans.

CMS-4068-P-1301

Submitter : Ms. Kathleen Means **Date & Time:** 10/04/2004 09:10:01

Organization : Patton Boggs LLP

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

see attached letter

CMS-4068-P-1301-Attach-1.doc

PATTON BOGGS LLP
ATTORNEYS AT LAW

2550 M Street NW
Washington DC 20037
(202) 457-6000

October 4, 2004

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4068-P, Comments on the "Medicare Program; Medicare Prescription Drug Benefit; 69 Fed. Reg. 46631 (Proposed Rule, August 3, 2004)."

Patton Boggs LLP respectfully submits these comments on behalf of QMed, Inc. in response to the proposed rule on the Medicare Prescription Drug Benefit as issued by the Centers for Medicare and Medicaid Services ("CMS") in the Federal Register on August 3, 2004. Patton Boggs LLP, with offices in the United States and abroad, is a major law firm with a leading public policy and health care practice. The foregoing comments are relevant to the "General Provisions" section of the proposed regulations.

QMed provides coordinated disease management services to chronically ill individuals (including diabetes and cardiovascular diseases), enrolled in commercial health insurance plans, Medicare+Choice, and Medicare demonstrations. The company's physician and patient engagement model is designed to ensure high rates of participation, to optimize medical therapies, and to reduce unexplainable variations in medical practice. QMed's information management systems provide quality assessment data for clinical and policy purposes at the individual. physician, plan and/or market level. QMed's comments focus on the area of specialty health plans.

QMed believes that Specialized MA Plans (SMAPs) must coordinate physicians, patients, pharmacy, formulary, clinical laboratory data, Disease Management nurses and educators into a seamless clinical information loop. When this coordination is present, evidence-based best practice medicine (EBM) becomes a reality, not just a goal. Relying on mere administrative claims data will allow neither satisfactory risk assessment nor optimized medical therapies. QMed accomplishes this for individuals suffering from heart failure, stroke, coronary artery disease, complex diabetes, hypertension.

QMed believes that such SMAPs will have to incorporate disease management (DM). Such DM services must be fully coordinated since standard non-coordinated DM services cannot ensure that special needs patients will have received optimized medical therapies from physicians. In consequence, educating and motivating SMAP patients will not ensure that health and financial outcomes will be optimized.

Clinical programs targeted to individuals must incorporate clinical information, which is found most fully in patient charts at physician offices. Clinical programs can then be devised that respond directly to clinical evidence. The programs ought to have processes that assure that clinical lab data is current. The clinical data obviously form a more fine-grained diagnosis than administrative data. Patient self-reported data is also only supplementary to this clinical data but is not a substitute. Clinical programs for SMAPs ought to meet this criterion.

Clearly, coordinating clinical data to optimized and efficient pharmacy use require full integration of physicians into the information loop. QMed accomplishes this through generating recommendations specific to each individual patient. Recommendations are based on charted clinical data, claims and continuously updated clinical lab values.

Chronic sufferers of heart failure, stroke, coronary artery disease, complex diabetes, or hypertension form an ideal set for SMAPs because the disease progression and medical therapy treatments are well supported by scientific literature. In addition, this group is clearly the most expensive in Medicare. The opportunity to improve quality and reduce variation of medical practice is enormous. QMed has numerous implementations with health plans demonstrating outcomes, and is engaged in several CMS demonstrations.

Oversight in QMed's system includes identifying quality at the physician level through their adherence to evidence-based medicine. The program comports well with CMS' stated desire to measure quality.

Thank you for the opportunity to provide comments on behalf of QMed. We respectfully request that any inquiries be directed to the firm's representative, Mr. Robert Mosby on (732) 544-5544.

Sincerely,

Kathleen E. Means

Submitter : Dr. Paul Wettengel **Date & Time:** 10/04/2004 08:10:00

Organization : FirstChoice Healthcare

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Thank you for your attention to this matter.

CMS-4068-P-1261-Attach-1.rtf

CMS-4068-P-1262

Submitter : Mr. Randall Binning **Date & Time:** 10/04/2004 08:10:38

Organization : Mr. Randall Binning

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS,

I write this comment in hopes that you will consider the role pharmacists can play in the improvement of healthcare given to the clients covered by medicare and medicaid.

Pharmacists are in an important position to manage medication therapy for patients who need to take chronic medications. Pharmacists are highly accessible, as well as most patients pick up medications monthly.

Currently pharmacists get paid to dispense medications regardless of the amount of time or information that is given to the patient. FOr the most part there is little incentive for pharmacists to make sure patients are using their medications properly. If pharmacists are given reimbursement for their services, patients with chronic conditions could be monitored on a monthly, or some other regular basis that would improve the medication therapy.

In the new CMS bill, I believe there needs to be a definition of what pharmacy management of medication therapy is and it must not be left up to the pharmacy benefit managers (PBM) to determine what this reimbursement is.

This medication management is already in place but could be vastly improved if reimbursement for it was appropriate.

It is also important that all pharmacists would be elligible to receive reimbursement if medication therapy management is given. Please do not allow the PBMs to dictate which pharmacist can give the management.

In closing, pharmacies can be an integral component of the new Medicare benefit. Medicare recipients often rely on their pharmacist for advice and counsel. Pharmacists will be able to assist in making this new benefit successful or they will speak out against it. Medicare must make specific requirements of the plan sponsors otherwise many of the nation?s foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacists must be allowed to participate equally and fully. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program.

Thank you for your consideration.

Sincerly,

Randall Binning PharmD (graduated 2004)
Pharmacy Resident

CMS-4068-P-1263

Submitter : Mr. John Bynon **Date & Time:** 10/04/2004 08:10:48

Organization : TVA Retirees Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attached letter.

CMS-4068-P-1263-Attach-1.doc

CMS-4068-P-1264

Submitter : Mr. Timothy Schuerch **Date & Time:** 10/04/2004 08:10:51

Organization : Alaska Native Tribal Health Consortium

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please find enclosed MS Word document containing comments applicable to a number of provisions of the proposed Part D regulations; dd

CMS-4068-P-1264-Attach-1.doc

Submitter : Ms. Jennifer Dripps **Date & Time:** 10/04/2004 08:10:01

Organization : UNC School of Pharmacy

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

I believe patients should be able to choose the pharmacy and pharmacists they prefer. Limiting medicare patients to preferred pharmacies takes away there freedom to choose!

CMS-4068-P-1266

Submitter : Mr. William von Oehsen **Date & Time:** 10/04/2004 08:10:18

Organization : Public Hospital Pharmacy Coalition

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

PHPC wishes to submit the attached comments. If you have questions, please contact William von Oehsen or Ted Slafsky at (202) 466-6550.

CMS-4068-P-1266-Attach-1.pdf

Submitter : Mr. Nelson Soltman **Date & Time:** 10/04/2004 08:10:46

Organization : Legal Assistance Foundation of Met. Chicago

Category : Individual

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

III. Subpart J: ?423.464(e)(1): Requirements to be a State Pharmaceutical Program.

Many elderly Medicare beneficiaries in Illinois participate in the SeniorCare program for pharmaceutical assistance. Illinois estimates that about 200,000 participants age 65 and over are in SeniorCare, which provides comprehensive prescription drug coverage. Seniors in Illinois with incomes at or below 200% FPL, and who otherwise meet the eligibility standards for Medicaid, may use SeniorCare. Cost sharing is generally minimal with no premiums, $4 copays for brand name drugs and $1 copays for generics for the first $1,750 of drug spending. After $1,750 of drug spending has been reached, a senior pays a coinsurance of 20 percent in addition to the copays.

SeniorCare is more generous than the proposed Part D program, according to estimates by the Illinois Department of Public Aid (IDPA), Illinois? Medicaid agency. CMS should allow for the continuation and renewal of the Senior Care Program, and should not mandate that the Senior Care population switch its coverage to Part D. CMS should provide flexibility for Illinois to modify SeniorCare to coordinate benefits with Medicare Part D to maximize coverage and minimize costs for beneficiaries.

Part D should be implemented to protect and maintain these beneficiaries? current ability to access affordable prescription drugs. The definition of SPAP should be modified to provide for the continuation of Illinois? SeniorCare program, and to assure that SeniorCare participants are not penalized for participation in SeniorCare. The SeniorCare structure has been in operation for several years, and works well for beneficiaries. They should be able to continue to benefit from SeniorCare.

ELIGIBILITY, ELECTION, AND ENROLLMENT

I. Transition of Dual Eligibles: 423.34(d) Enrollment requirement for full benefit
dual eligibles

Transition of the dual eligibles to Part D coverage is a major problem. CMS should eliminate any potential gap in coverage between the time that Part D takes effect (January 1, 2006) and the end of the initial enrollment period, when auto-enrollment would occur (May 15,2006). The Part D dual eligible population does not generally have experience in choosing prescription plans. They will have been on Medicaid, without the need for making such a choice. Some, such as those with cognitive impairments, may find it especially difficult to make such choices.
CMS? proposed delayed timeline for automatic enrollment could expose dual eligibles to a four and half month coverage gap that would cause hardship and could have serious health consequences for this vulnerable population. Creating such a gap will also run the risk of increasing hospital costs nationwide for services provided to beneficiaries hospitalized due to the deterioration of their health resulting from the gap in prescription coverage.

To prevent these consequences for dual eligibles, the transition of drug coverage for dual eligibles should be delayed for at least six months. Dual eligibles will need this long, given their higher prescription use, increased incidence of cognitive impairment, and need for individualized counseling and assistance, to select the most appropriate Part D coverage.

In addition, CMS should fund a comprehensive campaign of individualized counseling and assistance to explain to individuals in advance of their required enrollment what their choices are and how to enroll in a plan; if applicable, to explain how to get benefits under the plan to which they have been auto-assigned; and, if applicable, explain that they can choose a different plan from the one to which they have been auto-assigned and assist in choosing and enrolling in such a plan.
II. Section 423.46: Late enrollment penalty.

CMS should delay implementation of this section for all enrollees for at least one year. Part D is a new and particularly complex program. Many

beneficiaries will be confused about the program, not understand that they must choose a plan and enroll, or not be able to complete the enrollment steps. Many who require prescription drug coverage and are eligible for it do not necessarily know how to access it. For instance, Illinois estimates that almost 360,000 Illinois seniors are eligible for SeniorCare, but only about 200,000 are enrolled.

The people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness. Many Medicare beneficiaries will need more than six months to understand the program, understand how Part D coordinates with other drug coverage they may have, and choose the drug plan that is right for them. Beneficiaries should not be penalized because of the complexity of Part D and its implementation.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

IV. Subpart M: Grievances, Coverage Determinations and Appeals

This subpart should be simplified. The timeframes, required paperwork, and procedures should be simplified into one system, understandable to beneficiaries, that meets the requirements of the Due Process. The current system does not meet that test. The appeals process described in Subpart M does not provide dual eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity to a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes. It should be modified to meet those requirements.

CMS-4068-P-1268

Submitter : Mrs. Gerald Shea **Date & Time:** 10/04/2004 08:10:49

Organization : AFL-CIO

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4068-P-1268-Attach-1.pdf

Submitter : Dr. Steven Daviss **Date & Time:** 10/04/2004 08:10:01

Organization : Maryland Psychiatric Society

Category : Physician

Issue Areas/Comments

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Research indicates that, in general, the earlier one gets EFFECTIVE treatment, the better the outcome. Delays in getting these treatments may result in worse long-term outcome. Access to a variety of drugs with different mechanisms of action and side effect profiles is critical to these patients and their families.

The classification system used by CMS is based on a disease-linked therapeutic category or indications followed by pharmacologic classes primarily based on mechanism of action with some exceptions, i.e., based on chemical structure. However, the draft "Pharmacologic Classes" fail to adequately recognize mechanism of action. For example, lumped together in one class under the heading "Reuptake Inhibitors" are two different classes of tricyclic antidepressants, all the serotonin reuptake inhibitors, and all the dual serotonin and norepinephrine reuptake inhibitors. This lumping together ? also seen in the lumping together of all the atypical antipsychotics into a single drug class ? when carried through to the Pharmacy Benefit Managers who will craft formularies based on these pharmacologic classes, will:

-fail to pass the discouragement-from-enrollment test, and
-fail to pass the non-discrimination test.

Why?

1- Patients now on medications which are tailored to their SPECIFIC needs ? based on mechanism of action, drug side effects (which relate to receptor binding profile), and potential for drug interactions ? may be required to switch to less effective drugs with more unwanted side effects and greater risks of drug interactions.

2- Many psychotropic drugs are metabolized by the liver's P450 enzymes. Some people have genetic variations in these enzymes, which would cause increased drug levels and more side effects. As it turns out, people of African and Asian ancestry have a much greater risk of some of these genetic variations (3- or 4-fold in some cases). Failure to account for these pharmacogenetic differences in the classification scheme may require some individuals to suffer worse side effects due to their genetic profile, discriminating against these populations.

3- Other populations at risk of unintended discrimination will include seniors and those on multiple medications for other medical illnesses.

We anticipate that CMS will work with the APA and other organizations to correct these deficiencies and to improve the safety of drug use based on these categories.

Submitter : David Hanig **Date & Time:** 10/04/2004 08:10:01

Organization : WA State Medical Assistance Administration

Category : State Government

Issue Areas/Comments

Issues 1-10

BACKGROUND

Part 423.774
In completing re-determinations of eligibility, changes in the client?s circumstances must be addressed. However, they are not addressed in these rules. We suggest that the processes for re-determinations and appeals be the same for whether conducted by the State Medicaid agency or SSA. This would provide uniformity in the re-determinations and appeals process.
CMS envisions a verification process whereby States and SSA will build on the existing verification processes used for other programs, maximizing the use of automated data matches for verification of income and certain liquid resources. A major problem is access to data for the States (i.e. data matches with 1099 files from the IRS) and the timeframe needed for building access to data. We do not believe that the automation envisioned will be available when this program is implemented and recommend that this provision be removed.
The section notes that the Act provides that ?statements from financial institutions shall accompany applications in support of the information provided therein,? can not happen automatically. The financial institution statements must be provided by the individual; this will be problematic with this aged, blind and disabled population. Unless liberalized, this requirement will result in many elderly and disabled individuals losing prescription drug coverage. This is not acceptable.
If, as stated in this section, CMS will permit the use of a ?proxy signature process? to allow applications to be taken over the phone or by an Internet process, does this mean that CMS is relaxing their requirement for signatures on applications?
CMS states that the time and effort for an individual or personal representative to complete the low-income subsidy application, provide financial statements and certify that the information provided is accurate is 10 minutes. This estimate is grossly understated. It also does not include the time it will take the individual or personal representative to select a plan. Depending on the number of plans available, selecting a plan could take 30 minutes to two hours for this population.

Section H
CMS did not include the States costs for conducting eligibility determinations for low-income benefits in the estimate of net State savings. They roughly estimate the State share of costs for these determinations at approximately $100 million a year, beginning in FY 2005. Due to the complexity of the program and the incidence of cognitive impairment in this population, we believe this figure is underestimated and should be reconsidered.

Part 423.904
States will be required to begin accepting application forms for the low-income subsidy no later than July 1, 2005. This is not a reasonable expectation. Once rules are established, States will have to adopt new rules, program their technology systems and train staff. Interfaces between State and SSA systems also must be established. July 1, 2005 does not provide enough time to implement this new program. We recommend that states be allowed to provide applicants with the SSA application, provide assistance to complete the application, and forward the application to SSA for determination.

BENEFITS AND BENEFICIARY PROTECTIONS

Enrollment for the Prescription Drug Plans (PDPs) opens on November 15, 2005. If dual eligibles have not selected a plan, CMS states that they will be randomly assigned a plan by December 1 with an effective date of the benefit of January 1, 2006. These plans will have their own formulary and their own network of pharmacies. It is possible that clients will not be assigned to a plan that covers their specific ongoing medications or uses their preferred pharmacy.
? Impact on Clients. Individuals will have only 2 weeks to examine the choice of plans or face auto enrollment. Considering the incidence of dementia, mental disabilities, and confusion in the dual eligible population, a significant number will require assistance to choose a plan. Once they know their plan, they will have only a few weeks to compare the formulary to their own drug profile, obtain different prescriptions for the necessary changes, pick a new pharmacy, and transfer all their prescriptions to the new pharmacy. This all occurs over the holiday season. We recommend providing additional time for dual eligibles to select and convert to a plan. Dual eligibles should also be able to continue receiving existing medications without interruption until the plan can implement changes without destabilizing the condition of the beneficiary.
? Impact on Facilities. Facilities usually have working relationships with a single, main pharmacy. Their individual residents could be auto-

enrolled randomly in PDPs whose formularies are not a good match for the residents? medication profiles and whose network of pharmacies are not used to providing services to their facility and/or providing them the safeguards currently needed at the facilities. Facilities which currently work with a single, main pharmacy may find they need to develop new relationships with many different pharmacies. It is highly likely that facilities will attempt to get each resident enrolled with a ?house? plan. However, the ?house? plan?s formulary may not be the best choice for all of the clients? medication profiles, resulting in chaos as clients and the facility attempt to change medications to match the applicable formulary. Because the Medicare enrollment information is likely to be mailed directly to the resident or their designee, facilities will not know of the plans selected or auto assigned for all of their residents. Since most residents of nursing home, Assisted Living facilities, etc. have Medicare, this, at best, will be an extremely chaotic time for the facilities. We recommend provisions to assure that pharmacies providing services to long-term care facilities be able to participate with all local PDPs or MAs which serve individuals in those facilities.
? Impact on the State. The State will be unable to obtain federal match for any Part D medications for dual eligibles after January 1, 2006; therefore, any attempts to ease this transition would be very costly for the State. In addition, for the significant number of Medicare/Medicaid eligibles unable to choose their own plan (such as those with developmental disabilities, mental health issues, or dementia), the 2 weeks prior to auto enrollment will create an impossible workload for DSHS and AAA staff and providers who will be assisting clients with their choices. With such a tight timeframe and the holiday season, it will be impossible to hire sufficient staff, even if properly funded. Moreover, it is not yet clear whether the State will have responsibility to auto-enroll dual eligibles. If so, this would create a workload at a time when staff are dealing with end-of-calendar year requirements. We recommend providing additional time for dual eligibles to select and convert to a plan.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Transition Issues

There will be transition issues that adversely affect a very vulnerable population unless adequate provisions are made. Part D enrollment represents incredibly complicated system changes occurring over the holiday season. At best, dual eligibles will have 3 weeks to identify which of their current medications do not match their new plan?s formulary, contact their physician, obtain a new prescription, send that new prescription to their new pharmacy and pick up their medications. In addition, they may need to switch the remaining prescriptions to an in-network pharmacy. When you consider dual eligibles who reside in some sort of congregate care, either nursing facilities or a variety of community-based care settings, this becomes even more difficult. Facilities frequently use one major pharmacy and in this transition there will have to be extensive, timely work with residents to ensure that appropriate plans are chosen, or facilities will have to develop business relationships and communication with numerous, potentially unknown pharmacies. In order to protect the health and welfare of the most vulnerable beneficiaries, CMS should incorporate the following protections:
? Require Part D plans to reimburse current pharmacies for current medications for at least 6 months. This will allow a smooth transition for all parties and allow prescriptions to be switched to formulary medications and allow everyone to switch to in-network pharmacies in a manner that does not endanger health.
? Allow States to obtain federal financial participation for any wrap-around medication until July 1, 2006. It is not likely that auto- enrollment will be a completely smooth process without errors. In addition, many disabled and elderly individuals in the dual eligible population will be confused by change and paperwork. There will be beneficiaries who accidentally opt out of Part D and will lose all drug coverage, placing their health in jeopardy, increasing hospitalizations, and placing the facilities and homes in an untenable position. Licensing requirements (including federal regulations for nursing facilities) require them to meet the health needs of their clients; but there will be no resources to purchase these needed medications. States need the option to provide a matched program to assist dual eligible citizens whose health could be harmed in this transition without coverage.
? CMS must develop the system to notify the facilities of each resident?s plan choice.

GENERAL PROVISIONS

General

The responsibility is given to State Medicaid offices and Social Security for eligibility determinations for the low-income subsidies, increasing the workload substantially in providing information, making eligibility determinations for known and also for all the currently unknown clients, training staff and dealing with appeals. Despite the additional workload, states will receive at most 50% FFP. This represents an unfunded mandate and states require additional federal dollars to perform these new duties.

SPECIAL RULES FOR STATES

Part 423.34
This section states that a process will be established to automatically enroll full benefit dual-eligible individuals who fail to enroll in a PDP or MA-PD plan timely. We recommend that this function be fulfilled by a CMS hired outside contractor. Benefits include:
? Nationally consistent information dissemination
? Nationally consistent implementation
? Nationally consistent oversight of the function
? Reduction of information dissemination between States and CMS regarding this function.
Prior to the automatic enrollment this section mentions a widespread education and information campaign to equip full benefit dual-eligibles to make an informed decision on enrollment. This education and information campaign is not described: how the information will be distributed, especially for the transition of the full benefit dual-eligible people when this law is implemented 1/06. States need more information about how CMS will distribute the information and assist this population in selecting a plan that will work for them.
Part 423.36
There is no definition of ?institutionalized individuals? ? the assumption is that the definition is the same as in Part 423.772 and excludes full benefit dual eligible individuals receiving services under a waiver program or those in ICF/MRs.

Part 423.120
Under the proposed regulations, prescription drug plans are required to cover only two medications in each therapeutic category and class. PDPs are not at risk for down-stream health costs from an inadequate drug formulary and the better bid prices of a limited number of formulary medications create a fiscal incentive to limit formularies. This is acceptable for some categories and classes, but not all. For some clients there will be a significant risk to their health if they are required to switch medications, or the client and their physician will be required to appeal through a potentially cumbersome process. A multi-state consortium has examined several drug classes and concluded that anti-seizure medications and atypical antipsychotics should not be limited for current recipients of these medications. The regulations should be revised to reflect this and similar evidence-based pharmaceutical reviews in order to protect the health and safety of the beneficiaries. In the absence of this change, we anticipate that many individuals with mental disabilities will destabilize and require costly hospitalizations and endure increased symptoms. At a minimum, the regulations should require PDPs to provide current medications to current recipients of antipsychotics and anti-seizure medications indefinitely.

Part 423.772
The proposed regulations is not clear whether individuals in 1915c waivers and 1115 waivers should be treated as fully Medicaid eligible, making them eligible for full dual benefits. We recommend clarifying that individuals in 1915c and 1115 community-based care waivers be treated as full Medicaid dual eligibles.

Part 423.773
While all dual-eligible individuals and SSI beneficiaries will be eligible for the full low-income subsidy without regard to income and resources, co-payment subsidies for these individual will vary depending on their institutional status and income. Institutionalized full-benefit dual eligibles pay no co-payments. The definition of ?institutionalized? in Part 423.772 excludes waiver program individuals, resulting in waiver program clients paying co-payments. Waiver program clients also participate in the cost of their services. Their participation is reduced by the cost of their medical expenses and since the co-payments are considered a medical expense, the client?s participation will have to be adjusted regularly. This will create a significant workload for the Medicaid agencies. We recommend changing the definition of ?institutionalized individual? to include clients receiving waiver program services since they already have to participate in the cost of their care.

CMS-4068-P-1270-Attach-1.doc

CMS-4068-P-1270-Attach-1.doc

CMS-4068-P-1270-Attach-1.doc

CMS-4068-P-1270-Attach-1.doc

CMS-4068-P-1270-Attach-1.doc

CMS-4068-P-1271

Submitter : Mrs. Mary Ninos **Date & Time:** 10/04/2004 08:10:51

Organization : Coventry Health Care

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached Word document

CMS-4068-P-1271-Attach-1.doc

CMS-4068-P-1272

Submitter : Ms. Julie Ward **Date & Time:** 10/04/2004 08:10:22

Organization : United Cerebral Palsy

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter from United Cerebral Palsy regarding the Medicare Prescription Drug Benefit regulations.

CMS-4068-P-1272-Attach-1.doc

CMS-4068-P-1273

Submitter : **Date & Time:** 10/04/2004 08:10:11

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Pharmacy Access Standards: Patient autonomy in choosing healthcare services is a defining characteristic that pharmacists ethically respect when it comes to interacting with our patients. Thus, allowing patients to have fair access to the pharmacy and pharmacy services of their choice is crucial to upholding the patient-pharmacist relationship.

Level Playing Field: While mail order pharmacies do provide some advantages at this time for patients in obtaining their prescription medications, it is important to again consider that it is the patient?s choice in determining which services they would prefer, whether this is thru mail order or thru the traditional retail setting. Face-to-face interactions with patients are essential in developing and furthering the patient-pharmacist relationship. This relationship is the key to the patient care focus of the pharmacy profession.

Medication Therapy Management (MTM) Program: While it is feasible that plans inform providers which patients are eligible for MTM, it can be foreseen that eligibility requirements for MTM may not always allow likely targeted beneficiaries to be selected for eligibility. For example, requirements for eligibility should not deny access to any patient desiring participation in a medication therapy management program due to income or access requirements. While it may not be as feasible to allow access to all individuals who have a need for these services, it should be considered that baseline MTM services are likely to be necessary for many patients, and then follow-up MTM services may be required with discretion to meet the providers? goals for patient outcomes. For example, all patients could have access to baseline MTM services, and further services could be made available based on the plan?s coverage criteria and limitations.

E-Prescribing Incentives: As a student pharmacist, I feel that there are several incentives as to why e-prescribing could be considered a positive widespread initiative within the pharmacy profession. First and foremost, the initiative decreases medication errors in the prescribing and dispensing processes. This initiative also allows for greater accuracy in physician verification and increased awareness about generic prescribing opportunities. Also, access to formulary tier information would prove to be very valuable to all healthcare professionals who depend on access to information about formularies. This includes retail pharmacists, who on a day-to-day basis field many questions from patients related to their prescription drug coverage.

CMS-4068-P-1274

Submitter : Mr. David Viele **Date & Time:** 10/04/2004 08:10:58

Organization : First Health Services Corporation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4068-P-1275

Submitter : Mr. Charles Fallis **Date & Time:** 10/04/2004 09:10:27

Organization : National Association of Retired Federal Employees

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

BACKGROUND

The nearly 400,000 members of the National Association of Retired Federal Employees (NARFE) have significant concerns regarding a broad range of policies and issues presented in the proposed regulations to implement Medicare Part D, the Medicare prescription drug benefit in 69 Federal Register 46632 (August 3, 2004) (File Code CMS-4068-P). We are writing to highlight several critically important areas, which we feel deserve particular attention.

BENEFITS AND BENEFICIARY PROTECTIONS

Qualified prescription drug coverage: We recommend that the final rule define ?person? so that family members can pay for covered Part D cost sharing.

Treatment of Health Savings Accounts (HSAs) as group health plans: We recommend that the final rule clearly state that health saving accounts (HSAs) meet the definition of employment-based retiree health coverage in Sec. 1860D-22 and the ?insurance or otherwise? provision in Sec. 1860D-24 of the MMA. The law precludes contributions from employer sponsored health plans from being counted as incurred costs and counting toward the deductible or out of pocket limit. We do not believe that contributions from one employer-sponsored benefit should receive differential treatment over contributions from another type of employer-sponsored benefit. Therefore, the final rule must not preferentially treat contributions from HSAs and Health Reimbursement Accounts (HRAs) by counting them as incurred costs when contributions from employer-sponsored group health coverage are not counted as an incurred cost.
Establishing limits on tiered copayments: We strongly oppose the provision in the proposed rule that permits Part D plans to ?apply tiered co-payments without limit?. The final rule must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs.

The MMA permits tiered cost sharing so that Part D plans are permitted to incentivize the use of preferred drugs within a class, when it is clinically appropriate. By placing no limits on the use of tiered cost-sharing, the proposed rule undermines the balance achieved by the Congress between permitting plans to use formularies with numerous provisions (including the Pharmacy and Therapeutics (P&T) committee requirements and the exceptions process) that seek to ensure that individuals receive all of the covered Part D drugs they need when medically necessary.

The absence of reasonable limits on cost-sharing tiers combined with an inadequate and unworkable exceptions process would provide Medicare Part D enrollees with a catch-22. Permitting unlimited cost-sharing tiers could permit a Part D plan to effectively bar access to clinically necessary covered Part D drugs because cost-sharing is unaffordable and the exceptions process does not include adequate safeguards or standards to ensure a fair review of an individual?s request for an exception to a Part D plan?s non-preferred cost-sharing. Moreover, allowing plans unlimited flexibility in establishing cost-sharing tiers increases their opportunity to discriminate against people who need costly medications or who need multiple medications. We also believe that permitting multiple cost-sharing tiers will greatly complicate the ability of CMS to determine actuarial equivalence and to determine that the design of a plan does not substantially discourage enrollment by certain eligible Part D eligible individuals under the plan. We also note that, in 2004, 85 percent of private sector plans that use tiered cost sharing had only two or three tiers, (Employer Health Benefits, 2004, Annual Survey, Kaiser Family Foundation and Health Research and Educational Trust, 2004).

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Employer Retiree Subsidy

Allowable retiree costs: In considering allowable costs for a qualified retiree prescription drug plan, CMS must apply a test that considers only an employer?s financial contribution to retiree prescription drug coverage, net of any payments by the retiree.

In addition, to be consistent with the requirements of the law under Section 1860 D?22 and CMS?s own stated goal (69 Federal Register 46741,

August 3, 2004), CMS must require the employer?s contribution to be at least as generous as the net value of the standard Medicare Part D benefit (i.e., the expected amount of paid claims under Medicare Part D minus beneficiary premiums).

Furthermore, as the Preamble discussion makes clear (p. 46736ff), accounting for retiree costs eligible for the subsidy will be a difficult accounting problem that may be subject to confusion or abuse. We believe one of the best ways to ensure a fair and equitable use of the subsidy amounts is to make the information on employer costs and reimbursements from Medicare public data which employee organizations and advocates can monitor.

Actuarial Attestation: CMS has proposed the use of random audits to ensure qualifying employment-based retiree prescription drug plans meet the actuarial equivalence test. However, we suggest that CMS take additional protections against improper payment of the federal subsidy. In order to help accomplish that, the attestation submitted by employers must include information on the assumptions that are the basis for the valuation of the plan for purposes of determining actuarial equivalence. This information must be available for public inspection.

Late enrollment penalties: The appropriate regulation should make it clear that employees should be held harmless from late enrollment penalties in the event that a retiree plan is discovered to have been in violation of creditable coverage due to an error or misrepresentation of the value of a retiree plan.

Payment methods, including provision of necessary information: The information required to be submitted to ensure accurate subsidy payments should include information on how actual spending compares to projected spending (submitted as basis for actuarial equivalence attestation). Such information should be available for public inspection.

Appeals: To provide further protection against improper payment of the employer subsidy, third parties (such as employee and retiree organizations or other advocates) should be granted the right to appeal a CMS determination regarding the actuarial equivalence of an employer?s retiree prescription drug plan.

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Basic alternative benefit designs that go beyond actuarially equivalent standard coverage: We are strongly opposed to the provisions of Section 423.104(g). We recommend that the final rule exclude provisions for ?enhanced alternative coverage?. The MMA provides for standard prescription drug coverage and alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices.

We believe that the proposed provisions at Section 423.104(g) exceed the authority of the statute and defeat the purpose of the Act, which is to provide meaningful choice of prescription drug plans by eligible Part D beneficiaries. The different options make it virtually impossible to compare plans, and thus make it nearly impossible for older people and people with disabilities to make an informed choice of private plan options. See, for example, Geraldine Dallek, Consumer Protection Issues Raised by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Kaiser Family Foundation, July 2004.

Further, a 2001 study found that ?elderly consumers have much more difficulty accurately using comparative information to inform health plan choice than nonelderly consumers have,? (Judith H. Hibbard and others, ?Is the Informed-Choice Policy Approach Appropriate for Medicare Beneficiaries??, Health Affairs, May/June 2001, Vol. 20, number 3; 199-203). The authors state that, ?given the population-related differences we observed, moving Medicare in the direction of mirroring the market approach used for the under sixty-five population may not be feasible or desirable.? Given that the MMA adopts a consumer choice model, it is imperative that the final rule ensure that elderly beneficiaries and people with disabilities have access to plans with benefit designs that are sufficiently standardized to permit an objective comparison among plan options.

Access to negotiated prices when the beneficiary is responsible for 100 percent cost sharing: We strongly oppose allowing any plan to impose 100 percent cost sharing for any drug. Such cost sharing should be considered as per se discrimination against the group or groups of individuals who require that prescription.

Further, the purpose of the drug benefit is to provide assistance with the high cost of prescription drugs. Therefore, the final rule should require plans to pass along all of their negotiated savings to beneficiaries.

Counting purchases of on-formulary covered Part D drugs as incurred costs: We strongly recommend that the final rule ensure that all beneficiary costs used for the purchase of covered Part D drugs count as incurred costs, including any costs incurred by individuals to purchase a covered Part D drug that is on the plan?s formulary, which has been prescribed by a physician, but which has been denied coverage by the Part D plan.

Requiring PDP sponsors and MA organizations to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call centers: We believe that it is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center. The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program. This is a critical requirement that must be included in the final rule.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Late Enrollment Penalty: We urge CMS to delay implementation of Section 423.46 for all enrollees for two years. The drug benefit is a new program and particularly complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. We see from the Medicare-endorsed prescription drug discount card that, even with significant outreach, the majority of individuals eligible for the low-income subsidy have not yet taken advantage of the $600 subsidy available to them.

We disagree with CMS' observation that healthy beneficiaries will not apply; we believe that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness and cognitive disabilities. The Medicare Part D program is new and confusing. Indeed, people delayed enrollment in the Medicare drug card because they did not understand the program and found the choices overwhelming. Many Medicare beneficiaries will need more than 6 months to understand the program, understand how Part D coordinates with other drug coverage they may have, and then to choose the drug plan that is right for them. During the initial implementation process, people should not be penalized because of the complexity of the program.

Until such time as beneficiaries become familiar with the program, they should not be penalized because of its complications.

Outreach and funding the State Health Insurance Assistance Programs (SHIPs). The preamble references concerns with outreach and enrollment. An extensive network of local, face-to-face counseling services will be needed. The toll free phone number and literature alone will not be adequate.

SHIPs, Area Agencies on Aging (AAA), and other local groups can provide the kind of detailed help needed, but they need additional resources. We believe that the SHIPs and AAAs, and related local counseling services are woefully under-funded. Current funding for SHIPs, even after the much-needed and welcome increases announced this spring, are about 50 to 75 cents per year per beneficiary. This is barely enough for 2 mailings per year, let alone the highly labor intensive one-on-counseling that is needed. The Senate-passed version of the MMA had originally proposed $1 per beneficiary for the SHIPs, but unfortunately that was deleted in the final law. We urge that SHIP/AAA funding be increased further.

Approval of marketing material and enrollment: The marketing rules for the Prescription Drug Plans (PDPs) and Medicare-Advantage (MA)-PDPs should be developed in the historical context of other Medicare programs. From selective marketing to outright fraud, Medicare programs historically have been afflicted with marketing abuses and scams. We urge that CMS be vigilant to identify and prohibit these problematic areas and practices as it develops final regulations.

Procedures to determine and document creditable status of prescription drug coverage: It is absolutely essential that beneficiaries understand whether or not they have creditable coverage. Failure to understand the issue of creditable coverage can lead to a lifetime of higher Part D premiums.

CMS must set forth specific requirements that plans provide information to Medicare beneficiaries enrolled in those plans clearly stating whether or not the coverage they have is creditable.

GENERAL PROVISIONS

We believe that the legislation and regulations should make no Medicare beneficiary worse off than they would have been without this law. The Medicare Moderization Act (MMA) should be a means to improve the quality and quantity of care provided to its constituencies. To ensure that our primary goals are met, we ask the Secretary to institute a second round of comments before promulgating final regulations. The proposed regulations contain many substantive areas about which the Centers for Medicare and Medicaid Services (CMS) seeks broad guidance and for which the agency?s proposal expresses several optional approaches. We find it difficult to imagine that the regulations as proposed will be ready for implementation without a second comment period to follow any CMS revisions that are made.

SUBMISSION OF BIDS, PREMIUMS AND RELATED INFORMATION, AND PLAN APPROVAL

Explanation Of Benefits: We support the inclusion in the final rule of provisions in the proposed rule regarding elements of the explanation of benefits. These elements, however, must be supplemented by:

? Appeals rights and processes: Information about relevant requirements for accessing the exceptions process, the grievance process, and the appeals process.

? Access to formulary information: Plans should be required to provide information to all Part D eligible individuals, and not just plan enrollees, about the plan formulary. Moreover, while we are supportive of the provision in the proposed rule that requires plans to make available access to the plan?s formulary, in isolation, that is insufficient. Beneficiaries need precise and detailed information about the formulary both to make an informed choice about enrollment and then to minimize their out-of-pocket costs once enrolled in a plan. Simply giving beneficiaries a description of how they can obtain information about the formulary is insufficient to further the goals of the statute. Plan descriptions should include a detailed formulary, listing not only all the drugs but the tier and amount of co-payment upon which each drug is placed, especially if plans will be allowed to require beneficiaries to pay 100 percent of the cost of certain formulary drugs.

? Plan terminations: 423.128(c)(iii) requires plans to tell all Part D eligible individuals that the part D plan has the right to terminate or not renew its contract, but only if the individuals request this information. Information about the potential for contract termination needs to be included in all plan descriptions and in all marketing materials, and not just if requested by an enrollee or Part D eligible individual. Based upon experience with the Medicare+Choice (M+C) market, the drug plan market will experience volatility that results in adverse consequences to many beneficiaries. The Medicare+Choice model summary of benefits requires this information to be in the summary of benefits and in the evidence of coverage; the same rule should apply for Part D.

Requiring that an explanation of benefits be provided at least monthly for individuals utilizing their prescription drug benefits in a given month: We recommend that the final rule retain the provision that requires an explanation of benefits be provided at least monthly for individuals utilizing their prescription drug benefits in a given month. The explanation of benefits should include the drugs the plan paid for, the beneficiary cost sharing, whether the deductible has been met, and how much remains to be met in out-of-pocket costs before stop-loss coverage begins. The notice should also tell people how to appeal or to request an exception.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

The grievance and appeals sections need to be simplified and improved. They weaken constitutionally protected rights for all Medicare beneficiaries. As drafted, the time frames for every step of the process is too long. The proposed regulations do not provide adequate and timely, constitutionally required notice, and they do not adequately provide for emergency supplies of medicines while an individual is appealing. Many events (such as a change in formulary) that can harm beneficiaries do not appear to be appealable. CMS should set the criteria plans must use for evaluating requests for exceptions, and not leave the standards to each individual plan. As drafted, the proposed rule sets an impossibly high requirement for receiving an exception to cover non-formulary drug or to provide a formulary drug at a lower tiered cost sharing.

CMS-4068-P-1275-Attach-1.doc

CMS-4068-P-1275-Attach-1.doc

CMS-4068-P-1275-Attach-1.doc

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CMS-4068-P-1275-Attach-1.doc

CMS-4068-P-1275-Attach-1.doc

CMS-4068-P-1276

Submitter : Tim Palmer **Date & Time:** 10/04/2004 08:10:14

Organization : Kings Daughters Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As a pharmacist of Kings Daughters Hospital Home Infusion in Madison Indiana, I am pleased to submit my comments on the proposed rule to implement the new medicare part D prescription drug benefit. Being a small town infusion provider I find myself being both the pharmacist and the billing clerk for our company and therefor have a great appreciation for the daunting task that CMS confronts in implementing this benefit. I applaud CMS for recoginizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system. The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients homes but the essential services, supplies and equipment that are intergral to the provision of home infusion therapy (dispnesing fee option 3 as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans. At that point, Medicare will finally be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

My experience leads me to believe that dispensing fee option 3 is the only proposed option that will enabel Medicare beneficiaries to receive home infuison therapy under the Part D benefit. CMS should follow the well established home infusion per diem model encoded using the national hcpcs S codes. If implemented properly this model will ensure access and avoid duplication of services just as it does in the private payer sector.

Thank you in advance for your consideration
Sincerely,

Tim Palmer R.Ph.
Kings Daughters Hospital Home Infusion
1 KDH Drive
Madison, IN 47250
(812)265-0670 ext 224
PalmerT@kdhhs.org

CMS-4068-P-1277

Submitter : Mr. Paul Tibbits Jr **Date & Time:** 10/04/2004 08:10:52

Organization : American Diabetes Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4068-P-1277-Attach-1.doc

CMS-4068-P-1278

Submitter : **Ms. Elizabeth Blackston** **Date & Time:** **10/04/2004 08:10:46**

Organization : **Office of the Illinois Attorney General**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Marketing

CMS-4068-P-1278-Attach-1.doc

CMS-4068-P-1279

Submitter : Ms. Lynne Gross **Date & Time:** 10/04/2004 08:10:05

Organization : Anthem Blue Cross and Blue Shield

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached comment letter

CMS-4068-P-1279-Attach-1.pdf

Submitter : Mr. Steven Hitov **Date & Time:** 10/04/2004 08:10:40

Organization : National Health Law Program Inc

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See comments on Subpart M attached.

Submitter : Mr. Amar Vyas **Date & Time:** 10/04/2004 08:10:38

Organization : Mr. Amar Vyas

Category : Academic

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plana??s overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy.

I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. This will adversely affect a pharmacista??s ability to continue to serve patients. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congressa?? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Congress wanted to ensure that patients could continue to use the pharmacy and pharmacist of their choice. Requiring plans to provide patients fair access to their pharmacy was a promise made by Congress that CMS should honor. That will help patients access a local pharmacy for their full benefit. a??Accessa?? isna??t a??accessa?? if patients are forced to use other pharmacies.

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

The Medication Therapy Management MTM) services may prove to be the most significant provision. It has the potential to improve the quality, and to reduce the cost of drug therapy for Medicare.
The current pharmacy education system is preparing pharmacists who capable of performing this role. Additionally, Continuing Education programs have been available to pharmacists to update and prepare them to perform this role. Since this provision has the potential to set the standards for MTM services for other plans, it is important that the program is carried out correctly. It is my concern that leaving the decision of who can provide MTM to the plans may allow plans to choose less qualified
providers to provide MTM services. There are several models, such as the NC Polypharmacy Project in nursing homes which reveal that pharmacists do MTM well, so I urge you to encourage plans to use pharmacists unless they have documented evidence that their alternative approach works as well as having that service provided by a pharmacist.
Many North Carolina pharmacists are providing MTM services in their practice that meet the MTM Services Definition and Program Criteria approved July 27, 2004 by eleven supporting organization in pharmacy. Based on our experience in the Asheville Project, face-to-face interaction between the patient and the provider So we urge CMS to require face-to-face interaction for MTM Services, at least for the initial visit.

Some other concerns to help make this program work appropriately:
Plans must be required to inform beneficiaries when they are eligible for MTMS and inform them about their choices (including their local pharmacy) for obtaining MTMS.
Once a beneficiary becomes eligible for MTMS, the beneficiary should remain eligible for MTMS for the entire year.
CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries.
Pharmacists should be allowed to provide MTMS to non-targeted beneficiaries. Since MTMS is not a covered benefit for nontargeted beneficiaries, pharmacists should be able to bill patients directly for the services.
Plans must be required to pay the same fee for MTMS to all providers. For example, plans should be prohibited from paying pharmacists at non-preferred pharmacies less than pharmacists at preferred pharmacies for the same service.
CMS must carefully evaluate each plana??s application to provide an MTM benefit. CMS must examine whether the fee the plan proposes to pay for the MTM services is high enough to entice pharmacists to provide MTMS.

In conclusion, I urge CMS to revise the regulation: to require plans to meet the TRICARE requirements at the local level; to not allow a plan to have both preferred and non-preferred providers; to only allow price differentials for providing an extended drug supply based on cost of service and not on the differentials in drug costs; require MTMS to be performed by pharmacists unless a plan has evidence their approach works as well as a pharmacist providing MTMS; make sure the proposed payment for MTMS is adequate to encourage pharmacistsa?? participation.

Submitter : Melanie Bella **Date & Time:** 10/04/2004 09:10:53

Organization : Indiana - Medicaid Policy and Planning

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Indiana Medicaid and the State Children?s Health Insurance Program (SCHIP) combined provide comprehensive drug coverage to approximately 784,000 individuals. Of those 784,000 enrollees, approximately 93,000 are full benefit dual eligibles as of June 1, 2004.

In addition to Medicaid and CHIP, Indiana also operates a State Pharmaceutical Assistance Program (SPAP), called HoosierRx. HoosierRx provides financial assistance to seniors up to 135% of the federal poverty level. Current enrollment in HoosierRx is approximately 22,800 individuals. Unlike the new Medicare Part D benefit, HoosierRx has no asset test. We support the requirement that the new Medicare Prescription Drug Plans (PDPs) and Medicare Advantage drug plans (MA-PDPs) coordinate with SPAPs but are concerned about CMS? interpretation of the antidiscrimination language in the law at Sec. 1860D-23(b)(2), which would preclude the use of a preferred PDP.

A significant area of concern to us is the transition of dual eligibles to a PDP or MA-PDP and the potential for a gap in coverage between the effective date of Medicare Part D (January 1, 2006) and the time it takes for a dual eligible individual to either choose a plan or to be auto-enrolled (which will not occur until May 2006). This is a vulnerable population and extra care must be taken to ensure they experience no gap in coverage once Medicaid pharmacy benefits end on January 1, 2006.

We recommend that CMS allow for temporary Medicaid coverage via a continuation of federal financial participation until an individual has either voluntarily chosen a plan or has been auto-enrolled into a plan. We realize CMS may be constrained by the law in this area and would urge CMS to seek modification of the law in this area for the dual eligibles. The negative clinical and financial ramifications of a gap in coverage provide ample rationale for seeking statutory change in this area.

Another major area of concern is the cost of the Medicare Modernization Act (MMA) to states. We are particularly concerned that the ?phasedown state contribution? may not fully recognize the aggressive cost containment measures enacted by states in recent years. While congressional intent was to phase down state contributions, by using a growth factor that overstates cost increases and a rebate number that may not reflect current rebate collection levels, states will likely pay more rather than less for prescription drug coverage for dual eligibles under Medicare Part D. In addition, states, such as Indiana, who receive supplemental rebates, will see a substantial part of their leverage taken away when the dual benefit covered lives leave the Medicaid program (even though the majority of their costs remain through the phasedown), which will result in lower rebates for the states. We urge CMS to exercise the flexibility in the statute to use the most appropriate growth factor that actually is representative of Medicaid program prescription drug cost increases.

States will also incur costs through the administrative functions they are required to assume. And, those costs may increase if CMS requires states to develop a completely separate process for determining eligibility for the low-income subsidy, an issue we will address in greater detail in the comments that follow. Additionally, while we support enrolling those individuals eligible for Medicare cost sharing, it will result in an increase in dual eligible individuals, which will result in additional increased expenditures for states. Lastly, we are concerned that CMS/HHS will not be directly negotiating prescription drug prices for Part D. This, combined with the fact that prices will not be subject to Medicaid best price, leaves states exposed to higher costs that otherwise might be reduced.

Medicare Part D leaves states in the undesirable position of having no control over the spending or management of the benefit yet responsible for the costs.

CMS-4068-P-1282-Attach-1.pdf

CMS-4068-P-1283

Submitter : Ruchi Twiari **Date & Time:** 10/04/2004 08:10:45

Organization : UNC- Chapel Hill

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

RE: CMS-4068-P

Dear Sir or Madam:

I would like thank you for accepting comments in behalf of the MTMS regulations and ask you to consider a perspective on behalf of a future pharmacist and my concerns with the proper implementation of this regulation.

Subpart C: Benefits and Beneficiary Protections

The TRICARE retail pharmacy access standards should be amended to propose that only pharmacies that are on the preferred plan should meet the access requirements.
The current access regulations include preferred pharmacy and non-preferred pharmacies; this presents a burden on beneficiaries and compromises effective therapeutic management.
Beneficiaries should be allowed fair access to all pharmacies. This coerced method of providing care takes away the patient's choice of receiving care from a pharmacist they have previously built a personal and confidential relationship with. Patients should have the option to choose a convenient pharmacy.
Forcing patients to travel distances to receive MTMS will affect patient?s behavior by resulting in an increased disregard of their own therapeutic care as a result of frustrations of traveling inconvenience. Patients will arrive to pharmacies irritated and reluctant to spend adequate time engaged in an active MTMS session with the pharmacist.
The current access requirements also place less incentive for proper contracts with pharmacies. I am afraid many pharmacies will be left out of the plan?s pharmacy network. This compromises and excludes the level of service many pharmacists can provide to this patient population.

Subpart D: Cost Control & Quality Improvement Requirements for
Prescription Drug Plans

Medication Management Services

After four years of graduate training for a Doctor of Pharmacy degree, I will become a drug expert on therapeutic medication management. Four years of training in multiple chronic and acute disease states has prepared pharmacists to make effective therapeutic decisions. With extensive preparation we are competent in providing the following services:

? Patient health assessment
? Creating medication treatment plans
? Managing high-cost ?specialty? medications
? Monitoring response to drug therapy
? Monitoring and adjusting for drug interactions
? Educating and training patients on disease states
? Educating patients on medications related concerns such as proper administration, side-effects, contraindications, precautions, monitoring parameters, etc.
? Managing special patient populations ie. children, pregnant females, geriatric

The great thing about implementing pharmacists as primary providers of MTMS is they have the knowledge to manage a great array of chronic conditions which present in one patient. The average Medicaid/Medicare patient is on 8 prescription drugs. We have the ability to decrease duplications/poly-therapy, thus decreasing costs and providing MTMS in one step. Pharmacists along with therapeutic knowledge have the insight of the remarkably increasing drug costs and the specifics of optimizing the use of an agent that is cost effective yet does not sacrifice efficacy.

If pharmacists were not permitted to be the primary providers of MTMS our education would be a waste of time. Please do not take this opportunity away from us. Medication therapy management is the prime focus of our education and this is the first hope for a shift in our role in the current health-care system to one that is more representative of our training/abilities.

In the hospital system, pharmacists continue to prove their effectiveness and value to America?s current health care system. Clinical trials and studies continue to prove that the approach of integrating a pharmacist on a team of health care professionals, to provide patient care has and continues to reduce costs, reduce adverse

CMS-4068-P-1284

Submitter : Mr. Timothy Schuerch **Date & Time:** 10/04/2004 08:10:07

Organization : Alaska Native Tribal Health Consortium

Category : Hospital

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

Please see attached comments in MS Word

CMS-4068-P-1284-Attach-1.doc

Submitter : Mr. Russ McDaid **Date & Time:** 10/04/2004 09:10:36

Organization : PANPHA

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

The following comments on the Centers for Medicare and Medicaid Services proposed rule, ?Medicare Program; Medicare Prescription Drug Benefit?, file code CMS-4068-P, are provided by PANPHA, an association of more than 300 Pennsylvania non-profit senior service providers. PANPHA?s members provide nursing homes, personal care homes (also known as ?assisted living?), continuing care retirement communities, and housing.

Section 423.124(a)(2) Of primary concern is the implementation of the prescription benefit for residents of nursing facilities. We recommend allowing several models to be tested prior to implementing the regulation, including allowing LTC pharmacies to function as ?out-of-network? pharmacies, encouraging PDPs and MA-PDs to contract with LTC pharmacies, as discussed in the regulation summary, as well as other models that may be proposed by other commentors.

As regulations are implemented and our members work through them, we will provide additional comments. Thank you for this opportunity to comment.

Sincerely,

W. Russell McDaid
VP/Chief Public Policy Officer
russ@panpha.org

CMS-4068-P-1286

Submitter : Mr. Leonard S. Holman, Jr., R.Ph. **Date & Time:** 10/04/2004 08:10:25

Organization : Option Care of Northeast Ohio

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see comments in attached word document.

CMS-4068-P-1286-Attach-1.doc

CMS-4068-P-1287

Submitter : Mrs. Ann Berkey **Date & Time:** 10/04/2004 09:10:11

Organization : McKesson Corporation

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

On behalf of McKesson Corporation, I am pleased to submit comments regarding the proposed rule to create the new Medicare Prescription Drug Benefit.

CMS-4068-P-1287-Attach-1.doc

CMS-4068-P-1288

Submitter : Thomas Boudreau **Date & Time:** 10/04/2004 09:10:58

Organization : Express Scripts, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Comment on Title I - Prescription Drug Programs

CMS-4068-P-1288-Attach-1.doc

CMS-4068-P-1289

Submitter : Ms. Kathleen Jaeger **Date & Time:** 10/04/2004 09:10:07

Organization : Generic Pharmaceutical Association

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

CMS-4068-P-1290

Submitter : Deanne Birch **Date & Time:** 10/04/2004 09:10:31

Organization : Region D DAC - IV A Team

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4068-P-1290-Attach-1.doc

CMS-4068-P-1291

Submitter : sirotkin **Date & Time:** 10/04/2004 09:10:27

Organization : community of Vermont eders

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

see attached document- your first address failed

CMS-4068-P-1291-Attach-2.doc

CMS-4068-P-1291-Attach-1.doc

CMS-4068-P-1292

Submitter : Valrie Wilbur **Date & Time:** 10/04/2004 09:10:25

Organization : Medicare Policy Coalition

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

National Health Policy Group

Improving Payment and Performance for High-Risk Beneficiaries

October 4, 2004

Center for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

ATTENTION: CMS - 4068- P

Dear Sirs:

The National Health Policy Group appreciates the opportunity to submit comments on the Notice for Proposed Rule Making, which will establish requirements for the Medicare Prescription Drug Program, on behalf of the Medicare Policy Coalition for High Risk Beneficiaries (MPC).

The Medicare Policy Coalition is an alliance of Medicare Advantage Plans and providers that have made a unique commitment to serving high-risk beneficiaries such as the frail elderly and adult disabled. MPC members have a strong interest in the Special Needs Plan designation and other aspects of the Medicare Advantage proposed rule affecting high-risk Medicare beneficiaries as they all currently offer special programs of care for these beneficiaries, many under Medicare demonstrations. Special Needs Plans offer a potential vehicle for the demonstrations to transition to permanent plan status and for non-demonstrations to intensify their focus on targeted beneficiary groups. They also provide a vehicle for more traditional plans and provider networks to develop a specialization in serving special needs beneficiaries.

Thank you for your consideration of our views on the implementation of the Medicare Modernization Act of 2003. If you have any questions regarding the attached comments, please do not hesitate to contact us at 202-264-1508.

Sincerely,

Richard J. Bringewatt Valerie S. Wilbur
President Vice President
Chair, Medicare Policy Coalition Co-chair, Medicare Policy Coalition

801 Pennsylvania Avenue, Suite 245, Washington DC 20004 (202) 624-1516 Fax: (202) 737-6462 www.nhpg.org

CMS-4068-P-1293

Submitter : Mr. Raj Rai **Date & Time:** 10/04/2004 09:10:32

Organization : Option Care, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Pls see attached comments

CMS-4068-P-1293-Attach-1.doc

CMS-4068-P-1294

Submitter : Ms. Collin Conway **Date & Time:** 10/04/2004 09:10:46

Organization : student pharmacist

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

As a future pharmacist, Medication Therapy Management will be an exciting part of my practice. The training and education we receive as students make us well trained to provide pharmacy services to elderly patients with multiple chronic disease states.

A couple comments as follows: 1) it would be wonderful if plan providers provided up to date information on patients to all people on the health care team (patient and pharmcist) who are eligible for these services so that we may inform them if they qualify 2) once a patient becomes eligible for services, they should qualitfy for one year so that we may maintain a relationship and allow us to work together to manage their drug therapy

Thank you so much for your consideration of these comments and I look forward to helping my patients in the future. Thank you

CMS-4068-P-1295

Submitter : Mr. Benjamin Loy **Date & Time:** 10/04/2004 09:10:01

Organization : PDX-NHIN-Rx.com

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P Baltimore, MD 21244-8014

Re: CMS-4068-P

Dear Sir or Madam:

PDX, Inc. appreciates the opportunity to submit written comments to the Department of Health and Human Services (HHS) concerning the impact on our companies and our retail pharmacy customers of the proposed HIPAA Privacy Rule changes.

PDX, Inc., a major provider of retail pharmacy software to retail pharmacy, was established in 1985 in Granbury, Texas and was preceded by pc1, Inc., a software application provider primarily directed toward independent pharmacies. PDX is the most widely distributed single code-based pharmacy application used in North America. PDX and its affiliated companies provide pharmacy technology to a customer base of approximately 1,000 independent pharmacies and over 60 chains comprising an additional 9,000 chain pharmacies. PDX has software installations in all 50 states, District of Columbia, Puerto Rico, the U.S. Virgin Islands and most of the provinces of Canada. As such, PDX has a good understanding of the technology issues facing the retail pharmacy industry.

Our comments are provided in an effort to assist HHS in making the implementation of Medicare Part D, the most significant health initiative of recent history, as successful as possible.

Subpart B?Eligibility and Enrollment.
The preamble states that CMS is considering the establishment of the Medicare beneficiary eligibility and other coverage query system using the HIPAA 270/271 eligibility query. Information collected under this section for the purpose of TrOOP application would be available to be queried by pharmacies to facilitate proper billing.

However, since a significant number, if not the majority, of the providers under the Plan D program will be retail pharmacies it is only reasonable that these entities be allowed to use the eligibility standard to which they are accustomed and that is consistent with the HIPAA Final Transactions and Code Sets Rule.

? 162.1202 Standards for eligibility for a health plan.
The Secretary adopts the following standards for the eligibility for a health plan transaction:
(a) Retail pharmacy drugs. The NCPDP Telecommunication Standard Implementation Guide, Version 5 Release 1, September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1 Release 0, February 1, 1996. The implementation specifications are available at the addresses specified in ? 162.920(a)(2).

Therefore, we request that CMS include support for the NCPDP on-line real-time eligibility transaction contained in NCPDP Telecommunication Standard Version 5 Release 1 as this is the most commonly used format for retail pharmacy and that a requirement for retail pharmacy to change to using the X12N-270/271 batch eligibility formats would impose a significant obstacle to the Medicare drug benefit program.

Sincerely,

Benjamin E. (Ben) Loy, R.Ph.
Sr. VP Inudstry Relations

PDX-NHIN-Rx.com

CMS-4068-P-1296

Submitter : Dr. Barbara Manard **Date & Time:** 10/04/2004 09:10:17

Organization : American Association Homes and Services for the Ag

Category : Long-term Care

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

SUBPART AGENERAL PROVISIONS

LTC residentsincluding those in hospital-based facilities--must be able to access LTC pharmacies without paying out of network prices that are higher than in network prices

The proposed rule recognizes that LTC facilities generally contract with specialized pharmacies (LTC pharmacies) that provide important services to LTC residents, enhancing safe pharmacy practices in LTC facilities. A critical question for design of the new Part D program is this: What happens if the LTC pharmacy contracted with by a resident?s LTC facility is not in the network of the enrollee?s Part D plan? In Subpart A, CMS gives four examples of situations when a plan will be required to all an enrollee to use a non-network pharmacy and includes the situation of the out of network LTC pharmacy used by a LTC resident.

AAHSA agrees with this formulation so long as it does not mean that LTC residents will be required to pay the higher prices frequently associated with out of network transactions. Plans must be explicitly prohibited from charging LTC residents out of network prices for using a LTC facility's LTC pharmacy when that pharmacy is not part of the plan's network.

Furthermore, since hospital-based LTC facilities typically get pharmacy services from the affiliated hospital's pharmacy, the definition of LTC pharmacy must be sufficiently inclusive so that residents/patients in hospital-based LTC facilities have the same access to pharmacy services (without paying out of network prices) as residents/patients of free-standing LTC facilities that contract with typical LTC pharmacies.

CMS-4068-P-1296-Attach-1.doc

CMS-4068-P-1296-Attach-2.doc

CMS-4068-P-1297

Submitter : Mr. David Viele **Date & Time:** 10/04/2004 09:10:18

Organization : First Health Serivces Corporation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attached comments

CMS-4068-P-1297-Attach-1.doc

CMS-4068-P-1298

Submitter : Ms. Liz Savage **Date & Time:** 10/04/2004 09:10:20

Organization : The Arc of the United States

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter from The Arc of the United States on the Medicare Prescription Drug Benefit

CMS-4068-P-1298-Attach-1.doc

Submitter : Mr. Thomas Arnold **Date & Time:** 10/04/2004 09:10:57

Organization : Agency for Health Care Administration

Category : State Government

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Definition of Long Term Care Facility

CMS is requesting comments regarding the definition of long-term care facilities. In section 423.100 of the proposed rule, long-term care facility is interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act; or a nursing facility as defined in section 1919(a) of the Act. The definition is limited to these two types because it is CMS? understanding that those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies. The definition does not include other long-term care facilities such as those for the developmentally disabled or mental health centers.

CMS expresses particular interest in whether other facilities such as intermediate care facilities for mentally retarded or related conditions (ICF/MRs), described in section 440.150 of the proposed rule, should be included explicitly in this definition. Many of these individuals are covered by both Medicare and Medicaid and will need continued access to drugs under Part D. We encourage CMS to consider ICF/MRs and other types of facilities that contract with long-term care pharmacies exclusively, in a manner similar to SNFs and other nursing facilities, in its definition of long-term care facilities.

Formularies

We applaud the intent to level the playing field with respect to mail order and community pharmacies by allowing 90-day supplies to be dispensed by both entities.

As provided under section 1860D-4-(b)(3)(c)(ii) of the Act, CMS has requested that the U.S. Pharmacopoeia (USP) develop a model set of guidelines that consist of a list of drug categories and classes that may be used by PDP sponsors and MA organizations to develop formularies for their qualified prescription drug coverage, including their therapeutic categories and classes. CMS expects that the model categories and classes developed by USP will be defined so that each includes at least two drugs approved by the FDA for the indications in the category or class. That is, no category or class would be created for which there is no FDA-approved drug, thus avoiding having to include a drug based on its off-label indication. It is likely, in some cases, that only two drugs will be included in a class. We believe that any established formulary exception criteria must be flexible enough to take into account the actual circumstances of particular recipients. MA-PDs and PDPs should be required to be flexible to accommodate individual recipients.

We would like to note that the AHSP therapeutic classification system is out of date for a number of therapeutic classes and needs to be updated. In addition, the requirement prohibiting any PD or MA PD from changing its therapeutic classification for a drug more than one time per year at the beginning of the plan year does not reflect the rapid changes in the pharmacologic knowledge base and therapeutic uses of many drugs.

Also, the prohibition against changing the cost-sharing tier of co-payment for specific drugs without providing 30-day advance notice to prescribers, pharmacies and enrollees may be counter-productive unless this notice can be made electronically. If mailed notices are required, the costs associated could easily exceed savings to the plan or to enrollees for many products. It is unclear whether the regulations anticipate web-posting as satisfactory notice or whether direct mailing would be required. The regulations may be contradictory in view of the ?at least weekly? update requirement in the following section, 423.128

We agree with the requirement that plans include cost utilization management, medication therapy management programs (MTMP) and fraud and abuse control programs. We feel the regulations should provide more guidance to plans in the structure and reimbursement for MTMPs and we applaud the effort to encourage electronic prescribing by

ELIGIBILITY, ELECTION, AND ENROLLMENT

The Florida Agency for Health Care Administration (AHCA) respectfully submits the following comments about the proposed rule on the Medicare

program and the Medicare prescription drug benefit. AHCA administers Florida's $14 billion Medicaid program and serves more than 2.2 million recipients annually. Nearly 460,000 of the state?s Medicaid recipients are also eligible for Medicare and account for more than $1 billion of the state?s prescription drug budget. This includes spending for approximately 55,000 recipients enrolled in the Silver SaveRx program, Florida?s Pharmacy Plus Program.

Florida?s dual eligibles, like seniors across the country, are expected to take advantage of the opportunity to gain coverage under the new Medicare Part D benefit. We applaud CMS for its efforts in addressing many of the issues that states and recipients will face when the benefit is implemented.

Enrollment

In accordance with Section 1860D-1(b)(1) of the MMA, CMS has proposed rules related to enrollment of Part D eligibles in prescription drug plans. Specifically, the rule proposes an enrollment process by which the state may randomly enroll full dual-eligible individuals who fail to select and enroll in a PDP or a MA-PD plan by a specified date. The process as proposed raises significant concerns and questions.

For full dual eligibles, the time frame allowed for initial enrollment runs from November 2005, through May 2006. This provision can be interpreted to mean that any individual who does not select a plan will be enrolled randomly in May 2006. There are several reasons why a recipient may fail to enroll in a PDP or MA-PD in a timely manner. One possibility is apprehension about relinquishing the familiar benefits available under Medicaid; another is uncertainty about subsidies, program design, and plan availability. Nonetheless, this interpretation, fails to consider the possible lapse in coverage a recipient could face between January 1, 2006, and the date on which he/she actively enrolls in a plan or is automatically enrolled in May. We understand that federal matching funds would no longer be available to state Medicaid agencies for this population after January 1, 2006; however, we are certain it is your intent to ensure that seniors have prescription coverage during this six-month period.

As an alternative we suggest allowing for a delay in enrollment or establishing a phased-in enrollment process for this population, during which time the states could continue to receive federal matching funds for providing prescription drug coverage. This would allow time for adequate outreach and education to ensure that recipients understand the program and the options available to them. Furthermore, it would help ensure that beneficiaries would not lose coverage for any period.

CMS is also seeking input on the appropriate entity to perform automatic and random enrollment functions. These functions include enrollment during initial and special enrollment periods, as well as tracking premium subsidy qualifications. Options include having enrollment conducted by CMS, the state, or a contracted entity. As a condition of state performance, CMS requires proper and efficient administration of the state plan. In the preamble, CMS recognizes that states will need accurate and timely Part D data to perform enrollment functions. We recommend that states have the option of performing automatic and random enrollment functions. CMS should also consider giving the states that choose to perform those functions full federal participation match rather than the administrative match.

Issues 11-20

SPECIAL RULES FOR STATES

Phased Down State Contribution

Under the proposed rule, states are required to contribute to the cost of the Medicare Part D drug benefit. The phased down state contribution is based on expenditures for covered Part D drugs during calendar year 2003 and adjusted by a growth factor in subsequent years. The growth factor will be based on increases in per capita expenditures for Part D drugs for Part D eligible individuals.

We have questions about the methodology with respect to values used in the base year. Specifically, the PDSC calculation includes rebates earned in the base year but collected in subsequent years. We would like clarification as to how CMS intends to account for rebates earned but not collected.

Moreover, we believe that states should be allowed to appeal CMS calculations of the PDSC amount. The preamble and other information suggest that CMS will attempt to arrive at a number that the state and CMS will agree on. This process is not spelled out, and we believe it should include an opportunity for states to dispute calculations that would result in a higher contribution.

CMS-4068-P-1299-Attach-1.doc

CMS-4068-P-1299-Attach-1.doc

CMS-4068-P-1299-Attach-1.doc

Submitter : Mrs. Mary Thompson **Date & Time:** 10/04/2004 09:10:24

Organization : YKHC

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-4068-P-1300-Attach-1.doc

CMS-4068-P-1202

Submitter : Ms. Mary Dewane **Date & Time:** 10/04/2004 08:10:20

Organization : Schaller Anderson

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached document

CMS-4068-P-1202-Attach-1.doc

Comments on 42 CFR (CMS-4068-P)

Subpart B-Eligibility. Election and Enrollment

This section invites comment on the auto-enrollment process for full benefit dual eligible individuals who do not select a MA-PD or PDP plan. We recommend that CMS consider auto-enrollment of full benefit dually eligible individuals who do not select an MA-PD or PDP plan into an MA Special Needs plan, if that plan currently provides prescription drug coverage under Medicaid to such individuals. This would help CMS maintain continuity of care and to minimize potential beneficiary disruption.

Subpart C-Benefits and Beneficiary Protections

Many dually eligible individuals have multiple chronic medical and behavioral health conditions. Adverse selection is a potential issue among MA Special Needs plans, as well as MA-PD or PDP plans that enroll large numbers of dual eligibles. MA Special Needs plans may have an incentive to structure their formularies to minimize enrollment of specific types of high needs dually eligible individuals. The proposed rule does not appear to establish any additional formulary requirements for MA Special Needs plans that provide prescription drug coverage. We recommend that CMS consider requiring MA Special Needs plans to provide more extensive coverage of certain types of prescription drugs than required for other MA-PD or PDP plans. In particular, CMS should consider mandating more extensive coverage of anti-retrovirals and mental health drugs. This may help to prevent some of the potential adverse selection that could occur through formulary design.

Subpart J-Coordination Under Part D with Other Prescription Drug Coverage and Coordination of Benefits

This section delineates the drug coverage under Part D with respect to coordination of benefits for drugs covered by other plans, including Medicaid. It states there are relatively limited applicability of coordination of benefits between Part D plans and State Medicaid programs because drugs that must be excluded from Medicare coverage are drugs that also may be excluded from Medicaid. Drugs such as benzodiazepines are frequently utilized in the Medicaid population; this coordination issue will result in a large number of medically necessary drugs that must be covered by State Medicaid plans. Additionally, coverage of Drugs under Part B must meet very strict approval criteria. According to Medicare guidelines, certain medical services, which are deemed reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, are, covered services. FDA approval is often one of the main criteria of Medicare's coverage guidelines for drugs and biologicals. However, in the case of chemotherapeutic agents, for example, FDA approval does not always keep pace with clinically indicated efficacy. Therefore, the need exists to address off-label drug uses, which have been validated by clinical trials.

Otherwise a large number of drugs potentially covered under Part B will fall on Part D plans. There is also the potential for "double-dipping" for drugs potentially covered under Part B and Part D. Ideally, Part B drug coverage should be eliminated altogether (with all drugs covered through Part D).

CMS-4068-P-1203

Submitter : Mr. Charles Thompson **Date & Time:** 10/04/2004 08:10:52

Organization : Med Four LLC

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Please see comments in attached word document

CMS-4068-P-1203-Attach-1.doc

Specialized Pharmaceutical Services for Chronic Disease Management

3555 Rutherford Road
Taylors, SC 29687

Phone: 864.370.3529
Fax: 864.235.4514

Med Four LLC is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Med Four is an independently owned home infusion company located in Taylors, SC just outside of Greenville, SC which has been servicing the home infusion needs of the Upstate South Carolina region since 1989.

Med Four appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

* Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm.

* CMS should establish specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require specific standards for home infusion pharmacies under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the X12N 837 P billing format for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should mandate that prescription drug plans maintain open formularies for infusion drugs to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Charles Thompson
President
Med Four LLC

CMS-4068-P-1204

Submitter : Mrs. Jody Horak **Date & Time:** 10/04/2004 08:10:52

Organization : Toledo IV Care

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Please see comment in attached word document.

CMS-4068-P-1205

Submitter : **Date & Time:** **10/04/2004 08:10:07**

Organization : **Illinois Campaign for Better Health Care**

Category : **Consumer Group**

Issue Areas/Comments

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

423.120 (b) P&T Committee Decisions should be binding

We strongly recommend that the final rule ensures that decisions made by a PDP?s P&T committee are considered binding. We feel that congress?s intentions in requiring P&T committees will be undermined if they are not empowered to make binding decisions and recommendations regarding proposed formularies. We also feel that decisions regarding cost-containment strategies, as they related to access to covered Part D Medications and formulary structures, should be subject to binding recommendations of the P&T committee. We fell that only with these provisions will beneficiaries be ensured access to the covered Part D medications as intended by congress.

423.120(b)(1) Regarding the independence of P&T committees

Although we support the intentions in the proposed rule to ensure the independence of P&T committees from PDP-sponsor influences, we feel that the provisions in the proposed rule are wholly inadequate. We strongly encourage the final rule to include the following provisions:

1. P&T committee members must not only be ?free and independent? of the PDP sponsor, but also of pharmaceutical manufacturers. This should be explicitly stated in the final rule.
2. Committee appointments should be public record, and CMS must be required to create a process whereby the ?independence? of a committee member can be challenged and reviewed.
3. All PDP sponsors should be explicitly required in the final rule to operate a P&T committee, regardless of whether they initially plan to have a formulary.
4. All P&T committee meetings should be public to encourage accountability. In addition, the minutes and decisions of P&T committees should be available upon request to beneficiaries and their advocates.
5. Because the proposed rules only required a numerical value for independent members but not for the size of the committee, a statistical majority of free and independent members needs to be required.
6. Regardless of the final requirements regarding independent membership, the final rules should stipulate that the free and independent members must be present at any given meeting in order to make a binding decision.
7. The final rule must not only encourage but require P&T committees to seek input from plan enrollees, or in initial decisions before January of 2006, from Part-D eligible beneficiaries within that plan?s service area, and specifically from within the most vulnerable populations: disabled individuals, those with rare or pharmacologically complex conditions, and beneficiaries over the age of 75.

This is not an exhaustive list of ways to strength the power and independence of P&T committees. We strongly urge CMS to consider additional and alternative provisions

BENEFITS AND BENEFICIARY PROTECTIONS

423.104 Definition of "person"

We recommend that the definition of "person" explicitly include family members, charities, and caretakers. Also, we encourage individuals who receive prescription medications through pharmaceutical manufacturer patient assistance programs be allowed to count these medications as ?incurred costs? consistent with the average cost of these medications through an individual?s PDP. Pharmaceutical manufacturer patient assistance programs provided medications only to individuals whom they certify, in conjunction with the treating physician, as not able to afford medications without assistance. Due to the nature of the vulnerable populations receiving this type of assistance, we feel that it is unfair to restrict their access to catastrophic coverage.

423.104 (e)(2)(ii) Limiting cost-sharing tiers

The proposed rules do not include a limit on tiered cost-sharing. We strongly encourage such a limit to be placed on the use of cost-sharing tiers. Also, applying different cost-sharing tiers to different classes of drugs would inherently discriminate against certain populations and we urge CMS to explicitly prohibit this as a valid cost-containment mechanism. We believe that unlimited cost-sharing tiers undermine Congress? stipulation for representation of every drug class within a formulary, and strongly oppose unlimited tiers. We suggest three cost-sharing tiers as an appropriate and acceptable limit to cost-sharing tiers.

On-formulary Drugs

We encourage the final rule to include all beneficiary expenses towards covered Part D drugs to count towards ?incurred costs?, even if the drug was denied coverage by the Part D Plan. On-formulary drugs prescribed by a physician should be explicitly state as counting towards incurred costs in the final regulations.

423.120 (a) Access Standards

We strongly support the provision to require PDP sponsors to meet access standards in each local area as opposed to meeting access standards across a region.

We also strongly support the explicit inclusion of the provision to count only retail pharmacies towards meeting access standards, and the proposed definition of ?retail pharmacy? as stated in the preamble.

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Section 423.153 Cost Management

We strongly recommend that cost containment strategies of individual PDP sponsors are subject other P&T committee. Because their P&T committees exist as an independent entity to protect Medicare beneficiaries, they should be empowered to protect beneficiaries in all aspects. It is unacceptable to allow PDP sponsors? concerns for their profit margins to superseded beneficiaries? well-being. It is also unrealistic to expect sponsors and other businesses associated with the sponsors to willingly emphasis beneficiaries? needs over profits. This must be subject to outside, independent regulation this is more extensive and ongoing than the initial approval by CMS.

Error Rates

The preamble notes that ?In the future, we may require quality reporting that includes error rates?? This should be required immediately, and made public as soon as possible in order to encourage accountability.

Section 423.156 Consumer Satisfaction Surveys

The proposed rules do not enumerate an effective date for consumer surveys. We strongly urge consumer satisfaction surveys to being in conjunction with the beginning of the Part D benefit in 2006.

GENERAL PROVISIONS

Second public commenting period

The first draft of the proposed rules poses many questions, and leaves the rules regarding many areas unwritten. These areas deserve the scrutiny of public comment as much as the regulation proposed in this draft. We urge the consideration of a second commenting period after the unwritten sections of regulations are completed.

423.120 (b) P&T Committee Decisions should be binding

We strongly recommend that the final rule ensures that decisions made by a PDP?s P&T committee are considered binding. We feel that congress?s intentions in requiring P&T committees will be undermined if they are not empowered to make binding decisions and recommendations regarding proposed formularies. We also feel that decisions regarding cost-containment strategies, as they related to access to covered Part D Medications and formulary structures, should be subject to binding recommendations of the P&T committee. We fell that only with these provisions will beneficiaries be ensured access to the covered Part D medications as intended by congress.

423.120(b)(1) Regarding the independence of P&T committees

Although we support the intentions in the proposed rule to ensure the independence of P&T committees from PDP-sponsor influences, we feel that the provisions in the proposed rule are wholly inadequate. We strongly encourage the final rule to include the following provisions:

1. P&T committee members must not only be ?free and independent? of the PDP sponsor, but also of pharmaceutical manufacturers. This should be explicitly stated in the final rule.
2. Committee appointments should be public record, and CMS must be required to create a process whereby the ?independence? of a committee member can be challenged and reviewed.
3. All PDP sponsors should be explicitly required in the final rule to operate a P&T committee, regardless of whether they initially plan to have a formulary.
4. All P&T committee meetings should be public to encourage accountability. In addition, the minutes and decisions of P&T committees should be available upon request to beneficiaries and their advocates.
5. Because the proposed rules only required a numerical value for independent members but not for the size of the committee, a statistical majority of free and independent members needs to be required.
6. Regardless of the final requirements regarding independent membership, the final rules should stipulate that the free and independent members must be present at any given meeting in order to make a binding decision.
7. The final rule must not only encourage but require P&T committees to seek input from plan enrollees, or in initial decisions before January of 2006, from Part-D eligible beneficiaries within that plan?s service area, and specifically from within the most vulnerable populations: disabled individuals, those with rare or pharmacologically complex conditions, and beneficiaries over the age of 75.

This is not an exhaustive list of ways to strength the power and independence of P&T committees. We strongly urge CMS to consider additional and alternative provisions.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

423.882 Employment-based Retiree Coverage and Subsidies

We are very concerned about the possibility of employer windfalls resulting from the retirement benefit subsidy. Although we believe the cost to the beneficiaries should be taken into account when determining ?creditable coverage?, the subsidy should be based solely on the contributions of the employer. We understand that the accounting and determining of employer subsidies will be a complicated procedure, and we support measures to increase accountability and decrease fraud, including making this accounting public record. We support and encourage involving employee groups and advocates in the monitoring of this accounting, and feel that it could lead to reduced fraud and errors.

423.884 (a) Assuring validity of employer?s actuarial attestation

Information regarding an employer?s actuarial attestation should be made public record so as to allow employee groups and advocates to best work for the protection of their retirees. We also feel that CMS proposed used of random audits to ensure that employment-based retiree coverage meets actuarial equivalence tests in insufficient. We recommend that additional quality control measures be proposed and evaluated as possibilities.

The regulations should explicitly state that employees will not be held responsible for late enrollment penalties in the event that a retiree plan is found to have been in violation of creditable coverage due to error or misrepresentation. Additionally, employees should not be held responsible for late enrollment fees in the event of a failure on behalf of an employer plan to notify retirees of changes in the certification of creditable coverage.

423.890 Appeals

We recommend that third-parties (including employee groups) should be granted the right to appeal a CMS determination regarding actuarial equivalence of an employer?s retiree coverage. We further recommend that CMS be required to provide information regarding their decision on the actuarial equivalence test and how to appeal the decision to all affected beneficiaries and their advocates upon request.

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Comments on the Centers for Medicare and Medicaid Services' Proposed Medicare Regulations: CMS-4068-P

General

Second public commenting period

The first draft of the proposed rules poses many questions, and leaves the rules regarding many areas unwritten. These areas deserve the scrutiny of public comment as much as the regulation proposed in this draft. We urge the consideration of a second commenting period after the unwritten sections of regulations are completed.

Subpart D

Section 423.153 Cost Management

We strongly recommend that cost containment strategies of individual PDP sponsors are subject other P&T committee. Because their P&T committees exist as an independent entity to protect Medicare beneficiaries, they should be empowered to protect beneficiaries in all aspects. It is unacceptable to allow PDP sponsors' concerns for their profit margins to superseded beneficiaries' well-being. It is also unrealistic to expect sponsors and other businesses associated with the sponsors to willingly emphasis beneficiaries' needs over profits. This must be subject to outside, independent regulation this is more extensive and ongoing than the initial approval by CMS.

Error Rates

The preamble notes that "In the future, we may require quality reporting that includes error rates…" This should be required immediately, and made public as soon as possible in order to encourage accountability.

Section 423.156 Consumer Satisfaction Surveys

The proposed rules do not enumerate an effective date for consumer surveys. We strongly urge consumer satisfaction surveys to being in conjunction with the beginning of the Part D benefit in 2006.

Subpart R

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Subpart C

423.104 Definition of "person"

We recommend that the definition of "person" explicitly include family members, charities, and caretakers. Also, we encourage individuals who receive prescription medications through pharmaceutical manufacturer patient assistance programs be allowed to count these medications as "incurred costs" consistent with the average cost of these medications through an individual's

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PDP. Pharmaceutical manufacturer patient assistance programs provided medications only to individuals whom they certify, in conjunction with the treating physician, as not able to afford medications without assistance. Due to the nature of the vulnerable populations receiving this type of assistance, we feel that it is unfair to restrict their access to catastrophic coverage.

423.104 (e)(2)(ii) Limiting cost-sharing tiers

The proposed rules do not include a limit on tiered cost-sharing. We strongly encourage such a limit to be placed on the use of cost-sharing tiers. Also, applying different cost-sharing tiers to different classes of drugs would inherently discriminate against certain populations and we urge CMS to explicitly prohibit this as a valid cost-containment mechanism. We believe that unlimited cost-sharing tiers undermine Congress' stipulation for representation of every drug class within a formulary, and strongly oppose unlimited tiers. We suggest three cost-sharing tiers as an appropriate and acceptable limit to cost-sharing tiers.

On-formulary Drugs

We encourage the final rule to include all beneficiary expenses towards covered Part D drugs to count towards "incurred costs", even if the drug was denied coverage by the Part D Plan. On-formulary drugs prescribed by a physician should be explicitly state as counting towards incurred costs in the final regulations.

423.120 (a) Access Standards

We strongly support the provision to require PDP sponsors to meet access standards in each local area as opposed to meeting access standards across a region.

We also strongly support the explicit inclusion of the provision to count only retail pharmacies towards meeting access standards, and the proposed definition of "retail pharmacy" as stated in the preamble.

423.120 (b) P&T Committee Decisions should be binding

We strongly recommend that the final rule ensures that decisions made by a PDP's P&T committee are considered binding. We feel that congress's intentions in requiring P&T committees will be undermined if they are not empowered to make binding decisions and recommendations regarding proposed formularies. We also feel that decisions regarding cost-containment strategies, as they related to access to covered Part D Medications and formulary structures, should be subject to binding recommendations of the P&T committee. We fell that only with these provisions will beneficiaries be ensured access to the covered Part D medications as intended by congress.

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423.120(b)(1) Regarding the independence of P&T committees

Although we support the intentions in the proposed rule to ensure the independence of P&T committees from PDP-sponsor influences, we feel that the provisions in the proposed rule are wholly inadequate. We strongly encourage the final rule to include the following provisions:

1. P&T committee members must not only be "free and independent" of the PDP sponsor, but also of pharmaceutical manufacturers. This should be explicitly stated in the final rule.
2. Committee appointments should be public record, and CMS must be required to create a process whereby the "independence" of a committee member can be challenged and reviewed.
3. All PDP sponsors should be explicitly required in the final rule to operate a P&T committee, regardless of whether they initially plan to have a formulary.
4. All P&T committee meetings should be public to encourage accountability. In addition, the minutes and decisions of P&T committees should be available upon request to beneficiaries and their advocates.
5. Because the proposed rules only required a numerical value for independent members but not for the size of the committee, a statistical majority of free and independent members needs to be required.
6. Regardless of the final requirements regarding independent membership, the final rules should stipulate that the free and independent members must be present at any given meeting in order to make a binding decision.
7. The final rule must not only encourage but require P&T committees to seek input from plan enrollees, or in initial decisions before January of 2006, from Part-D eligible beneficiaries within that plan's service area, and specifically from within the most vulnerable populations: disabled individuals, those with rare or pharmacologically complex conditions, and beneficiaries over the age of 75.

This is not an exhaustive list of ways to strength the power and independence of P&T committees. We strongly urge CMS to consider additional and alternative provisions.

CMS-4068-P-1206

Submitter : Mr. Scott Melvill **Date & Time:** 10/04/2004 08:10:27

Organization : Healthcare Distribution Management Association

Category : Association

Issue Areas/Comments

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Please see the attached file.

CMS-4068-P-1206-Attach-1.doc

Healthcare Distribution Management Association
Products, Services and Information for Your Health

John M. Gray, President and CEO
Eric Schuss, Chairman of the Board

October 4, 2004

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Via Electronic Submission

Re: Medicare Program; Medicare Prescription Drug Benefit, Section 423.153 (d) [CMS-4068-P]. 69 Fed. Reg. 46632 (August 3, 2004).

Dear Dr. McClellan:

The Healthcare Distribution Management Association submits the following comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed rule, *Medicare Program; Medicare Prescription Drug Benefit*. 69 Fed. Reg. 46632 (August 3, 2004). I am writing to commend CMS for its efforts to implement the Medication Therapy Management Programs (MTMPs) included in the new Medicare Part D benefit, to be codified in section 423.153 of the proposed rule. HDMA believes that MTMPs will be an important addition to the benefits that seniors can receive under the Medicare program and we encourage you to work with the pharmacy community to craft a benefit program that adequately meets the needs of chronically ill beneficiaries.

HDMA is the national trade association representing full-service distribution companies responsible for ensuring that billions of units of medication are safely distributed to retail pharmacies, hospitals, nursing homes, clinics, and other provider sites across the United States. HDMA's distributor members provide services to approximately 141,591 pharmacy settings, including: 17,913 independent pharmacies; 19,824 chain pharmacies; 9,918 food stores; 9,992 hospital pharmacies; 4,872 mass merchandisers; 5,397 long-term care and home health facilities; 62,364 clinics; 1,170 healthcare plans; and 366 mail order pharmacies.[1] It is within these settings that patients interact with their pharmacists and receive important direction regarding their medications.

[1] Table 228 – Class of Trade Analysis – Manufacturer Sales by Customer Categories: 2002-2003.HDMA Industry Profile and Healthcare Factbook, Healthcare Distribution Management Association. (2004).

HDMA has long-believed that appropriate use of prescription drugs not only enhances the patient's quality of life but can also decrease the need for hospitalization or surgery. We believe that disease management and medication therapy management programs will contribute to obtaining favorable patient outcomes. Additionally, when chronically ill patients have access to specialized guidance regarding their medications and their drug therapies are more carefully monitored, it is possible that they can achieve greater results from their course of treatment and perhaps suffer fewer adverse events related to their illness or drug interaction.

It is also important for CMS to recognize the demonstrated value of individualized patient care services and to ensure appropriate and fair reimbursement for the professionals who provide such services. MTMPs involve the collaboration of the pharmacist with physicians, nurses and other healthcare professionals to ensure that medications are used appropriately to improve patient health status, improve the patient's quality of life and contain healthcare costs. CMS should devise appropriate payment mechanisms that acknowledge the important role of the pharmacist and the resources involved in providing individualized guidance for beneficiaries in order to ensure that they receive the most favorable results possible from their prescribed course of treatment.

HDMA distributor members do not serve patients directly, but as part of our role in facilitating patient access to necessary medications, we believe that it is important to support development of MTMPs that contribute to favorable outcomes and that are flexible enough to provide individualized patient care. In addition, MTMPs can lead to an overall reduction in healthcare costs. Therefore, it is critical that CMS develop this benefit in cooperation with the pharmacist and pharmacy communities. In determining the parameters of MTMPs, CMS should consider patient-specific treatment requirements; patient education relative to prescribed medications; the pharmacist's ability to monitor patient progress, and identify and resolve problems that are medication related; in-person consultations between the pharmacist and patient; and reimbursement rates that accurately reflect the resources and expertise that are required to provide effective medication therapy management. HDMA supports development of a MTMP benefit that ensures that the beneficiaries who have the greatest need for such programs are identified and ensured access to these important services.

HDMA appreciates this opportunity to provide CMS with its comments regarding the new Medicare Part D benefit and CMS policy regarding Medication Therapy Management. If we can be of assistance as you continue implementation of Part D regulations, please contact me or Elizabeth Gallenagh, Manager, Regulatory Affairs at 703-787-0000 ext. 234.

Sincerely,

Scott Melville

Scott Melville
Sr. Vice President of Government Relations

CMS-4068-P-1207

Submitter : Ms. Lisa M. Getson **Date & Time:** 10/04/2004 08:10:41

Organization : Apria Healthcare

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

Please reference Apria Healthcare's formal, comprehensive comments in the Word attachment being submitted on this form.

CMS-4068-P-1207-Attach-1.doc

CMS-4068-P-1207-Attach-2.doc

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Re: Comments on CMS-4068-P
The Proposed Rule for the Medicare Prescription Drug Benefit

Dear Dr. McClellan:

On behalf of Apria Healthcare Inc., I am pleased to submit these comments regarding the proposed rule to implement the new Medicare Part D prescription drug benefit. Specifically, these comments pertain to the recent notice published in the *Federal Register* on August 3, 2004.[1]

Apria is a leading provider of integrated home care services and products. Apria offers a full range of home infusion drug therapy, as well as home medical equipment and home respiratory therapy. Through 30 wholly-owned, licensed and JCAHO-accredited infusion pharmacies, Apria serves adult and pediatric patients with a wide range of infectious diseases, nutritional disorders, cancer and chronic illnesses such as Lou Gehrig's Disease and multiple sclerosis. Aside from the thousands of people covered by private managed care organizations who benefit from Apria's home infusion services, the company also cares for a significant number of elderly patients throughout the United States who have complex medical problems and multiple co-morbidities who require home infusion therapy and are covered by Medicare Advantage (MA. formerly Medicare+Choice) plans.

These comments are divided into the following sections:

I. General
II. Dispensing Fees for Home Infusion Drug Therapy
III. Contracting with Home Infusion Drug Pharmacies
IV. Formulary Development

[1] Medicare Program; Medicare Prescription Drug Benefit; 69 *Fed. Reg.* 46632 (Aug. 3, 2004).

I. General

We wish to commend CMS for engaging in the research necessary to understand many of the unique characteristics of home infusion drug therapy. These findings are reflected in the preamble of the proposed rule, which summarizes the various services and functions that are required to provide home infusion drug therapy safely and effectively in the home care setting.

We applaud CMS for recognizing in the proposed rule the clinical and cost benefits of home infusion drug therapy, as well as the essential role this area of therapy plays in the private sector health system and under Medicare managed care programs. The proposed regulation describes an interpretation of the Part D benefit that would include the essential services, supplies and equipment that are integral to the provision of infusion drug therapy provided in the home (see discussion of "Dispensing Fee Option 3" below).

If Dispensing Fee Option 3 is adopted in the final regulation, as we recommend, then the Medicare fee-for-service program can offer coverage of home infusion drug therapy comparable to what private sector health plans and Medicare Advantage plans have offered for years. In doing so, Medicare would realize the significant system-wide savings that come from the provision of infusion drug therapy in the most cost-effective setting.

A. Home infusion drug therapy provides an opportunity for Medicare Part D to replicate the success achieved by private sector health plans and Medicare Advantage plans.

Currently, many of the infusion drug therapies used commonly in the private sector, such as antibiotic therapy used in the treatment of severe infections, are not covered under the Medicare Part B durable medical equipment (DME) benefit. Coverage under the DME benefit is based on the use of an item of DME – in this case, an infusion pump − and extends only to a few designated drugs, most of which are used in the treatment of cancer and intractable pain. As a result, Medicare beneficiaries who could have received infusion drug therapy at home have been forced into far more costly settings, such as acute care hospitals, hospital outpatient departments, hospital emergency rooms and long term care facilities.

In contrast to the limited coverage that exists under Medicare Part B, Medicare coverage of home infusion therapy has worked well under Part C with the Medicare Advantage plans. Many if not most Medicare Advantage plans provide coverage for a broad range of home infusion therapies and related services as a <u>medical</u> benefit. Examples include Aetna US Healthcare, Humana Health Plans, PacifiCare's Secure Horizons plans and Presbyterian Salud in New Mexico. Clearly, these plans would not provide this optional coverage unless they were convinced that coverage of home infusion therapy in the home setting is cost-effective.

For Medicare Advantage plans, home infusion has provided significant system-wide savings by enabling beneficiaries to receive infusion therapy without incurring hospital or nursing facility costs. Medicare Advantage plans cover the homecare pharmacy, nursing and other in-home services, supplies, equipment and same-day, in-home delivery/patient teaching necessary for the provision of home infusion therapy. The effectiveness of home infusion therapy under Part C, and the manner in which Medicare Advantage plans define and cover this therapy, can be a model for infusion coverage under Part D.

B. Specific requirements must be established by CMS to ensure that Medicare Part D makes use of home infusion drug therapy in the same fashion as private sector and Medicare Advantage plans.

Stand-alone Part D prescription drug plans (PDPs), in the absence of specific requirements or direction from CMS, will not embrace drug therapies such as home infusion drug therapy because the PDPs will be rewarded for contributing to system-wide savings on the drugs alone. As a result, the financial incentives that have driven private payer acceptance and use of home infusion drug therapy will not exist for stand-alone PDPs.

As a result, specific requirements and direction from CMS are necessary for the coverage of home infusion drugs to work properly. We urge CMS to ensure that the Final Rule contains provisions relating to home infusion drug therapy on the issues discussed in the remainder of these comments, including such issues as dispensing fees, pharmacy access, formulary provisions and the formatting of claims.

II. Dispensing Fees for Home Infusion Drug Therapy

A. CMS should adopt Dispensing Fee Option 3, which is the only proposed option that would adequately recognize the services and items that are necessary to provide home infusion drug therapy.

Congress' definition of prescription drugs under the statute clearly includes infusion drugs provided in the home, and the proposed rule likewise reinforces the fact that infusion drugs (other than the few drugs currently covered under Part B) are included in the Part D benefit.

However, for the coverage of home infusion drugs to be meaningful for Medicare beneficiaries, CMS also must cover the services, supplies and equipment related to the provision of these drugs. Limiting coverage to the drugs only without the services, supplies and equipment will not produce meaningful coverage of infusion drugs in outpatient settings. This is because infusion pharmacies will be unable to provide infusion drugs without adequate payment for the services, supplies and equipment.

The most appropriate mechanism for such coverage of infusion services, supplies and equipment provided under the proposed rule is the dispensing fee. In the preamble, CMS sets out three options for defining dispensing fees under the new benefit and invites comment on each.

- Option 3 comes closest to accurately recognizing the fundamental elements – including the services, supplies and equipment – that are essential for the provision of home infusion drug therapy. Option 3 is the only option that reflects the fundamental elements of home infusion drug therapy (see additional discussion in subsequent sections of these comments).

- In contrast, Option 1 only provides the perspective of retail pharmacies and does not meet the needs of Medicare beneficiaries requiring home infusion drug therapy.

- Although Option 2 captures the supplies and equipment used in the provision of home infusion drug therapy, this option falls far short of recognizing the essential professional services required to provide home infusion drug therapy because it does not recognize the professional services that are required to provide safe and effective infusion therapy in the home.

B. CMS should adopt Dispensing Fee Option 3 because it is consistent with the well-established standards of practice for home infusion drug therapy.

The major independent accreditation organizations, including the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), have established extensive, detailed standards regarding the patient management, support services, facilities, patient safety, policies, procedures and functions that must be provided by home infusion pharmacies. These standards, which address issues ranging from the requirements for sterile preparation of infusion drugs to the oversight of patient therapy, are significantly different from the standards governing traditional retail pharmacies.

Option 3 is the only dispensing fee option that adequately reflects the content of these national accreditation standards. For example, one major difference between retail pharmacies and home infusion pharmacies is the urgency surrounding the initial referral from a physician or hospital and the resulting home delivery/patient education requirements. Due to the severity of the patient's illness (such as a serious infection which has not responded to oral medications), pressures on hospitals to discharge patients as soon as possible, and stability/refrigeration requirements for many medications, home infusion pharmacy staff frequently have to deliver directly to patients' homes the same day as the referral. This is considerably more expensive than a retail pharmacy model where the patient or caregiver visits the pharmacy in person to pick up the drug. All of this must take place in conjunction with insurance verification, coordination with the nurse who will teach the patient, compounding by a home infusion pharmacist, and eventually, billing third party payors and collecting patient co-pays – all activities that are not applicable to the retail setting.

The well-established understanding of the professional services involved in providing in home infusion drug therapy is not merely an industry definition. Payers, clinicians, clinical societies, providers and accrediting organizations share a common understanding of what is involved in providing these therapies in outpatient settings.

C. CMS should adopt accreditation requirements under Dispensing Fee Option 3 as a straightforward means to protect Part D enrollees.

As the first homecare provider to seek and obtain JCAHO accreditation in the 1980s, Apria has a longstanding commitment to ensuring that the professional services and functions we provide meet a demanding set of quality standards. Apria recently completed its latest triennial survey cycle, with a successful outcome in all infusion pharmacies, respiratory and medical equipment locations. Our company has served as a pilot for innovative survey techniques developed by the JCAHO, and our management has formally served on advisory committees of the organization. Today, our quality standards meet or exceed JCAHO's requirements, which is a requirement of the over 2500 private sector managed care plans with which we contract to provide home infusion services.

In the final rule, CMS should address the qualifications of the infusion pharmacies that may provide the elements of care described under Dispensing Fee Option 3. We recommend that CMS require every pharmacy providing infusion services to be accredited as a home care pharmacy by a recognized national accrediting organization. We also recommend that every entity that provides nursing services to Part D infusion patients be either accredited as a nursing agency as an extension of their existing home infusion accreditation, or be a Medicare-certified home health agency.

Private sector plans require accreditation as a basic assurance that the pharmacists and nurses are experienced and the pharmacies are staffed properly to provide the necessary care. The quality standards required of home infusion pharmacies and nursing agencies by the accreditation organizations have become the community standard for the provision of home infusion therapy.

D. CMS should use a refined version of Dispensing Fee Option 3 to define the full scope of necessary professional infusion pharmacy services.

All infusion patients, whether or not they qualify for the home health benefit, require professional pharmacy services that again differ from those found in the retail setting. The general categories of such services are:

- Compounding medications in a sterile environment
- Dispensing
- Ongoing Clinical Monitoring
- Care Coordination with other agencies involved in patient care

- Provision of Supplies and Equipment
- Multiple Categories of Pharmacy Professional Services, such as pharmacokinetic drug monitoring or parenteral nutrition formula development
- Administrative Services
- In-home delivery, patient and caregiver education
- Third party billing
- Other Support Costs

These services are described in greater detail in a number of accreditation materials and other forums, including a document on the website of the National Home Infusion Association describing the "per diem" model.[2]

We propose a modification to Dispensing Fee Option 3 to more explicitly describe the pharmacy professional services that are needed for home drug infusion therapy. The pharmacy services referenced above in the model per diem definition (and generally described in Dispensing Fee Option 3) should be included in the dispensing fee for all Part D infusion patients. Most of these functions would be captured in the Option 3 definition of dispensing fees.

Both private payers and Medicare Advantage plans use per diem payments that are tied to the intensity level of the particular infusion therapy. For over 20 years, these plans have essentially developed resource-based relative value scales to capture the intensity, in terms of time and resources involved in providing each infusion therapy safely and effectively. Thus, the plans do not use a single per diem amount for all infusion therapies. We recommend that the PDPs follow this approach under Medicare Part D.

E. CMS can establish easily-administered safeguards to avoid any duplicate payments for nursing services

CMS raises a question in the proposed rule regarding how to ensure that the services captured in Dispensing Fee Option 3 are not reimbursed under the home health benefit or otherwise.

The potential area of concern involves the infusion patients who also qualify for the Medicare home health benefit. For this subset of infusion patients who also qualify for the home health benefit, it would be a simple matter to first determine whether a beneficiary qualifies for the home health benefit before reimbursing Part D funds for nursing services. The majority of beneficiaries who require infusion drug therapy do not qualify for the home health benefit, and their nursing services should be paid under the Part D benefit as part of the dispensing fee.

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[2] National Home Infusion Association. National Definition of Per Diem. June 2003. *Available at* www.nhianet.org/perdiemfinal.htm.

Importantly, the home health benefit does not cover any of the pharmacy services described in the preceding subsection of these comments.

By first identifying beneficiaries who qualify for the home health benefit, the nursing component, when medically necessary, should be reflected in the dispensing fee but only for beneficiaries who do not qualify under the home health benefit for nursing services. Importantly, nursing care is not included in the model per diem definition (discussed above) nor in the HCPCS "S" coding structure (discussed below) used by private payers.

Private payers typically separate out nursing from the pharmacy-related costs represented by the per diem. They share the Medicare program's natural concern about nursing costs, and these plans have concluded the best means of tracking and controlling nursing costs is to use a separate payment mechanism for nursing.

F. CMS can establish easily-administered safeguards to avoid duplicate payments under Medication Therapy Management Programs.

CMS asks for comments regarding how to ensure that the Medicare program avoids making duplicate payments if the PDPs pay for infusion-related dispensing fees as well as medication therapy management services.

Generally, the dispensing fee as defined in Dispensing Fee Option 3 will capture most of the services and functions described in our per diem model plus the nursing component, and there will not be a clear need for a separate payment to infusion pharmacies for additional medication therapy management services. We believe that the primary situation where medication therapy management services may be indicated is where an infusion pharmacy has to coordinate the activities of another pharmacy.

However, if CMS does not choose Dispensing Fee Option 3 for defining dispensing fees, then CMS should not consider the medication therapy management program as a substitute for covering the services, supplies and equipment required to provide infusion drug therapy. The limitations on the applicability of the medication therapy management program (*i.e.*, it is limited to patients with chronic conditions and multiple medications) make it a poor vehicle for capturing the clinical monitoring functions required of infusion pharmacies for all infusion patients.

III. Contracting with Home Infusion Pharmacies

A. CMS should establish separate and distinct requirements for PDPs to contract with sufficient numbers of home infusion pharmacies to ensure adequate enrollee access to home infusion drug therapy under Medicare Part D.

CMS should establish specific safeguards for home infusion pharmacies to ensure meaningful enrollee access to home infusion drug therapies. A number of important differences exist between home infusion pharmacies and traditional retail pharmacies that highlight the need to create separate requirements for the two types of pharmacies. For example–

- Home infusion pharmacies provide specific essential services that are not provided by the vast majority of retail pharmacies or mail order pharmacies.

- Home infusion pharmacies must maintain facilities, equipment and safeguards for compounding and storing sterile parenteral drug solutions, which is not common among retail pharmacies.

- Home infusion pharmacies are responsible for the care of their patients 24 hours a day, seven days a week, while retail pharmacies are not.

- Home infusion pharmacies are subject to separate state licensure, regulations and accreditation standards from retail pharmacies.

- The contracts used by private health plans for home infusion pharmacies are structured differently from the contracts used for retail pharmacies.

- The total number of traditional retail pharmacies in the United States far outweighs the total number of home infusion pharmacies.

These differences are echoed in the preamble of the proposed rule, where CMS discusses its findings regarding important distinctions between home infusion pharmacies and retail pharmacies.[3]

To ensure that Part D enrollees have sufficient access to home infusion drug therapy, CMS should adopt its proposal to establish distinct access standards for home infusion pharmacies in the Final Rule. This would be consistent with Congress' general mandate that CMS must ensure enrollees have convenient access to pharmacies, as access to a retail pharmacy does not by itself meet the needs of a beneficiary who requires infusion therapy.

B. CMS should require use of the ASC X12N 837 claims format for infusion drug therapy, consistent with CMS' recent determination, because infusion claims formats are different from retail pharmacy claims.

CMS' Office of HIPAA Standards has carefully reviewed how home infusion therapy is provided, and recently issued a Program Memorandum[4] and a Frequently Asked Question (FAQ)[5] document on the CMS website summarizing its conclusion.

[3] 69 *Federal Register* at 46648 and 46658.

For example, the FAQ document states:

> …Home infusion therapy typically has components of professional services and products that include ongoing clinical monitoring, care coordination, supplies and equipment, and the drugs and biologics administered – all provided by the home infusion therapy provider.

In a letter dated April 8, 2003, Jared Adair, director of the CMS Office of HIPAA Standards, wrote:

> …we have determined that home drug infusion therapy services are different from services provided by retail pharmacies, and that the business model for home drug infusion therapy providers is fundamentally different from a retail pharmacy for dispensing drugs…. We also acknowledge that a requirement to bill home infusion drugs using the NCPDP format would fail to meet the administrative, clinical, coordination of care, and medical necessity requirements for home drug infusion therapy claims." (emphasis added)

As a result, CMS determined that the National Council for Prescription Drugs Program (NCPDP) claim format, which is the HIPAA standard for the processing of retail pharmacy drug claims, is not appropriate for the filing of home infusion drug therapy claims. Instead, CMS instructed that home infusion claims, to be compliant with HIPAA, must be filed under the ASC X12N 837 claims format.

Please note that the description of infusion therapy as described in the FAQ tracks very closely with the language of Dispensing Option 3 in the proposed rule. We recommend that the specific wording already posted on CMS's FAQ be included as the infusion claiming requirement in Part D regulations. To do so will increase the level of administrative standardization in infusion claims transactions per the objectives of HIPAA, while also ensuring that home infusion providers and Part D payers comply with the HIPAA regulation when implementing Part D claiming transactions. If CMS does not require that Part D home infusion therapy claims be submitted on the 837, then it would open up the possibility for some Part D payers to ignore the fundamental differences of home infusion therapy from retail pharmacy and implement only NCPDP claiming—forcing infusion pharmacies to be out of compliance with HIPAA.

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[4] Centers for Medicare & Medicaid Services, Program Memorandum, Carriers, Transmittal B-03-024 (4/11/03), *available at* http://cms.hhs.gov/manuals/pm_trans/B03024.pdf.

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This would deprive the PDPs and CMS of a valuable tool for tracking important patient-specific data. Consolidated 837 claiming would facilitate the consolidation of all drugs along with the professional pharmacy "per diem" services, equipment and supplies into single claims billed for infusion therapies, easily mapped into patient services utilization data bases for analysis—whereas the possibility of billing infusion drugs separately via the retail NCPDP claim format results in loss of this consolidated data for analysis.

C. CMS should recognize that infusion coding is different from retail pharmacy drug coding.

Since 2002 the Healthcare Common Procedure Coding System (HCPCS) provides approximately 80 "S" codes for home infusion therapy services. Most codes reflect a "bundled" per diem approach in which most or all of the supplies and services provided to a home infusion patient are billed under a single code. This complete system of "S" codes for home infusion therapy services is specifically designed for use by private payers, and are available for use by government payers that adopt this widely used private sector methodology for infusion coding and payment. These codes are not used in coding of retail pharmacy drug claims and are not permitted for HIPAA-compliant use on the NCPDP transaction).

Although CMS does not have a single HIPAA coding standard for drugs, we believe that the PDPs and CMS will find requiring NDC drug coding for Part D claims will provide best opportunity for patient utilization analysis and tracking of total Part D drug costs for CMS's program administration. We believe the Part D regulations should require that all claims for drugs be coded with NDC numbers.

D. Coordination of benefits.

In addition to these reasons for infusion claiming and coding consistency, the COB portion of the Part D program is also best implemented by CMS's establishing a requirement for 837 claiming and use of the established coding systems. The majority of COB will occur with commercial payers such as the Blues and other private health plans. As the private sector has already widely adopted the established coding systems described above, it will be important for CMS to require consistent coding adoption to make COB work, ensuring that the allocation of payment for services between Part D plans and other primary or secondary plans works well.

Since the private payer sector accepts home infusion therapy claims using the HIPAA-compliant X12 N 837 format, for COB to work effectively is another reason that CMS should require PDPs to use the 837 claim format for infusion claims. Because a very large majority of private infusion payers use the HIPAA-complaint *professional* 837 (837P) claim format, to make COB work we believe that CMS's Part D regulations should require PDPs to adopt the HIPAA-compliant 837P format only, excluding both the *institutional* 837 and NCPDP transaction from use.

E. CMS should clarify the any willing provider requirements with respect to home infusion drug therapy.

CMS should clarify that this access safeguard is to be applied to any willing provider of home infusion therapy meeting the infusion-specific quality standards (see below), as distinct from retail pharmacies. Such a requirement is consistent with the statutory language.[6]

In addition, for the purpose of the any willing provider requirements, CMS should clarify that prescription drug plans should have a standard contract for home infusion pharmacies.

These recommendations for the network access standards will help safeguard enrollee access by ensuring that the Medicare Part D benefit reflects common private sector practices for home infusion drug therapy. In addition, the recommended clarifications will not impose significant burdens on PDPs.

F. CMS should recognize that OBRA 1990 standards do not represent the standard of care for infusion pharmacies.

In the preamble, CMS refers to Section 54401 of the Omnibus Reconciliation Act of 1990, stating that the regulations issued pursuant to that section in 42 CFR 456.705 "describe currently accepted standards for contemporary pharmacy practice and our intent is to require plans to continue to comply with contemporary standards." CMS seeks comments on whether these standards are industry standards and whether they are appropriate for Part D.

The OBRA 1990 standards were written for retail pharmacies. The drafters of these standards did not attempt to address the standard of care for infusion pharmacies. Infusion pharmacies that are in compliance with the infusion-specific standards established by accrediting organizations meet the OBRA 1990 standards, but the OBRA 1990 standards do not reflect "contemporary pharmacy practice" for infusion pharmacies. The community standard of care for infusion pharmacies is found in the accreditation standards that are required by virtually every private health plan, as well as numerous MA plans, to participate in their provider networks.

The quality assurance standards followed by home infusion pharmacies—and as required for accreditation--far exceed the OBRA 1990 standards. Due to advances in newly-approved drugs and technology and additional laws and regulations established in the intervening years (such as HIPAA), and development of knowledge surrounding patient safety and medication management at home, the level of patient data collection, assessment and intervention in the infusion clinical model goes far above and beyond the quality standards currently used for Medicaid. Again we respectfully direct your attention to Jared Adair's April 8, 2003 comments concerning the key differences between retail and home infusion pharmacies.

[6] Social Security Act, Section 1860D-4(b)(1)(A).

IV. Formulary Development

A. CMS should mandate that PDP and MA-PD plan sponsors maintain an open formulary for infusion drugs to ensure this population of vulnerable patients has appropriate access to necessary medications.

Much of the MMA is based on the premise that Medicare can take advantage of cost-savings techniques commonly used in the private sector and still deliver quality services to Medicare beneficiaries. CMS should note that although private health plans commonly use restricted or preferred formularies for drugs delivered orally, via patch or other non-invasive methods, private plans rarely apply these formulary restrictions to infusion drugs.

As discussed in greater detail below, there are numerous clinical and operational barriers to establishing formularies for infusion drugs. As a result, with respect to infusion drugs, formularies should remain open.

B. CMS should recognize that PDPs and pharmacy and therapeutics committees are not well situated to evaluate infusion drugs.

It will be difficult for PDPs and traditional pharmacy and therapeutics committees (P&T committees) to evaluate infusion drugs in the same manner that they evaluate orally administered drugs.

P&T committees generally evaluate the relative safety, efficacy, and effectiveness of prescription drugs within a class of prescriptions drugs and make recommendations to a health plan for the development of a formulary or preferred drug list. Frequently, P&T committees focus on the "therapeutic equivalence" of different multisource drugs (*i.e.*, whether one drug will have the same desired clinical impact as another). However, such evaluations are performed in a context where the method of administering the drug is not significant.

In contrast to oral drugs, the method of administration for an infusion drug may have separate and significant clinical and cost implications. All infusion drugs require a device of some type to deliver the drug into the body, including various catheters temporarily or semi-permanently implanted in each patient depending on the anticipated duration of therapy, potential side effects of the drug and the patient's diagnosis itself. Various methods of drug delivery also exist, from IV bags hung on poles to sophisticated external or internal infusion pumps. A patient's clinical condition may determine not only what device is selected for delivery, but also what drug should be used. For instance, many patients receiving infusion therapy are at high risk of infection or complications from infection. Consequently, a physician may need to choose a medication that can be prepared in advance in a pharmacy clean room and administered once a day to reduce the risk of infection from preparation in the home or multiple intravenous access device manipulations.

Similarly, in selecting a medication for a patient, a physician often needs to consider administration access type and what delivery technology will be best suited for use in a particular patient's home. If the patient is capable of managing a portable infusion pump, drugs requiring longer infusion times may become more clinically appropriate. If other technologies are used, such as IV bags hung on poles, the patient may require more frequent nursing visits to monitor the risk of infection.

The typical P&T Committee would usually not have the experience to evaluate the administration technology or professional support requirements, such as nursing visits, in reviewing infusion drugs. Furthermore, such committees do not typically make decisions considering all available treatment options throughout the continuum. Drugs considered ideal in an inpatient setting are often not desirable in the home setting and visa versa, especially where the first dose of the drug is concerned. Examples include Taxol® for ovarian cancer, Lovenox® for deep vein thromboses and certain immune globulins.

In addition, most infusion drugs must be compounded by the pharmacy. Once compounded, these drugs lose stability over time or be impacted by changes in temperature. For oral drugs, the frequency of administration or stability issues usually do not pose challenges for a P&T Committees as they try to determine therapeutic equivalence.

Ultimately, the infrastructure for protecting patient interests in formulary decisions—the traditional P&T Committee—does not have the ability to evaluate the extra-pharmacological considerations that must be taken into account for infusion treatment, including the administration device, drug stability, proximity to a compounding pharmacy, available administration access site and infection risk. Typically, these factors would be addressed by a physician or pharmacist knowledgeable about an individual's patient's circumstances and history when selecting a drug and delivery device.

C. CMS should recognize home infusion patients as a particularly vulnerable population that requires additional protection.

Patients receiving home infusion therapy are one of the truly vulnerable populations of the Medicare population, and as CMS acknowledged in the Proposed Rule,[7] the medical needs of such populations necessitate that they receive special protection under Medicare Part D. Infusion drugs are used to treat some of the most severe illnesses, including cancer, severe infections, pain and loss of gastrointestinal integrity.

Although the Medicare Part D regulations do create an appeals process for patients if their physician's choice of medication is not on formulary, patients with these compromising illnesses are the least capable of exercising an appeals right. If a patient does not have a family member or physician willing to take on the burden of being an advocate, then the patient's care could be compromised.

[7] 69 Fed. Reg. at 46661.

* * * *

We commend CMS for its initial efforts to understand and accurately define home infusion drug therapy under Medicare Part D. There is an important opportunity for the program to replicate the successes achieved by private health plans and Medicare managed care plans. There is also a risk that in the absence of sufficient direction from CMS and some targeted safeguards, the benefits of home infusion drug therapy will be lost for both beneficiaries and the overall Medicare program.

We would be pleased to provide additional assistance regarding these important issues. Please contact Lisa Getson, Apria's executive vice president, at 949-639- 2021 if you have any questions or comments.

Sincerely,

Lawrence M. Higby
President and Chief Executive Officer

CC: Herb Kuhn
Leslie Norwalk

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Re: Comments on CMS-4068-P
The Proposed Rule for the Medicare Prescription Drug Benefit

Dear Dr. McClellan:

On behalf of Apria Healthcare Inc., I am pleased to submit these comments regarding the proposed rule to implement the new Medicare Part D prescription drug benefit. Specifically, these comments pertain to the recent notice published in the *Federal Register* on August 3, 2004.[1]

Apria is a leading provider of integrated home care services and products. Apria offers a full range of home infusion drug therapy, as well as home medical equipment and home respiratory therapy. Through 30 wholly-owned, licensed and JCAHO-accredited infusion pharmacies, Apria serves adult and pediatric patients with a wide range of infectious diseases, nutritional disorders, cancer and chronic illnesses such as Lou Gehrig's Disease and multiple sclerosis. Aside from the thousands of people covered by private managed care organizations who benefit from Apria's home infusion services, the company also cares for a significant number of elderly patients throughout the United States who have complex medical problems and multiple co-morbidities who require home infusion therapy and are covered by Medicare Advantage (MA. formerly Medicare+Choice) plans.

These comments are divided into the following sections:

I. General
II. Dispensing Fees for Home Infusion Drug Therapy
III. Contracting with Home Infusion Drug Pharmacies
IV. Formulary Development

[1] Medicare Program; Medicare Prescription Drug Benefit; 69 *Fed. Reg.* 46632 (Aug. 3, 2004).

I. General

We wish to commend CMS for engaging in the research necessary to understand many of the unique characteristics of home infusion drug therapy. These findings are reflected in the preamble of the proposed rule, which summarizes the various services and functions that are required to provide home infusion drug therapy safely and effectively in the home care setting.

We applaud CMS for recognizing in the proposed rule the clinical and cost benefits of home infusion drug therapy, as well as the essential role this area of therapy plays in the private sector health system and under Medicare managed care programs. The proposed regulation describes an interpretation of the Part D benefit that would include the essential services, supplies and equipment that are integral to the provision of infusion drug therapy provided in the home (see discussion of "Dispensing Fee Option 3" below).

If Dispensing Fee Option 3 is adopted in the final regulation, as we recommend, then the Medicare fee-for-service program can offer coverage of home infusion drug therapy comparable to what private sector health plans and Medicare Advantage plans have offered for years. In doing so, Medicare would realize the significant system-wide savings that come from the provision of infusion drug therapy in the most cost-effective setting.

A. Home infusion drug therapy provides an opportunity for Medicare Part D to replicate the success achieved by private sector health plans and Medicare Advantage plans.

Currently, many of the infusion drug therapies used commonly in the private sector, such as antibiotic therapy used in the treatment of severe infections, are not covered under the Medicare Part B durable medical equipment (DME) benefit. Coverage under the DME benefit is based on the use of an item of DME – in this case, an infusion pump − and extends only to a few designated drugs, most of which are used in the treatment of cancer and intractable pain. As a result, Medicare beneficiaries who could have received infusion drug therapy at home have been forced into far more costly settings, such as acute care hospitals, hospital outpatient departments, hospital emergency rooms and long term care facilities.

In contrast to the limited coverage that exists under Medicare Part B, Medicare coverage of home infusion therapy has worked well under Part C with the Medicare Advantage plans. Many if not most Medicare Advantage plans provide coverage for a broad range of home infusion therapies and related services as a <u>medical</u> benefit. Examples include Aetna US Healthcare, Humana Health Plans, PacifiCare's Secure Horizons plans and Presbyterian Salud in New Mexico. Clearly, these plans would not provide this optional coverage unless they were convinced that coverage of home infusion therapy in the home setting is cost-effective.

For Medicare Advantage plans, home infusion has provided significant system-wide savings by enabling beneficiaries to receive infusion therapy without incurring hospital or nursing facility costs. Medicare Advantage plans cover the homecare pharmacy, nursing and other in-home services, supplies, equipment and same-day, in-home delivery/patient teaching necessary for the provision of home infusion therapy. The effectiveness of home infusion therapy under Part C, and the manner in which Medicare Advantage plans define and cover this therapy, can be a model for infusion coverage under Part D.

B. Specific requirements must be established by CMS to ensure that Medicare Part D makes use of home infusion drug therapy in the same fashion as private sector and Medicare Advantage plans.

Stand-alone Part D prescription drug plans (PDPs), in the absence of specific requirements or direction from CMS, will not embrace drug therapies such as home infusion drug therapy because the PDPs will be rewarded for contributing to system-wide savings on the drugs alone. As a result, the financial incentives that have driven private payer acceptance and use of home infusion drug therapy will not exist for stand-alone PDPs.

As a result, specific requirements and direction from CMS are necessary for the coverage of home infusion drugs to work properly. We urge CMS to ensure that the Final Rule contains provisions relating to home infusion drug therapy on the issues discussed in the remainder of these comments, including such issues as dispensing fees, pharmacy access, formulary provisions and the formatting of claims.

II. Dispensing Fees for Home Infusion Drug Therapy

A. CMS should adopt Dispensing Fee Option 3, which is the only proposed option that would adequately recognize the services and items that are necessary to provide home infusion drug therapy.

Congress' definition of prescription drugs under the statute clearly includes infusion drugs provided in the home, and the proposed rule likewise reinforces the fact that infusion drugs (other than the few drugs currently covered under Part B) are included in the Part D benefit.

However, for the coverage of home infusion drugs to be meaningful for Medicare beneficiaries, CMS also must cover the services, supplies and equipment related to the provision of these drugs. Limiting coverage to the drugs only without the services, supplies and equipment will not produce meaningful coverage of infusion drugs in outpatient settings. This is because infusion pharmacies will be unable to provide infusion drugs without adequate payment for the services, supplies and equipment.

The most appropriate mechanism for such coverage of infusion services, supplies and equipment provided under the proposed rule is the dispensing fee. In the preamble, CMS sets out three options for defining dispensing fees under the new benefit and invites comment on each.

- Option 3 comes closest to accurately recognizing the fundamental elements – including the services, supplies and equipment – that are essential for the provision of home infusion drug therapy. Option 3 is the only option that reflects the fundamental elements of home infusion drug therapy (see additional discussion in subsequent sections of these comments).

- In contrast, Option 1 only provides the perspective of retail pharmacies and does not meet the needs of Medicare beneficiaries requiring home infusion drug therapy.

- Although Option 2 captures the supplies and equipment used in the provision of home infusion drug therapy, this option falls far short of recognizing the essential professional services required to provide home infusion drug therapy because it does not recognize the professional services that are required to provide safe and effective infusion therapy in the home.

B. CMS should adopt Dispensing Fee Option 3 because it is consistent with the well-established standards of practice for home infusion drug therapy.

The major independent accreditation organizations, including the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), have established extensive, detailed standards regarding the patient management, support services, facilities, patient safety, policies, procedures and functions that must be provided by home infusion pharmacies. These standards, which address issues ranging from the requirements for sterile preparation of infusion drugs to the oversight of patient therapy, are significantly different from the standards governing traditional retail pharmacies.

Option 3 is the only dispensing fee option that adequately reflects the content of these national accreditation standards. For example, one major difference between retail pharmacies and home infusion pharmacies is the urgency surrounding the initial referral from a physician or hospital and the resulting home delivery/patient education requirements. Due to the severity of the patient's illness (such as a serious infection which has not responded to oral medications), pressures on hospitals to discharge patients as soon as possible, and stability/refrigeration requirements for many medications, home infusion pharmacy staff frequently have to deliver directly to patients' homes the same day as the referral. This is considerably more expensive than a retail pharmacy model where the patient or caregiver visits the pharmacy in person to pick up the drug. All of this must take place in conjunction with insurance verification, coordination with the nurse who will teach the patient, compounding by a home infusion pharmacist, and eventually, billing third party payors and collecting patient co-pays – all activities that are not applicable to the retail setting.

The well-established understanding of the professional services involved in providing in home infusion drug therapy is not merely an industry definition. Payers, clinicians, clinical societies, providers and accrediting organizations share a common understanding of what is involved in providing these therapies in outpatient settings.

C. CMS should adopt accreditation requirements under Dispensing Fee Option 3 as a straightforward means to protect Part D enrollees.

As the first homecare provider to seek and obtain JCAHO accreditation in the 1980s, Apria has a longstanding commitment to ensuring that the professional services and functions we provide meet a demanding set of quality standards. Apria recently completed its latest triennial survey cycle, with a successful outcome in all infusion pharmacies, respiratory and medical equipment locations. Our company has served as a pilot for innovative survey techniques developed by the JCAHO, and our management has formally served on advisory committees of the organization. Today, our quality standards meet or exceed JCAHO's requirements, which is a requirement of the over 2500 private sector managed care plans with which we contract to provide home infusion services.

In the final rule, CMS should address the qualifications of the infusion pharmacies that may provide the elements of care described under Dispensing Fee Option 3. We recommend that CMS require every pharmacy providing infusion services to be accredited as a home care pharmacy by a recognized national accrediting organization. We also recommend that every entity that provides nursing services to Part D infusion patients be either accredited as a nursing agency as an extension of their existing home infusion accreditation, or be a Medicare-certified home health agency.

Private sector plans require accreditation as a basic assurance that the pharmacists and nurses are experienced and the pharmacies are staffed properly to provide the necessary care. The quality standards required of home infusion pharmacies and nursing agencies by the accreditation organizations have become the community standard for the provision of home infusion therapy.

D. CMS should use a refined version of Dispensing Fee Option 3 to define the full scope of necessary professional infusion pharmacy services.

All infusion patients, whether or not they qualify for the home health benefit, require professional pharmacy services that again differ from those found in the retail setting. The general categories of such services are:

- Compounding medications in a sterile environment
- Dispensing
- Ongoing Clinical Monitoring
- Care Coordination with other agencies involved in patient care

- Provision of Supplies and Equipment
- Multiple Categories of Pharmacy Professional Services, such as pharmacokinetic drug monitoring or parenteral nutrition formula development
- Administrative Services
- In-home delivery, patient and caregiver education
- Third party billing
- Other Support Costs

These services are described in greater detail in a number of accreditation materials and other forums, including a document on the website of the National Home Infusion Association describing the "per diem" model.[2]

We propose a modification to Dispensing Fee Option 3 to more explicitly describe the pharmacy professional services that are needed for home drug infusion therapy. The pharmacy services referenced above in the model per diem definition (and generally described in Dispensing Fee Option 3) should be included in the dispensing fee for all Part D infusion patients. Most of these functions would be captured in the Option 3 definition of dispensing fees.

Both private payers and Medicare Advantage plans use per diem payments that are tied to the intensity level of the particular infusion therapy. For over 20 years, these plans have essentially developed resource-based relative value scales to capture the intensity, in terms of time and resources involved in providing each infusion therapy safely and effectively. Thus, the plans do not use a single per diem amount for all infusion therapies. We recommend that the PDPs follow this approach under Medicare Part D.

E. CMS can establish easily-administered safeguards to avoid any duplicate payments for nursing services

CMS raises a question in the proposed rule regarding how to ensure that the services captured in Dispensing Fee Option 3 are not reimbursed under the home health benefit or otherwise.

The potential area of concern involves the infusion patients who also qualify for the Medicare home health benefit. For this subset of infusion patients who also qualify for the home health benefit, it would be a simple matter to first determine whether a beneficiary qualifies for the home health benefit before reimbursing Part D funds for nursing services. The majority of beneficiaries who require infusion drug therapy do not qualify for the home health benefit, and their nursing services should be paid under the Part D benefit as part of the dispensing fee.

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[2] National Home Infusion Association. National Definition of Per Diem. June 2003. *Available at* www.nhianet.org/perdiemfinal.htm.

Importantly, the home health benefit does not cover any of the pharmacy services described in the preceding subsection of these comments.

By first identifying beneficiaries who qualify for the home health benefit, the nursing component, when medically necessary, should be reflected in the dispensing fee but only for beneficiaries who do not qualify under the home health benefit for nursing services. Importantly, nursing care is not included in the model per diem definition (discussed above) nor in the HCPCS "S" coding structure (discussed below) used by private payers.

Private payers typically separate out nursing from the pharmacy-related costs represented by the per diem. They share the Medicare program's natural concern about nursing costs, and these plans have concluded the best means of tracking and controlling nursing costs is to use a separate payment mechanism for nursing.

F. CMS can establish easily-administered safeguards to avoid duplicate payments under Medication Therapy Management Programs.

CMS asks for comments regarding how to ensure that the Medicare program avoids making duplicate payments if the PDPs pay for infusion-related dispensing fees as well as medication therapy management services.

Generally, the dispensing fee as defined in Dispensing Fee Option 3 will capture most of the services and functions described in our per diem model plus the nursing component, and there will not be a clear need for a separate payment to infusion pharmacies for additional medication therapy management services. We believe that the primary situation where medication therapy management services may be indicated is where an infusion pharmacy has to coordinate the activities of another pharmacy.

However, if CMS does not choose Dispensing Fee Option 3 for defining dispensing fees, then CMS should not consider the medication therapy management program as a substitute for covering the services, supplies and equipment required to provide infusion drug therapy. The limitations on the applicability of the medication therapy management program (*i.e.*, it is limited to patients with chronic conditions and multiple medications) make it a poor vehicle for capturing the clinical monitoring functions required of infusion pharmacies for all infusion patients.

III. Contracting with Home Infusion Pharmacies

A. CMS should establish separate and distinct requirements for PDPs to contract with sufficient numbers of home infusion pharmacies to ensure adequate enrollee access to home infusion drug therapy under Medicare Part D.

CMS should establish specific safeguards for home infusion pharmacies to ensure meaningful enrollee access to home infusion drug therapies. A number of important differences exist between home infusion pharmacies and traditional retail pharmacies that highlight the need to create separate requirements for the two types of pharmacies. For example–

- Home infusion pharmacies provide specific essential services that are not provided by the vast majority of retail pharmacies or mail order pharmacies.

- Home infusion pharmacies must maintain facilities, equipment and safeguards for compounding and storing sterile parenteral drug solutions, which is not common among retail pharmacies.

- Home infusion pharmacies are responsible for the care of their patients 24 hours a day, seven days a week, while retail pharmacies are not.

- Home infusion pharmacies are subject to separate state licensure, regulations and accreditation standards from retail pharmacies.

- The contracts used by private health plans for home infusion pharmacies are structured differently from the contracts used for retail pharmacies.

- The total number of traditional retail pharmacies in the United States far outweighs the total number of home infusion pharmacies.

These differences are echoed in the preamble of the proposed rule, where CMS discusses its findings regarding important distinctions between home infusion pharmacies and retail pharmacies.[3]

To ensure that Part D enrollees have sufficient access to home infusion drug therapy, CMS should adopt its proposal to establish distinct access standards for home infusion pharmacies in the Final Rule. This would be consistent with Congress' general mandate that CMS must ensure enrollees have convenient access to pharmacies, as access to a retail pharmacy does not by itself meet the needs of a beneficiary who requires infusion therapy.

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Please note that the description of infusion therapy as described in the FAQ tracks very closely with the language of Dispensing Option 3 in the proposed rule. We recommend that the specific wording already posted on CMS's FAQ be included as the infusion claiming requirement in Part D regulations. To do so will increase the level of administrative standardization in infusion claims transactions per the objectives of HIPAA, while also ensuring that home infusion providers and Part D payers comply with the HIPAA regulation when implementing Part D claiming transactions. If CMS does not require that Part D home infusion therapy claims be submitted on the 837, then it would open up the possibility for some Part D payers to ignore the fundamental differences of home infusion therapy from retail pharmacy and implement only NCPDP claiming—forcing infusion pharmacies to be out of compliance with HIPAA.

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This would deprive the PDPs and CMS of a valuable tool for tracking important patient-specific data. Consolidated 837 claiming would facilitate the consolidation of all drugs along with the professional pharmacy "per diem" services, equipment and supplies into single claims billed for infusion therapies, easily mapped into patient services utilization data bases for analysis—whereas the possibility of billing infusion drugs separately via the retail NCPDP claim format results in loss of this consolidated data for analysis.

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Although CMS does not have a single HIPAA coding standard for drugs, we believe that the PDPs and CMS will find requiring NDC drug coding for Part D claims will provide best opportunity for patient utilization analysis and tracking of total Part D drug costs for CMS's program administration. We believe the Part D regulations should require that all claims for drugs be coded with NDC numbers.

D. Coordination of benefits.

In addition to these reasons for infusion claiming and coding consistency, the COB portion of the Part D program is also best implemented by CMS's establishing a requirement for 837 claiming and use of the established coding systems. The majority of COB will occur with commercial payers such as the Blues and other private health plans. As the private sector has already widely adopted the established coding systems described above, it will be important for CMS to require consistent coding adoption to make COB work, ensuring that the allocation of payment for services between Part D plans and other primary or secondary plans works well.

Since the private payer sector accepts home infusion therapy claims using the HIPAA-compliant X12 N 837 format, for COB to work effectively is another reason that CMS should require PDPs to use the 837 claim format for infusion claims. Because a very large majority of private infusion payers use the HIPAA-complaint *professional* 837 (837P) claim format, to make COB work we believe that CMS's Part D regulations should require PDPs to adopt the HIPAA-compliant 837P format only, excluding both the *institutional* 837 and NCPDP transaction from use.

E. CMS should clarify the any willing provider requirements with respect to home infusion drug therapy.

CMS should clarify that this access safeguard is to be applied to any willing provider of home infusion therapy meeting the infusion-specific quality standards (see below), as distinct from retail pharmacies. Such a requirement is consistent with the statutory language.[6]

In addition, for the purpose of the any willing provider requirements, CMS should clarify that prescription drug plans should have a standard contract for home infusion pharmacies.

These recommendations for the network access standards will help safeguard enrollee access by ensuring that the Medicare Part D benefit reflects common private sector practices for home infusion drug therapy. In addition, the recommended clarifications will not impose significant burdens on PDPs.

F. CMS should recognize that OBRA 1990 standards do not represent the standard of care for infusion pharmacies.

In the preamble, CMS refers to Section 54401 of the Omnibus Reconciliation Act of 1990, stating that the regulations issued pursuant to that section in 42 CFR 456.705 "describe currently accepted standards for contemporary pharmacy practice and our intent is to require plans to continue to comply with contemporary standards." CMS seeks comments on whether these standards are industry standards and whether they are appropriate for Part D.

The OBRA 1990 standards were written for retail pharmacies. The drafters of these standards did not attempt to address the standard of care for infusion pharmacies. Infusion pharmacies that are in compliance with the infusion-specific standards established by accrediting organizations meet the OBRA 1990 standards, but the OBRA 1990 standards do not reflect "contemporary pharmacy practice" for infusion pharmacies. The community standard of care for infusion pharmacies is found in the accreditation standards that are required by virtually every private health plan, as well as numerous MA plans, to participate in their provider networks.

The quality assurance standards followed by home infusion pharmacies—and as required for accreditation--far exceed the OBRA 1990 standards. Due to advances in newly-approved drugs and technology and additional laws and regulations established in the intervening years (such as HIPAA), and development of knowledge surrounding patient safety and medication management at home, the level of patient data collection, assessment and intervention in the infusion clinical model goes far above and beyond the quality standards currently used for Medicaid. Again we respectfully direct your attention to Jared Adair's April 8, 2003 comments concerning the key differences between retail and home infusion pharmacies.

[6] Social Security Act, Section 1860D-4(b)(1)(A).

IV. Formulary Development

A. CMS should mandate that PDP and MA-PD plan sponsors maintain an open formulary for infusion drugs to ensure this population of vulnerable patients has appropriate access to necessary medications.

Much of the MMA is based on the premise that Medicare can take advantage of cost-savings techniques commonly used in the private sector and still deliver quality services to Medicare beneficiaries. CMS should note that although private health plans commonly use restricted or preferred formularies for drugs delivered orally, via patch or other non-invasive methods, private plans rarely apply these formulary restrictions to infusion drugs.

As discussed in greater detail below, there are numerous clinical and operational barriers to establishing formularies for infusion drugs. As a result, with respect to infusion drugs, formularies should remain open.

B. CMS should recognize that PDPs and pharmacy and therapeutics committees are not well situated to evaluate infusion drugs.

It will be difficult for PDPs and traditional pharmacy and therapeutics committees (P&T committees) to evaluate infusion drugs in the same manner that they evaluate orally administered drugs.

P&T committees generally evaluate the relative safety, efficacy, and effectiveness of prescription drugs within a class of prescriptions drugs and make recommendations to a health plan for the development of a formulary or preferred drug list. Frequently, P&T committees focus on the "therapeutic equivalence" of different multisource drugs (*i.e.*, whether one drug will have the same desired clinical impact as another). However, such evaluations are performed in a context where the method of administering the drug is not significant.

In contrast to oral drugs, the method of administration for an infusion drug may have separate and significant clinical and cost implications. All infusion drugs require a device of some type to deliver the drug into the body, including various catheters temporarily or semi-permanently implanted in each patient depending on the anticipated duration of therapy, potential side effects of the drug and the patient's diagnosis itself. Various methods of drug delivery also exist, from IV bags hung on poles to sophisticated external or internal infusion pumps. A patient's clinical condition may determine not only what device is selected for delivery, but also what drug should be used. For instance, many patients receiving infusion therapy are at high risk of infection or complications from infection. Consequently, a physician may need to choose a medication that can be prepared in advance in a pharmacy clean room and administered once a day to reduce the risk of infection from preparation in the home or multiple intravenous access device manipulations.

Similarly, in selecting a medication for a patient, a physician often needs to consider administration access type and what delivery technology will be best suited for use in a particular patient's home. If the patient is capable of managing a portable infusion pump, drugs requiring longer infusion times may become more clinically appropriate. If other technologies are used, such as IV bags hung on poles, the patient may require more frequent nursing visits to monitor the risk of infection.

The typical P&T Committee would usually not have the experience to evaluate the administration technology or professional support requirements, such as nursing visits, in reviewing infusion drugs. Furthermore, such committees do not typically make decisions considering all available treatment options throughout the continuum. Drugs considered ideal in an inpatient setting are often not desirable in the home setting and visa versa, especially where the first dose of the drug is concerned. Examples include Taxol® for ovarian cancer, Lovenox® for deep vein thromboses and certain immune globulins.

In addition, most infusion drugs must be compounded by the pharmacy. Once compounded, these drugs lose stability over time or be impacted by changes in temperature. For oral drugs, the frequency of administration or stability issues usually do not pose challenges for a P&T Committees as they try to determine therapeutic equivalence.

Ultimately, the infrastructure for protecting patient interests in formulary decisions—the traditional P&T Committee—does not have the ability to evaluate the extra-pharmacological considerations that must be taken into account for infusion treatment, including the administration device, drug stability, proximity to a compounding pharmacy, available administration access site and infection risk. Typically, these factors would be addressed by a physician or pharmacist knowledgeable about an individual's patient's circumstances and history when selecting a drug and delivery device.

C. CMS should recognize home infusion patients as a particularly vulnerable population that requires additional protection.

Patients receiving home infusion therapy are one of the truly vulnerable populations of the Medicare population, and as CMS acknowledged in the Proposed Rule,[7] the medical needs of such populations necessitate that they receive special protection under Medicare Part D. Infusion drugs are used to treat some of the most severe illnesses, including cancer, severe infections, pain and loss of gastrointestinal integrity.

Although the Medicare Part D regulations do create an appeals process for patients if their physician's choice of medication is not on formulary, patients with these compromising illnesses are the least capable of exercising an appeals right. If a patient does not have a family member or physician willing to take on the burden of being an advocate, then the patient's care could be compromised.

[7] 69 Fed. Reg. at 46661.

* * * *

We commend CMS for its initial efforts to understand and accurately define home infusion drug therapy under Medicare Part D. There is an important opportunity for the program to replicate the successes achieved by private health plans and Medicare managed care plans. There is also a risk that in the absence of sufficient direction from CMS and some targeted safeguards, the benefits of home infusion drug therapy will be lost for both beneficiaries and the overall Medicare program.

We would be pleased to provide additional assistance regarding these important issues. Please contact Lisa Getson, Apria's executive vice president, at 949-639- 2021 if you have any questions or comments.

Sincerely,

Lawrence M. Higby
President and Chief Executive Officer

CC: Herb Kuhn
Leslie Norwalk

Submitter : Ms. Connie Maranville **Date & Time:** 10/04/2004 08:10:02

Organization : HCR Manorcare

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

HCR Manorcare supports NHIA's position with regard to the issues relating to coverage for home infusion services as part of the Medicare Part D benefit. It is critically important that patients have access to infusion medications and the associated services required to provide them safely.

CMS-4068-P-1209

Submitter : Mr. Jon Rawlson **Date & Time:** 10/04/2004 08:10:59

Organization : PharMerica

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

See Attached Comments

CMS-4068-P-1209-Attach-1.doc

PHARMERICA

October 4, 2004

VIA OVERNIGHT MAIL AND ELECTRONIC SUBMISSION

The Hon. Mark McClellan, MD, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 309-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: CMS-4068-P

Re: Comments On Medicare Program; Medicare- Prescription Drug Benefit, Proposed Rule, 69 Federal Register 46632, August 3, 2004, CMS-4068-P

Dear Dr. McClellan,

PharMerica appreciates the opportunity to comment on the proposed rule *Medicare Program; Medicare- Prescription Drug Benefit, Proposed Rule, 69 Federal Register 46632, August 3, 2004, CMS-4068-P*. PharMerica Inc., is the third largest long-term care (LTC) pharmacy provider in the United States servicing more than 200,000 frail elderly in 2,000 skilled nursing facilities as well as hundreds of other dually eligible residents in similar institutional settings.

In the preamble for the MMA, CMS recognizes the value that LTC pharmacy providers bring to institutionalized residents of nursing facilities. This value extrapolates into enhanced patient care for our frailest, sickest and most unfortunate senior citizens. A synergistic one-to-one relationship has evolved between the skilled nursing and LTC pharmacy provider industries to provide optimal pharmaceutical care to these residents. PharMerica feels strongly that extreme care must be exercised during the implementation of the MMA to ensure that the one-to-one relationship between a skilled nursing facility and a LTC pharmacy provider is not weakened. A diminished one-to-one relationship could result in a decrease in the quality of pharmaceutical care for LTC residents. This

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has the potential to produce cost shifting to other healthcare providers and venues, such as state Medicaid and federal Medicare programs, when LTC residents require hospitalization due to drug related problems.

In order to reduce the potential for drug related problems and medication related errors and incidents, nursing homes and LTC pharmacy providers have invested significant time and resources to develop facility specific standards, policies and procedures, formulary management guidelines, dispensing systems, compliance packaging and other systems designed to decrease process variation and medication errors associated with that variation. Just as many nursing homes once had their own pharmacy within their walls (similar to hospitals), to provide optimal care to their residents; the current external one-to-one relationship has been designed to form a partnership that serves to improve medication therapy and outcomes.

In addition to safety related issues, long-term care pharmacies also work to develop and implement streamlined processes around ordering and delivery of medications. These systems allow nursing home staff to spend more time with direct patient care and less time managing pharmacy processes.

Multiple pharmacies servicing a single nursing home would require nursing home staff to manage multiple processes and systems, which in our experience would be detrimental to resident care. To assure patient safety while optimizing therapy, it is important to assure rapid access to safe and efficacious medications. If a nursing home is forced to interact with multiple pharmacies and PDPs, it is expected that formulary variations will cause confusion and delays in therapy. A delay in the commencement of therapy, in this patient population, could have significant negative results.

Nursing homes now care for the frailest and sickest of our elderly citizens. The litany of diseases and conditions that afflict nursing home residents commonly requires the administration of multiple medications each day. When prescribed and administered properly, medications can prolong survival and enhance quality of life. When prescribed or administered improperly or in error, these medications can cause morbidity and mortality.

Contracting With PDP's

PDPs should be required to contract with LTC pharmacies, and establish standards of access in order to preserve the one-to-one relationship between the LTC pharmacy provider and a nursing facility. Skilled nursing facilities must be able to continue their contractual relationships with their LTC pharmacy provider to maintain the quality and continuity of service for their residents. By requiring a contractual

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relationship between PDPs and LTC pharmacies, LTC pharmacies will be able to maintain the one-to-one pharmacy to facility relationship and ensure that plans have the capacity to meet the specialized needs of all Medicare enrollees in long term care facilities and ensure that long term care facilities meet federal and state quality, licensure and certification standards.

PDP's should also provide standardized long term care pharmacy contracts that recognize LTC pharmacy's essential role in the delivery of needed services to long term care facility residents.

Closed Versus Open Formularies

CMS should mandate an open, broad, geriatric-based formulary for all PDP's. Closed formularies for the geriatric population will result in a negative impact on quality of care and patient outcomes. The geriatric institutionalized patient has unique needs due to differences in drug clearance and metabolism, resulting in varied medication response from patient to patient. Additionally, unique concerns of the long term care resident, such as dysphasia and feeding tubes, require varied dose forms to ease administration (i.e. liquids, medications that can be crushed, injectibles, soluble dose forms). Each skilled nursing facility should have only one formulary to administer to its residents. Dealing with multiple formularies may result in medication errors due to the complexity and restrictions of ordering and administering. If a medication is not covered under a certain formulary, the nursing staff may not have the order changed to a covered item in a timely manner, resulting in a missed dose or possibly borrowing the unavailable medication from another resident. All LTC facilities are inspected at least annually by state and/or federal surveyors, and could be cited and fined for not administering medications according to physician's orders. Multiple formularies may delay the start of therapy – potentially putting the LTC facility at risk for regulatory non-compliance.

Inclusion of the Proposed Formulary Non-covered Drugs

PharMerica recommends that drugs proposed as exclusions in the MMA be covered for institutionalized patients and that payment for these medications be available by appeal for non-institutionalized patients. The draft regulations exclude benzodiazepines, barbiturates, medications used for weight gain, and over-the counter medications. Benzodiazepines are most often used in LTC facilities to treat anxiety, often associated in the adjustment process of being admitted to a facility. Additionally, some benzodiazepines are used to treat status epilepticus, a life threatening condition. Withdrawing benzodiazepines from patients who have been using them for an extended period may result in severe withdrawal symptoms and increased healthcare costs. Barbiturates are also excluded from coverage under the draft guidelines. Barbiturates such as phenobarbital are used to treat epilepsy in the geriatric population, and should be covered. Medications used to stimulate weight gain should also be covered.

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Unintentional weight loss in the elderly may result in unfavorable sequelae, such as a decrease in activities of daily living, and increased chance of depression and infection. Additionally, unintentional weight loss is a federal quality indicator used by federal and state surveyors to assess the quality of care in skilled nursing facilities. Lastly, if over-the-counter medications are categorically not covered, it may result in cost shifting to more expensive prescription medications, when a less expensive over-the-counter alternative is available.

Procedural Requirements for Expedited Coverage

CMS must mandate that PDP's provide an adjudication process that assures timely availability of non-formulary medications to institutionalized residents. If the formulary provisions of this regulation are implemented as proposed, CMS should anticipate an enormous number of formulary appeals. This will be due to that fact that many currently preferred medications for geriatric patients will not be included in PDP formularies because of their costs.

PDP appeal processes for non-covered medications should be streamlined, standardized, and approved by CMS. We also recommend that CMS should mandate that claims be adjudicated at point of sale. Appeal response time should be no longer than 24 hours. To assure that the long term care resident does not miss treatment, PDP's should cover a 3 day supply of the non-formulary medication to treat the resident while the appeal is under review. An appeal should be able to be initiated by the attending physician or the long-term care facility.

Payment for Non-formulary Yet Medically Necessary Drugs

If a PDP refuses or fails to pay for a non formulary medication that is determined to be medically necessary by the treating physician, CMS must establish who will cover these costs for a dually eligible institutionalized Medicare D recipient. Such reimbursement dilemmas are sure to occur unless provisions are included in the final regulations.

Fair Reimbursement Model for LTC Pharmacies.

LTC pharmacies focus on serving the needs of the frail elderly or disabled who reside in institutional settings. The patients we service represent some of the most dependent patients in the Medicare and Medicaid programs. Statistics now show that the average patient serviced is 83 years of age, has 7.8 different medical diagnoses, and takes 8 to 10 medications at any given time. (1)

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The needs of these patients differ vastly from the needs of a typical ambulatory (retail serviced) geriatric patient. To meet these needs a LTC pharmacy provides services greatly in excess of a retail pharmacy. These services include unit dose packaging for medications, emergency services, intravenous therapy, delivery, consulting services and medical records services. These services are necessary to ensure the best possible pharmacy care to these patients.

With the implementation of Medicare Part D the majority of a LTC pharmacy's reimbursement will come directly from a federal program. In order for this industry to continue to ensure the safety and care of LTC patients, reimbursement must be commensurate with the services provided.

Reimbursement should be adjusted periodically for inflation and must take into account the costs of administering the program. Payment terms should be comparable or better than payment terms with current Medicaid programs which vary between 7 - 30 days.

Usual and Customary Fee for A LTC Pharmacy

The dispensing fee paid should reflect the services provided. PharMerica recommends that CMS provide for a dispensing fee under Option 1 that encompasses the services that LTC pharmacies perform such as unit dose packaging for medications, emergency services, intravenous therapy, delivery, consulting services and medical records services. These services are vastly different from a retail pharmacy. A study done by BDO Seidman (see attached) in April, 2002 found that it costs long term care pharmacies, on average, $11.37 to dispense a prescription. This figure did not include a return on equity or a profit margin – it simply reflected the costs of operating a long-term care pharmacy. This study should guide CMS in establishing dispensing fees paid to LTC pharmacies. In contrast, the National Association of Chain Drug Stores (NACDS) estimated in 2000 that it costs a chain pharmacy, on average, $7.05 to dispense a prescription to a retail customer.

It is important to note that without adequate reimbursement, LTC pharmacies will have two options – reduce service levels or close their doors. Either scenario will negatively impact institutionalized patients, the most dependent segment of the Medicare and Medicaid populations.

PDP Assignments for Dual Eligibles

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Upon admission to a long term care facility, CMS should seek ways to limit the auto enrollment of dual eligible beneficiaries into PDP's that includes the LTC pharmacy that is serving the resident's nursing facility. If this is not possible, the beneficiary should be auto enrolled and the servicing pharmacy should have the ability to provide services for the resident as an out-of network provider.

The coordination with the LTC pharmacy will ensure the most efficient drug delivery system for the facility. Admission to a long term care facility should be construed as an address change for the resident and open the administrative option to enact a change in the dual eligible beneficiary's PDP election.

Expand the Definition of LTC

Based upon our experience, as a national provider to all types of facilities where residents and patients require assistance with the administration of their medications, we recommend that CMS expand the definition to cover assisted living facilities, ICFMR facilities, group home facilities and other waiver groups where dual eligibles are serviced. LTC pharmacies exist because of the needs of institutionalized patients. These patients typically require a large number of medications, need assistance with medication administration, and need more pharmacist oversight due to the complexity of their pharmaceutical care.

All of these needs equate to more stringent medication packaging and delivery systems. These requirements are typically met by a LTC pharmacy but in some cases are handled by a retail pharmacy. Any pharmacy that provides these services because of the needs of the institution should be reimbursed for these services. Service level should determine the reimbursement.

Conclusion

In summary, we provide the following list of recommendations to CMS.

- CMS should require, PDP plans to contract with LTC pharmacies by requiring plans serving LTC facilities to abide by a one nursing home – one LTC pharmacy relationship.

- CMS should mandate a broad, open and geriatric – based formulary for all PDP's.

- CMS should work closely with state Medicaid programs to ensure, in the short-term, that benzodiazepines and barbiturates, over-the-counter drugs, and medications used for intended weight loss be covered.

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- CMS should mandate that all PDP's provide a timely adjudication and appeals process to assure availability of medications to all long term care residents.

- CMS should determine adequate coverage and payment for non-formulary medications determined to be medically necessary for a long term care resident.

- CMS should provide for a fair and adequate reimbursement method including separate dispensing fees based on the complexity of dispensing a drug. We recommend a separate dispensing fee which recognizes the costs of specialized packaging, around – the –clock service and delivery, emergency services, services and supplies associated with infusion therapy, and other considerations deemed appropriate.

- CMS should expand the definition of "long-term care facility" to include residents of congregate alternative living arrangements for the elderly that "assist with" or "manage" medication administration for its residents. These facilities include intermediate care facilities for the mentally retarded and hospice, as well as any facilities regulated by State law.

We appreciate the opportunity to comment to CMS and want to express our appreciation to the agency for its hard work during the implementation process. We trust that our comments will assist the agency in developing regulations and policies which will enhance the delivery of medications to the nation's frail elderly residents of nursing homes and ensure their safety and well being.

Sincerely,

Jon B. Rawlson
Vice President, Government Affairs

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(1) D.E.Tobias and M.Sey, *General and Psychotherapeutic Medication Use in 328 Nursing Facilities: A Year 2000 National Survey*, 16 Consult. Pharm. 54 (2001)

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Submitter : Mr. John Hoff II **Date & Time:** 10/04/2004 08:10:20

Organization : Horizon Healthcare Services

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

see attached.

CMS-4068-P-1211

Submitter : Mr. Michael Wolf **Date & Time:** 10/04/2004 08:10:59

Organization : Horizon Healthcare Services

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

Please see attached

CMS-4068-P-1211-Attach-1.doc

Horizon Healthcare Services is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Horizon Healthcare services the home infusion needs of thousands of patients in south central Pennsylvania every year including many Medicare recipients. Founded in 1984, our highly trained healthcare professionals have the experience and skills necessary to create positive clinical outcomes for the patients we serve while at the same time conserving scarce healthcare dollars by treating patients at home and avoiding costly hospitalizations.

Horizon Healthcare Services appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

* Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm <http://www.nhianet.org/perdiemfinal.htm> .

* CMS should establish specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require specific standards for home infusion pharmacies under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the X12N 837 P billing format for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should mandate that prescription drug plans maintain open formularies for infusion drugs to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Michael F. Wolf, Jr

Account Executive

Horizon Healthcare Services
2106 Harrisburg Pike, Suite 101
Lancaster, PA 17601

CMS-4068-P-1212

Submitter : Mr. Scott Melville **Date & Time:** 10/04/2004 08:10:34

Organization : Healthcare Distribution Management Association

Category : Association

Issue Areas/Comments

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Please see the attached file.

CMS-4068-P-1212-Attach-1.doc

Healthcare Distribution Management Association
Products, Services and Information for Your Health

John M. Gray, President and CEO
Eric Schuss, Chairman of the Board

October 4, 2004

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Via Electronic Submission

Re: Medicare Program; Medicare Prescription Drug Benefit, Section 423.153 (d) [CMS-4068-P]. 69 Fed. Reg. 46632 (August 3, 2004).

Dear Dr. McClellan:

The Healthcare Distribution Management Association submits the following comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed rule, *Medicare Program; Medicare Prescription Drug Benefit*. 69 Fed. Reg. 46632 (August 3, 2004). I am writing to commend CMS for its efforts to implement the Medication Therapy Management Programs (MTMPs) included in the new Medicare Part D benefit, to be codified in section 423.153 of the proposed rule. HDMA believes that MTMPs will be an important addition to the benefits that seniors can receive under the Medicare program and we encourage you to work with the pharmacy community to craft a benefit program that adequately meets the needs of chronically ill beneficiaries.

HDMA is the national trade association representing full-service distribution companies responsible for ensuring that billions of units of medication are safely distributed to retail pharmacies, hospitals, nursing homes, clinics, and other provider sites across the United States. HDMA's distributor members provide services to approximately 141,591 pharmacy settings, including: 17,913 independent pharmacies; 19,824 chain pharmacies; 9,918 food stores; 9,992 hospital pharmacies; 4,872 mass merchandisers; 5,397 long-term care and home health facilities; 62,364 clinics; 1,170 healthcare plans; and 366 mail order pharmacies.[1] It is within these settings that patients interact with their pharmacists and receive important direction regarding their medications.

[1] Table 228 – Class of Trade Analysis – Manufacturer Sales by Customer Categories: 2002-2003.HDMA Industry Profile and Healthcare Factbook, Healthcare Distribution Management Association. (2004).

HDMA has long-believed that appropriate use of prescription drugs not only enhances the patient's quality of life but can also decrease the need for hospitalization or surgery. We believe that disease management and medication therapy management programs will contribute to obtaining favorable patient outcomes. Additionally, when chronically ill patients have access to specialized guidance regarding their medications and their drug therapies are more carefully monitored, it is possible that they can achieve greater results from their course of treatment and perhaps suffer fewer adverse events related to their illness or drug interaction.

It is also important for CMS to recognize the demonstrated value of individualized patient care services and to ensure appropriate and fair reimbursement for the professionals who provide such services. MTMPs involve the collaboration of the pharmacist with physicians, nurses and other healthcare professionals to ensure that medications are used appropriately to improve patient health status, improve the patient's quality of life and contain healthcare costs. CMS should devise appropriate payment mechanisms that acknowledge the important role of the pharmacist and the resources involved in providing individualized guidance for beneficiaries in order to ensure that they receive the most favorable results possible from their prescribed course of treatment.

HDMA distributor members do not serve patients directly, but as part of our role in facilitating patient access to necessary medications, we believe that it is important to support development of MTMPs that contribute to favorable outcomes and that are flexible enough to provide individualized patient care. In addition, MTMPs can lead to an overall reduction in healthcare costs. Therefore, it is critical that CMS develop this benefit in cooperation with the pharmacist and pharmacy communities. In determining the parameters of MTMPs, CMS should consider patient-specific treatment requirements; patient education relative to prescribed medications; the pharmacist's ability to monitor patient progress, and identify and resolve problems that are medication related; in-person consultations between the pharmacist and patient; and reimbursement rates that accurately reflect the resources and expertise that are required to provide effective medication therapy management. HDMA supports development of a MTMP benefit that ensures that the beneficiaries who have the greatest need for such programs are identified and ensured access to these important services.

HDMA appreciates this opportunity to provide CMS with its comments regarding the new Medicare Part D benefit and CMS policy regarding Medication Therapy Management. If we can be of assistance as you continue implementation of Part D regulations, please contact me or Elizabeth Gallenagh, Manager, Regulatory Affairs at 703-787-0000 ext. 234.

Sincerely,

Scott Melville

Scott Melville
Sr. Vice President of Government Relations

CMS-4068-P-1213

Submitter : Dr. Clifford Wong **Date & Time:** 10/04/2004 08:10:34

Organization : MedImpact Healthcare Systems, Inc.

Category : Health Care Industry

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

See attachment for comments

CMS-4068-P-1213-Attach-1.doc

MedImpact Healthcare Systems Inc, Comments for
Medicare Prescription Drug Benefit Proposed Rules Review: File Code CMS-4068 P

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections

Summary: The definition of a covered Part D drug is described, as well as those drugs which are excluded from coverage. Drugs covered under Part A or Part B are excluded from Part D coverage, although there may be potential problems in defining some drugs. The definition of dispensing fee is not yet final and currently there are several options being discussed. The definitions of standard prescription drug coverage and alternative prescription drug coverage are discussed in detail. The definition of incurred costs toward spending against out-of-pocket expenses is also defined. Covered Part D drugs for Part D eligible individuals are not taken into account in "best price" calculations. We will be required to disclose aggregate negotiated price concessions to CMS. PDP plan service areas are being defined and we will need to determine whether our pharmacy network meets the pharmacy access requirements. A model formulary is being developed by USP. We are not required to use the model formulary, but we will need to obtain approval for our current formulary. USP will define therapeutic classes and we are required to have at least two drugs for each therapeutic class. We are required to issue ID cards and conform to a specific standard in designing these cards. Out-of-network pharmacy use must be allowed for certain situations and we need to develop a process to capture out-of-pocket expenses at these pharmacies. The formularies, along with other information, is required to be posted on a public website, accessible to both members and non-members. We are also required to send monthly reports to beneficiaries who use Part D services. These reports will contain individualized information. CMS is proposing to offer waivers for the requirement to always disclose the differential in price of a covered part D drug and the lowest generic version of that drug at the point of service. Confidentiality requirements are similar to those we currently have as a MA plan.

MedImpact Healthcare Systems Inc, Comments for
Medicare Prescription Drug Benefit Proposed Rules Review: File Code CMS-4068 P

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46646 46646 423.100 C.1.a P 84	*Definition of covered Part D drugs* "… a covered Part D drug must be available only by prescription, approved by the Food and Drug Administration (FDA), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). A covered Part D drug would include prescription drugs, biological products, and insulin as described in specific paragraphs of section 1927(k) of the Act and vaccines licensed under section 351 of the Public Health Service Act. The definition also includes 'medical supplies associated with the injection of insulin (as defined in regulations of the Secretary).' We propose to define those medical supplies to include syringes, needles, alcohol swabs, and gauze.	1. We still don't know which vaccines are required to be covered under Part D. Currently, no vaccines are dispensed from a pharmacy except oral typhoid vaccine. 2. Are orphan drugs considered to be Part D drugs? Some of the drugs in this classification are provided free of charge from the manufacturer, but not all. Would coverage be dependent upon the FDA approval status of the orphan drug? One paragraph on page 46662 (second column, last paragraph) implies that orphan drugs may be considered a Part D drug. 3. Are needle-free insulin injectors covered under Part D? This product costs several hundred dollars and requires the purchase replacement supplies, such as special syringes and vial adapters. 4. As mentioned in previous e-mail, we may want to confirm our presumption that imported drugs are not covered by Part D. 5. The goal to cover the gap for Part B drugs administered pursuant to a physician's visit via Part D has merit but is fraught with operational problems. There may be overlaps where drugs that are administered pursuant to a physician's visit may also be dispensed as an outpatient ambulatory prescription. PBMs administering the drug benefit need as much specificity as possible to build formularies or files for specific adjudication at the point of service. PBMs have no way of coordinating adjudication with drugs that may have been administered or paid via Part B. Concurrently, national PBMs have no way to deal with local medical review board policies in all the different regions. Formularies are plan specific, not regional and certainly not LMRB directed.

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46646 46646 423.100 C.1.a P 84	*Smoking cessation agents* "In accordance with section 1860D-2(e)(2) of the Act, the definition of a covered Part D drug would specifically exclude drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid, with the exception of smoking cessation agents."	1. Can we still continue to require proof of patient attendance of smoking cessation classes as a condition of drug coverage? Members currently pay a fee to attend the class and obtain nicotine patches as a covered benefit. Would the cost of the class accrue to the out-of-pocket expense? 2. Some smoking cessation agents are classified as OTC drugs. Would these products require a prescription in order to be covered as a Part D drug or for the costs to incur as part of the out-of-pocket expense? 3. MCO with MA PDs may have varying policies regarding smoking cessation regarding limits to number of courses of treatment and required corresponding education and course work. We would need to allow flexibility in this realm, particularly where PBMs may adjudicate the number of treatments within a given time frame. 4. This section describes the exclusion of drugs restricted under Medicaid, but the concern arises over the grievance process. Will the grievance process allow for coverage of "excluded" drugs? Will the law permit this?

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46646 46646 423.100 C.1.a P 84	*Excluded Part D drugs* "..the drugs or classes of drugs that may currently be excluded or otherwise restricted under Medicaid include – (1) Agents when used for anorexia, weight loss, or weight gain; (2) agents when used to promote fertility; (3) agents when used for cosmetic purposes or hair growth; (4) agents when used for the symptomatic relief of cough and colds; (5) prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; (6) nonprescription drugs; (7) outpatient drugs for which the manufacturer to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale; (8) barbiturates; and (9) benzodiazepines."	1. This list of excluded Part D drugs is identical to the list provided for the Drug Discount Card. Some of the classes of drugs are fairly straightforward, but some are more difficult to define. The list sometimes defines a class of drugs by its intended use or indication and, at other times, the list defines a type of drug by its chemical and/or pharmacologic classification. Barbiturates and benzodiazepines are fairly straightforward in their definition. However, "drugs used for the symptomatic relief of cough and colds" may be more difficult to define since drugs are often used for multiple indications. For example, guaifenesin tablets are commonly prescribed to treat symptoms of cough and cold. However, guaifenesin is sometimes prescribed off-label for the treatment of fibromyalgia. Would we be responsible for determining whether a given indication is appropriate for an excluded drug in these circumstances? What type of process and documentation would CMS require? 2. For the Drug Discount Card program, CMS provided sponsors with a list of NDC numbers for drugs that fall in the categories of barbiturates and benzodiazepines. We believe this list will be expanded to include all categories but #7 3. If CMS has a specific foundation list of drugs covered under Part B, please provide such that we can build an appropriate file for adjudication. Also, we would like to review the assumptions behind the selection or exclusion of drugs if such is available. 4. If CMS has a specific foundation list of drugs covered under Part B, please provide such that we can build an appropriate file for adjudication. Also, we would like to review the assumptions behind the selection or exclusion of drugs if such is available. 5. Please describe the procedure for instances where a prescription drug becomes OTC during a contract year. This could change the beneficiary coverage and formulary composition and minimum formulary requirements. How would these situations be handled?

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	Excluded Part D drugs *(Continuted)*	6. CMS is requesting comments regarding their exclusion of drugs for which there is a manufacturer requirement for lab tests through a manufacturer relationship. CMS is wondering if this is a broad enough exclusion. We should advocate for exclusion of drugs under any manufacturer restricted distribution system due to the administrative burden of repatriating these claims and beneficiary OOP costs back into our accumulator. 7. The concern arises over the exclusion of the 9 specified areas and in the specific circumstance where a drug product is included in a drug class, but it a medically necessary product for valid medical conditions (e.g. diazepam and clonazepam are benzodiazepines, but have valid medical uses for seizure related medical conditions), are these precluded from coverage, even with the grievance procedure?

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46647 46647 423.100 C.1.a P 85	*Exclusion of drugs currently covered by Medicare* "Section 1860D-2(e)(2)(B) of the Act that specifies that a drug prescribed to a Part D eligible individual that would otherwise qualify as a Part D drug cannot be considered a covered Part D drug if payment for drug '* * * *is available* (or would be available but for the application of a deductible) under part A or B for that individual.'" "The Part D drug coverage described in this proposed rule does not alter the coverage or associated rules for drugs that are currently covered by Medicare prior to the MMA, such as those included in the following list….. 1. …Drugs used in immunosuppressive therapy furnished to a beneficiary who receives an organ transplant for which Medicare makes payment. "...We intend to ensure that the Part D benefit 'wraps around' Part B drug benefits to the greatest extent possible. For example, Part D would cover immunosuppressive drugs furnished to Medicare beneficiaries who did not have their transplant paid for by Medicare (e.g. a beneficiary who had his or her transplant paid for by a private insurer when he or [sic] was employed, and the beneficiary has not enrolled in Part B)."	1. CMS is requesting comments on how to avoid coverage gaps between Part B and Part D. This will be somewhat problematic for plans since Part B coverage varies by geographic region. Plans will be left to interpret correct Part B and D coverage based upon the historical Part B coverage interpretation in their geographic area. The fix is obvious in that CMS should rationalize Part B coverage, however, they lack the statutory authority to change existing Part B coverage. 2. In order to properly process prescriptions for immunosuppressive agents, the pharmacy staff will need to know whether 1) if the medication is used for immunosuppression following a transplant and 2) if the transplant was paid for by Medicare. In addition, these medications are usually quite expensive. For patients in the "donut hole", one or two prescriptions could easily surpass the $2850 out-of-pocket expenses and push the patient into catastrophic coverage, so it will be important for the pharmacies to correctly identify whether the drugs are being covered under Part B or Part D.

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	Exclusion of drugs currently covered by Medicare (Continued)	3. The intent to insure that Part D wraps around Part B is positive in intent but likewise creates operational problems. Our broad strategic guidance to CMS is to allow a degree of flexibility to the MA-PD or PDP in this instance. PBMs do not have systems yet developed to coordinate between B & D. The data is not readily available nor easily extracted to be provided to a PBM for quick POS adjudication at a pharmacy. The simplest way, would be for CMS to develop specific lists that allow some product overlap to be covered in BOTH B & D. The PBM has no way of knowing whether transplants are paid by CMS or some other private insurer. The interlink between Part B providers and pharmacy systems does not exist. Is it possible for CMS to become a clearinghouse for such data to cover all CMS regions?
		• How will pharmacists at Point-of-Sale know the medical indication for appropriate billing?
		  ◦ If a transplant was paid for by Medicare, then the claims should be adjudicated under Part B.
		  ◦ Otherwise, the claims should be submitted under Part D.
		• When a beneficiary transfers from a Medicare Employer Group, and is now covered under Part D, how will the pharmacy know if their drug should be covered under a prior Medicare paid procedure or submitted for Part D payment?
		• Currently there is no standard method to communicate medical procedure information to PBM's for appropriate determination of adjudication.

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46647-48 46647-48 423.100 C.1.b P 87	*Dispensing Fees* "Because the statute is ambiguous on the meaning of "dispensing fee," in this proposed rule we are not proposing a specific definition of "dispensing fee," but instead are offering three different options…."	1. CMS has three definitions of dispensing fee. Option 1 allows for the cost of only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead. MedImpact's recommendation would be to follow OPTION ONE. Our systems and contracts with the pharmacy network are built upon this key fundamental financial fact. The notion is that all functions such as phone calls, or pharmacist follow up are included within that negotiated fee. Clearly, pharmacies create additional margin in the spread between acquisition cost and sales price of the drug. Pricing network pharmacy contracted services at an actual acquisition cost plus a fully loaded dispensing fee is a complex issue and not within the Part D scope. 2. Option 2: This option would include supplies and equipment which may be required for or pursuant to administration of a prescribed outpatient drug. Dispensing fee should NOT include these components. Treat the components of supplies and equipment as a a prescription for a product. Have the product as a covered item as a drug or have it sold with an appropriate margin. A dispensing fee for the equipment or supply may then be applied separately for each piece. The equipment and supplies should be treated as prescriptions. 3. Option 3: This option would include Option 2 plus clinical services required to assure safe administration of the drug. This is NOT something that PBMs can currently administer. These are fees which may be paid to nursing or other ancillary staff besides pharmacists. These fees may in fact be included in contracts established between the health plan and the IV therapy vendor. We would have to check the NCPDP capability for providing a different field for services other than dispensing a prescription. Again, keep the products separate from the dispensing, administrative, or clinical service fee. This Option affects PBM network agreements and would require potential renegotiations with 55,000 pharmacies.

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	Dispensing Fees *(Continued)*	4. The crux of the differing definitions is how to limit the payment for clinical services in the outpatient pharmacy through dispensing fees versus the need to pay for appropriate clinical services for home infusion patients. 5. As a PBM, MedImpact would prefer to NOT administer clinical service fees in the home IV arena. PBMS may administer dispensing fees for prescriptions for IV drugs, for each supply item, or piece of equipment given the existence of an NDC for such. Home IV infusion pharmacies could be a part of a pharmacy network. Each IV drug supply should be dispensed as a prescription pursuant to state and federal law. We are not clear on the types of in house pharmacy systems used by home infusion facilities nor are we familiar with their ability to have claims adjudicated via a PBM. They may do medical claims processing to a payor.

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46649 C2a	*Benefit Requirements* PDPs and MA-PDs are required to offer "qualified prescription drug coverage", which is either standard prescription drug coverage (§423.104(e)) or alternative prescription drug coverage (§423.104(f)). These two coverages are illustrated in a chart in the Appendix to this summary. In addition to the benefits discussed below, PDPs and MA-PDs must also make available to their enrollees negotiated prices. • **Standard prescription drug coverage.** Standard prescription drug coverage for 2006 (amounts are indexed by the per capita increase in Part D expenditures) includes a $250 deductible and 25% coinsurance for the next $2,000 of costs for covered Part D drugs. At the point the costs are equal to $2,250, termed the initial coverage limit, the individual is responsible for all of the costs up to the annual out-of-pocket threshold. The PDP or MA-PD may revise the cost-sharing between the $250 deductible and the $2,250 initial coverage limit as long as the cost-sharing is actuarially equivalent to 25% coinsurance. At the point that catastrophic coverage commences, which is when the enrollee has incurred costs of $3,600, enrollees will pay a copayment of the greater of (1) 5% of the cost of the drug or (2) $2 for a generic drug or a preferred drug that is a multiple source drug and $5 for any other drug. PDPs and MA-PDPs may offer tiered copayments provided that the standard for being actuarially equivalent to the 25% coinsurance, noted above, is met. [Note: Medicare Advantage plans may also apply all or a portion of any beneficiary rebates achieved by submitting bids below the benchmark for Part A and B benefits to reducing Part D beneficiary premiums.]	1. CMS would review and approve PDP sponsors', MA-PD proposed prescription drug plans. All will be trying to develop products that are actuarially equivalent to the standard Part D model. It would be helpful if CMS would have its actuaries develop models showing variables as well as CMS assumptions supporting the model. We request that these be developed in detail as examples for the final rules and solicitation forthcoming. This could also save a lot of time and provide valuable guidance for all approved sponsors. What will be the process and infrastructure used by CMS to evaluate for actuarial equivalence? 2. The language requires sponsors to accept without restrictions all individuals who are eligible for an MA plan. What is a capacity waiver? And, why would a PDP not be allowed the same consideration as an MA? 3. C.2.a.1 to 3 46649 describes incurered costs for purposes of applicability towards the beneficiary spending against the OOP limit. The incurred costs must be tracked by a PDP of MA-PD using the standard Part D. The language also describes special circumstances where there are price differentials between mail & retail and OON and usual prices within network. Such OOP differentials count. Also charitable and certain individual costs are allowed to count towards incurred costs. Insurance contributions and wrap around programs are noted to NOT count towards incurred costs. We concur with this policy but wish to comment that tracking such accumulated costs from a multiplicity of sources outside the adjudication process is NOT something within the current capabilities of PBMs. The OOP differentials incurred at a POS Pharmacy may be tracked provided there is adjudication to a benefit design. Contributions from charitable sources and other insurance may not be known to and thus not trackable by PBMs. We would support the notion of a CMS sponsored facilitation center tracking such such incurred costs and providing such data in an NCPD file format to the requesting or designated PDPs, MA-PDs. Tracking accumulator for approved incurred costs will necessitate major systems design and development for enrollment, eligibility, and pharmacy systems and databases. These changes are not minor and require significant time and money resources to accomplish. Such system development will be required prior to adjudicating Plan D benefit designs.

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	Benefit Requirements (Continued) • **Alternative prescription drug coverage**. To qualify as alternative prescription drug coverage, which encompasses basic alternative coverage and enhanced alternative coverage, the following four requirements must be met: 2. Has an annual deductible that does not exceed the deductible for standard prescription drug coverage; 3. Imposes cost-sharing no more than the 5% or $2/$5 amounts stated above at the point the annual out-of-pocket threshold is reached; 4. Has an unsubsidized value that is at least equal to the unsubsidized value of standard prescription drug coverage; and 5. Provides coverage that is designed to provide for payment that is at least equal to the amount that would be paid under standard prescription drug coverage.	
46653 2.b.ii.	• **Enhanced alternative coverage**. A PDP sponsor may offer enhanced alternative coverage if it also provides basic prescription drug coverage in the area. Basic prescription drug coverage is either the standard coverage (above) or alternative prescription drug coverage that is actuarially equivalent to standard coverage. Enhanced alterative coverage is basic prescription drug coverage and supplemental benefits, which includes: 1. Coverage of drugs other than covered Part D drugs: and/or 2. Any of the following changes or combination of changes that increase the actuarial value of benefits: o A reduction of the annual deducible; o A reduction in the cost-sharing; or o An increase in the initial coverage limit.	1. MMA seeks to allow sponsors to develop alternative actuarially equivalent benefits to the basic design that will allow more effective utilization management. The described benefit options will necessitate changes to our enrollment, eligibility and pharmacy systems. Likewise a multiplicity of designs approved for different MA-PDs within the market place decreases PBM efficiency and could increase costs to the PBM or PD administrator. Reality indicates that different MAs and PDPs will NOT have precisely the same benefit designs. Nor will plans have only one product in a competitive market. New benefits, edits, cost shares will be created to be actuarially equivalent. Each may require CMS review. CMS has recognized that actuarially equivalence is difficult to define with specificity and thus may need to allow flexibility in this regard. There are too many variables and untested assumptions in this new arena with the noted potential reduction variables. Modeling from CMS may give additional guidance.

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46649-50 46649-50 423.100 C.2.a P 91 46659	*Costs considered incurred against the out-of-pocket limit* "As a point of clarification, we also propose that beneficiary costs incurred under the following circumstances count as incurred cots consistent with the definition of that term in §423.100 of our proposed rule (with plans explicitly accounting for such price differentials in the actuarial valuation of their coinsurance in their bids): 1. Any differential between a network retail pharmacy's negotiated price and a network mail-order pharmacy's negotiated price for an extended (for example, 90-day) supply of a covered Part D drug, as described in section II.C.4.1 of this preamble, and 2. Any differential between an out-of-network pharmacy's usual and customary price for a covered Part D drug purchased in accordance with the out-of-network access rules described in section II.C.5 of this preamble and the plan allowance for that covered Part D drug." "Thus, as provided under §423.120(a)(6) of the proposed rule, a plan enrollee who chooses to obtain an extended supply of a covered Part D drug through a network retail pharmacy would be responsible for any differential between the network retail pharmacy's and the network mail-order pharmacy's negotiated price for that covered Part D drug.	1. COMMENT: Pharmacy systems vary and do not have the capability at this time to track TrOOP from ALL the various sources CMS has outlined as allowable incurred costs. How would we get costs from SPAP or ADAP & Ryan White? As a PBM, MedImpact recommends that CMS contract with a central TrOOP Facilitator Contractor to provide a NCPDP approved format file to PBMs and PDPs to allow efficient management and reconciliations at the prescription POS and to populate our accumulators. Furthermore adding 340B utilization as contributing to incurred costs towards catastrophic and to insure access to Part D creates an operations challenge which will take significant investments to coordinate. We would assume that ADAP & Ryan White beneficiaries have established retail pharmacy and designated 340B pharmacies for service points. Data from these service points or from 340B reporting may perhaps be provided to CMS for reporting, reconciliations, and financials on a broader basis outside of the existing pharmacy systems. We would look to CMS to bring the data from such sources to a Central Facilitator to distribute to PBMs, PDPs, MA-PDs in a desired NCPDP format to populate our cost accumulators for incurred costs.

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46650 46650 423.100 C.2.a P 91	*Charity contributions incurred against the out-of-pocket limit* "Section 1860D-2(b)(4)(C)(ii) of the Act provides that any costs for which a Part D individual is reimbursed by insurance or otherwise, a group health plan, or other third-party payment arrangement do not count toward incurred costs…"	1. We need to identify which regions have SPAPs as these programs can pay members cost-sharing and it will count as part of their true OOP costs. Again, this speaks to the need for a national facilitator for tracking TrOOP for incurred costs and to allow ALL sponsors the information needed for accurate POS tracking towards the catastrophic benefit. 2. CMS requests comments on coordination of ADAP with Part D: ADAP would be allowed to pay bene premiums for PART D to assure access for AIDS population to Part D as well as deductibles and cost-sharing. The ADAP paid deductibles and cost sharings, however do not count towards incurred costs. Our perspective is that if such costs DO NOT count towards the incurred costs, then we have no position as we will not need to track such on our accumulators. However, if our MA-PD needs such data for adjustments to their own charitable programs, we will not have the capability to provide. Perhaps CMS should provide the actuarial data defining the forecast for how many beneficiaries will reach the $3600 TrOOP and help to assess what systems costs need to be invested to track the various contributing sources to TrOOP. Can an actuarial adjustment be made for AIDS RYAN WHITE patients enrolled in such programs pending development of sophisticated COB systems?

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46654 46654 423.100 C.2.c P 101	*Part D negotiated prices exempt from "best price"* "As required under section 1860D-2(d)(1)(C) of the Act, prices negotiated with manufacturers for: (1) Covered Part D drugs by either a prescription drug plan or an MA-PD plan; or (2) a qualified retiree prescription drug plan, as described in §423.882 of our proposed regulation on the Medicare retiree drug subside, with respect to covered Part D drugs provided on behalf of part D eligible individuals would not be taken into account in making "best price" determinations under the Medicaid program."	1. Currently, MedImpact passes through negotiated prices to the beneficiary at the point of sale in its DDC program. We retain only those administration fees permitted by the negotiate contract with the drug company. Relative to PART D, some of our MA PD clients who negotiate their own drug prices may wish to pass these discounts on to the beneficiary via premium subsidies as well as lower prices at the point of sale. We support these options as provided by MMA. We note that CMS will require reports relative to the aggregated savings. These reports deserve the highest level of confidentiality protection. We would ask CMS to develop rules that allow MA-PD plans to provide those reports direct to CMS with needed utilization data provided by the PBM administering the PD component. 2. Relative to negotiated prices, we recommend that CMS publicly urge the pharmaceutical industry to begin developing its public policy and commitment to the Part D initiative. For DDC, negotiations for discounts were prolonged and difficult due to the uncertainty of the rules, utilization, and application of a new process. Prices were not finalized until after open enrollment in many instances. Thus it was difficult to forecast prices for reporting to CMS. Prices shown on the Price Compare were initially higher pending negotiations with drug companies which take time and resources. Thus, any political pressure that may be asserted to prompt pharmaceutical industry support for Part D may be of great societal benefit. It would also be encouraging if the work done for discounts in DDC could be touted as a strong foundation for moving forward into Part D.

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46654 46654 423.100 C.2.c P 101	*Passing savings from negotiated prices to members* "Section 423.104(h)(3) would require, as stated in the provisions of section 1860D-2(d)(2) of the Act, that PDP sponsors offering a prescription drug plan and MA organizations offering an MA-PD plan disclose to us all aggregate negotiated price concessions – including discounts, direct or indirect subsidies, and direct or indirect renumerations- they obtain from each pharmaceutical manufacturer that are passed through to the Medicare program in the form of lower subsidies or to beneficiaries in the form of: (1) Lower monthly beneficiary premiums, and/or (2) lower covered Part D drug prices at the point of sale."	1. If a MA-PD choose to pass along savings in the form of lower monthly beneficiary premiums negotiated prices need to be determined well in advance of premium announcements. There will have to be an aggressive timeline to finalize contracts with pharmaceutical companies or to forecast potential rebates in order to estimate the reduction in premiums for 2006. This puts our MA PD clients at some risk, particularly if the forecasts for discounts are not achived in drug price negotiations. Adjustments in prescription pricing would then need to be made at the POS to offset lost premium revenue. Again, we speak to the point above. We all want the best possible drug prices and will need CMS assistance and political support to establish an environment which compels effective negotiations with drug industry in the immediate future. PBMs who may be serving MA-PD Plans almost need to begin discussions immediately to allow effective MA PD marketing and premium announcements in the late summer/Fall of 2005.
46655 46655 423.100 C.2.c P 102	*Periodic audits by the OIG on pricing practices* "We would be authorized to conduct periodic audits – either directly or through contracts with other organizations – of the financial statements and records of PDP sponsors and MA organizations pertaining to the prescription drug plans and MA-PD plans they offer."	MedImpact rebate and discount contracts are continuously subject to audit by clients, their accountancy firms, and by pharmaceutical industry. We are confident that we will be able to pass OIG periodic audit reviews.

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46655 C.4 P 138	*Access to covered Part D drugs (§423.120)* NOTE: Congress gave CMS broad authority to waive Part D requirements that duplicate or are in conflict with requirements under Medicare Part C (or under Section 1876 for cost plans and Sections 1894 and 1934 for PACE organizations). • **Assuring pharmacy access.** PDPs and MA-PDs must have a contracted pharmacy network, consisting of pharmacies other than mail-order pharmacies, that meet certain access standards. These access standards apply differently to urban, suburban and rural areas under which a specified percentage of beneficiaries, on average, must live within specified miles of a network pharmacy. The access standards do not apply to an MA-PD plan that provides enrollees with access to Part D drugs through pharmacies owned and operated by the organization. MA private fee-for-service plans that provide coverage for drugs from all pharmacies without differentials in cost-sharing are also not subject to the access standards. • **Any willing provider.** A PDP sponsor or MA organization is obligated to contract with any pharmacy willing to meet its terms and conditions. PDP sponsors and MA organizations may not require a pharmacy to accept insurance risk as a condition of participation. • **Discounts for preferred providers.** The proposed rules allow for a PDP sponsor or MA organization to reduce cost-sharing as part of a non-standard drug benefit plan when the enrollee receives drugs from a preferred pharmacy. Any cost-sharing must not increase CMS payments.	1. MedImpact has potential MA-PD clients who are fully integrated and own their pharmacies. These pharmacies exclusively serve their membership for commercial and MA plans. We recommend that CMS provide waivers to such clients regarding Pharmacy Access Standards. The rule waivers that were provided for DDC should likewise be considered for Part D in that exclusive provider pharmacies were exempt from posting as public pharmacies on the CMS website. There is no business rationale for mandating ANY WILLING PROVIDER to serve exclusive MA-PD beneficiaries. 2. MedImpact has a national network of over 50,000 pharmacies. We meet the current TRICARE standards. Thus, irrespective of the final CMS ruling on how the Regions will be designed, we are confident that our network can solve beneficiaries on a national basis using national retail chains. 3. MedImpact has contracts with national mail order vendors to allow access to remote rural areas. We have the ability to truly provide national service and access. This may serve snowbirds well. Snowbirds may also utilize key participating pharmacies in our network to obtain their prescriptions nationally via a “mail at retail” rate for 90 day drug supplies. We would offer this service and price convenience for our Part D plan.

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	Access to covered Part D drugs (§423.120) (Continued) • **Level playing field between mail-order and network pharmacies.** A PDP sponsor and an MA organization must allow enrollees to obtain a 90 day supply of covered Part D drugs from a network retail pharmacy. In such a case, the enrollee may be obligated to pay the differential between the price of the mail-order pharmacy and the retail pharmacy.	4. LTC PHARMACIES: If CMS proceeds with the notion of including LTC pharmacies within the required network, negotiations would need to be undertaken to define the roles, responsibilities of such LTC pharmacies as well as the price, discounts to be provided to the beneficiary residing at the LTC. The relationship between the LTC Pharmacy and the contracting payer will enter into the process and may thus preclude a practical role for a PBM serving a MA PD. This portion of costs may be best addressed in the payer contract with CMS. Relative to special clinical services provided by a LTC pharmacy, we would recommend keeping that component separate from the dispensing fee for providing the appropriate unit dosed product to the LTC for administration to the beneficiary. A bundled cost does not allow effective negotiation. LTC Pharmacies are required by state and federal law to provide a range of consulting and clinical services somewhat similar but less stringent than an inpatient hospital setting. Negotiation of their prices via a PBM network concept may run contrary to the contract between the LTC FACILITY and the LTC CONTRACTED PHARMACY. There are financial relationships and margins in which the PBM or MA-PD will be viewed as an interloper. There may be opportunities for residents of LTC facilities to have their prescriptions filled OUTSIDE of the LTC Facility/contracted LTC Pharmacy and delivered to the facility in appropriate UNIT DOSE (Unit of use) containers. Potential savings may be achieved therein, but there will be resistance from the LTC facility and pharmacy as it changes their usual processes and will require the contracted LTC pharmacy to examine the drugs to assure they are correct. This is another complex area which has been far removed from public debate.

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	Access to covered Part D drugs (§423.120) (Continued)	5. MedImpact currently contracts with over 50,000 pharmacies nationally. The Service Agreement language is consistent throughout. However, financial terms, reimbursement, conditions required by a plan sponsor, credentialing, state or local legal requirements may compel differences. The Service Areas have not yet been defined by CMS and these SAs may cut across multiple states. It is NOT feasible to have a singular "standard" contract for participation. Also, given the necessity to develop actuarially equivalent benefit designs which suggest total cost equivalence, the PBM or MA-PD must be given the flexibility to use all the tools at its disposal to help manage costs and utilization. The network contract is a financial management tool on behalf of the Plan Sponsor. A MA-PD or PDP may need to have customized networks with tiered pricing and reimbursement in a same Service Area. Credentialing requirements pursuant to Medication Therapy Management may further define capacity to participate within a network. Thus, we support the notion of distinctions between "preferred" and "non-preferred" pharmacies within a network. We support the ideas suggested in the access requirements relative to mail, rural, cost share, and price differentiation within a network. We therefore concur with inclusion of such differential costs towards the incurred costs. 6. With the noted comments above, we can provide focused networks for MA-PD clients requiring such to expand beyond their integrated models. In such instance benefit designs with price differentiation would suffice to allow a balance of choice and cost management.

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46659 46659 423.120 C.4.b P 111	*P&T Committee membership* "The majority of members comprising the P&T Committee would be required to be practicing physicians and/or practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician member would have to be experts in the care of elderly and disabled individuals." "Section §423.120(b)(1)(ii) of the proposed rule also provides that at least one practicing pharmacist and one practicing physician members on a plan's P&T Committee be independent experts. We interpret the statutory language at section 1860D-4(b)(3)(A)(ii) of the Act requiring certain members of the P&T Committee to be 'independent and free of conflict with respect to sponsor and plan' to mean that such P&T committee members must have no stake, financial or otherwise, in formulary determinations."	1. In order to comply with these proposed regulations, the P&T memberships will need to include at least one physician and pharmacist who specialize in the care of the elderly and disabled individuals for each P&T Committee. The key term is "at least one practicing pharmacist and one practicing physician member would have to be experts in the care of the elderly and disabled." This language suggests having geriatricians available to serve on P & T. Disabled is difficult to define as there are a host of disease which create eligibility for disability benefits. W e recommend that a broad interpretation of "expert" be applied in that many internists and family practitioners care for the elderly and would certainly be considered "experts". We would venture to guess that there are not enough board certified geriatricians available to serve on all the P & Ts across the nation. Nor are there likewise enough geriatric specialty pharmacists available. The key focus would be on appropriate dosage and posology for our senior population. The assignment of members to P & T is usually a CMO or Medical Staff process. We are confident that the Chairs of the P & T committees can appropriately assess the membership roster to determine which member has the appropriate "expert" credentials or whether there is a need to expand the membership to ensure such representation. 2. What is the CMS definition of a practicing pharmacist? Pharmacists may be experts in geriatrics care from a wide range of practice settings which include ambulatory clinical, LTC, dispensing to nursing homes, and even pharmacokinetics experts. The latter are experts in metabolism, excretion, and impact of age on the patients' ability to tolerate drugs. We wish to emphasize that practicing is much broader than dispensing. 3. Relative to the terminology "independent and free of conflict with respect to the sponsor and plan", we would like CMS to expand upon the associated term "independent and free of conflict with respect not only to a PDP sponsor and its prescription drug plan or an organization and its MA-PD plan, but also with respect to pharmaceutical manufacturers." Does this mean that MA-PDs must contract or hire consultant pharmacists and physicians to fulfill this role? How is the confidentiality of proprietary data protected? Does employment or contracting with a MA-PD plan preclude a physician or pharmacist from participation in its P & T? We would argue that physicians employed as part of group where the group subscribes to strong principles of responsibility will be much less at risk of financial influence than in other more independent practice modes which lack group guidance and commitment to core principles.

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	P&T Committee membership (Continued)	In our situation, P & T members are NOT compensated for these roles to assure optimal objectivity. We believe that our P & T is free of conflict based upon stringent qualification rules. Total independence would require CONTRACTING and paying for consultants with defined contractual agreements to roles, responsibilities, and confidentiality which increases administrative costs. There is significant preparation time prior to meetings. We would envision such contracted physicians and pharmacists potentially serving competing MA-PDs. Also, nationally recognized physician experts in key therapeutic arenas frequently do presentations or attend advisory boards or panels sponsored by pharmaceutical industry. Does this type of relationship between physicians and pharma preclude participation on a P & T? Seeking physician experts from teaching hospitals and universities may likewise create problems in that research grants are frequently provided by pharmaceutical industry. Does having received such a grant preclude participation on a P & T? It may be interesting to have CMS solicit a panel of experts to develop a strawman or model selection criteria and Principles of Responsibility statement for P & T membership. "No Stake, financial or otherwise, in formulary determinations" for independent P & T members suggests that other P & T members attached to a MA or MA-PD are not capable of appropriate clinical decisions based on quality and affordability.

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	USP model formulary "Although the USP will develop guidelines, under section 1860D-4(b)(3) of the Act PDP sponsors and MA organizations would have the flexibility to develop their own classification schemes." "If, on the other hand a PDP sponsor or MA organization offering an MA-PD plan designs its own formulary using therapeutic classes that vary from the USP classification model, CMS would evaluate the submitted formulary design to ensure that the proposed therapeutic classification system does not substantially discourage enrollment by certain Part D eligible individuals." "We interpret this requirement to mean that a PDP sponsor or MA organization's formulary be required to include at least two drugs within each therapeutic category and class of covered Part D drugs within the PDP sponsor or MA organization's formulary."	1. This section could be problematic for those drugs in which currently only one drug exists, but a "me-too" enters the market. Would we be obligated to add the "me-too" drug to the formulary for the sole purpose of meeting the two drug/class requirement? 2. We envision the USP draft model guidelines as exactly that: Model Guidelines to be finalized. It is up to the PDP and MA-PD to match or enhance this guideline to be competitive in the marketplace with a high quality, affordable, and accessible drug benefit. We would oppose developing stringent mandatory rules and support options and choices for the MA-PD and PDP which will be reflective of their organizations philosophy and commitment to serve the beneficiary population. The beneficiary will make the consumer choice for a PDP or MA PD plan. 3. What will be the CMS process for reviewing formularies to assure actuarial equivalence to Part D standard?
46660 46660 423.120(b)(2) C.4.b P 114	*Formulary coverage of dosages and strengths* "Section 423.120(b)(2) of our proposed rule would also require that the drugs included in each therapeutic class or category include a variety of strengths and doses to the extent that this is feasible."	1. Since we sometimes preferentially use only specific strengths of certain drugs (e.g. Actos 15 mg tablets, Lumigan 2.5 mL bottles), this may be problematic from a contracting perspective if CMS disallows this practice
46661 46661 423.120(b)(3) C.4.b P 115	*Frequency of changes in formulary therapeutic categories and classes* "…PDP sponsors and MA organizations could not change therapeutic categories and classes in a formulary other than at the beginning of a plan year, except as we would permit to take into account new therapeutic uses and newly approved covered Part D drugs."	We believe that this rule will have minimal impact.

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FR Page #	***Excerpt***	***Comment/Question***
46661 46661 423.120(b)(3) C.4.b P 115	*Frequency of formulary treatment protocol and procedure evaluations* "…PDP sponsors and MA organizations offering MA-PD plans would periodically be required to evaluate and analyze treatment protocols and procedures related to their formularies to ensure that their plan members were receiving the best possible care for conditions related to their use of covered Part D drugs. We invite comments as to minimum timeframes for periodic evaluation of protocols and procedures related to a plan's formulary by PDP plans and MA organizations offering MA-PD plans (for example, quarterly, annually)."	1. This statement appears to require us to review all formulary drugs and formulary guidelines on a routine basis. Recommend that the frequency of the review coincide with the annual formulary review (NCQA requirement?).

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FR Page #	*Excerpt*	*Comment/Question*
46661 46661 423.120(b)(3) 423.120(b)(5) C.4.b P 115	*Notification to CMS upon removing a drug from the formulary* "…PDP sponsors and MA organizations provide "appropriate notice" to us, affected enrollees, authorized prescribers, pharmacists, and pharmacies regarding any decision to either: (1) Remove a drug from its Formulary, or (2) make any change in the preferred or tiered-cost sharing status of a drug. Section 423.120(b)(5) would implement that requirement by defining appropriate notice as at least 30 days prior to such change taking effect during a given contract year."	1. This requirement will hinder the flexibility of Drug Use Management activities as initiatives may be delayed and the potential to capture maximal cost savings may decrease. 2. Note that the "appropriate notice" is not well-defined. It appears that website postings alone are insufficient for beneficiaries. MedImpact has over 50,000 pharmacies in its networks. We serve several hundred MCOs and employer groups. There are thousands of authorized prescribers contracted to serve the MCOs, TPAs, and employer groups. We anticipate serving a large population of Medicare enrollees. We urge CMS to consider the broad impact of such requirements on systems, communications processes, and costs. Communications to large populations is complex and must rely upon leveraging existing communications within the MCO infrastructure or via electronic mass communications on the internet. We would envision posting updated formularies on a MD-PD website as communications to all enrollees who should have a responsibility to manage their own care and knowledge of services. We would envision constant updates on our adjudication database as our mechanism for real time communication to network pharmacies. It makes NO SENSE to fax paper documents to 50,000 pharmacies. Specific benefit changes relative to tiers and cost share should be communicated as required by state and federal regulations in planned collaterals distributed by MA Plans. PBMs serving as PDPs or MA-PD engines are constantly working with clients to achieve the best possible prices and discounts on drugs. When serving populations, the ability to move quickly to affect the price of millions of prescriptions can save consumers and payers millions of dollars in premiums or direct costs. A formulary is not static. Drugs may be removed for safety reasons such as most recently with Vioxx. Drugs become generic and tiers can change instantly with PBM adjudication systems. If a newly negotiated price on a product available immediately is delayed access to the market, millions of dollars in savings may be lost. Appropriate notice needs to be flexible with reliance upon the MCO or MA PD to undertake business decisions based upon clinical quality and affordability. Benefits designs are usually coordinated on an annual basis for enrollment for the following year.

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	Notification to CMS upon removing a drug from the formulary (Continued)	3. For tiered cost sharing status, does this also include drugs that become multi-source or generic? Would members need to wait to take advantage of generic copays until 30 days after it becomes available? 4. For the purposes of tiered cost sharing, we should clearly define the tier for single-source generic drugs (i.e. brand vs. generic copays?). Older generic drugs may become single-source if all other manufacturers elect to discontinue production due to low use and the price for the single-source generic can escalate. CMS needs to be aware that our price files are updated frequently with national database vendors such as FDB.

Subpart C: Voluntary Prescription Drug Benefits and Beneficiary Protections

FR Page #	*Excerpt*	*Comment/Question*
46661 46661 423.36(b)(2) C.4.b P 116	*Prohibition against removing drugs from the formulary around the coordinated election period* "…PDP sponsors and MA organizations would be prohibited from removing a covered Part D drug or changing its preferred or tiered cost-sharing status of a covered Part D drug between the beginning of the annual coordinated election period described in §423.36(b)(2) and 30 days subsequent to the beginning of the contract year associated with that annual coordinated election period."	1. This requirement will hinder the flexibility of Drug Use Management activities as initiatives may be delayed and our capability to capture maximum cost savings will diminish. We would be unable to remove a drug from the Formulary between Nov 15 and Jan 30 (approximately 2.5 months) in a 12 month period of time. 2. Presumably, this requirement was added to prevent "bait and switch" by MA-PD plans. However, if a drug is slated to be removed from the formulary, would the enrollee be less angry/upset if the drug is removed in February versus a few months earlier? 3. The regulatory effort to protect beneficaries needs to balance the prevention of "bait and switch" with the loss of opportunity to achieve savings for beneficiaries and payors. This rule effectively precludes the ability to exercise formulary changes during 21% of the year (November 15th to January 30th). The frequency of bait and switch may be minimal. Would it be more direct and effective if CMS prohibited bait and switch rather than restrict formulary changes for 2.5 months a year? The prohibition as described can have serious cost consequences and effectively delays potential cost savings. Again, the ability for PBMs, MA-PDs, PDPs to rapidly take advantage of cost savings using our adjudication technology is hindered. There needs to be a balance in interpreting media and consumer concerns with the challenges and opportunities for managing the costs for large populations of potentially high utilizers. Drug costs are about 15% of the total medical costs. A beneficiaries decision to choose a PDP or MA-PD during an ACE period may not be totally focused on the formulary. Are there corresponding restrictions prohibiting surgeons from providing high risk surgeries during open enrollment to minimize adverse media complaints about increased morbidity and mortality for a hospital?

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FR Page #	***Excerpt***	***Comment/Question***
46661 46661 xxx.xx C.4.b P 116	*Publication of formularies on public website* "…PDP sponsors and MA organizations can get information regarding formulary changes to beneficiaries via an Internet Web site, as well as via explanations of benefits sent to enrollees who utilize their Part D benefits."	1. This requirement is vague regarding the precise information posted on the website. Do we only need to post drug name, or will we be required to post dosage forms, strengths, package sizes, formulary guidelines etc?
46662 46662 423.124 C.4.c P 117	*Access to out-of-network pharmacies* "…we would require that PDP sponsors and MA organizations offering MA-PD plans assure that their enrollees have adequate access to drugs dispensed at out-of-network pharmacies when they cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy."	1. MedImpact will construct a national network for its MA-PD clients. We anticipate that this network will be more aggressively priced than the cash DDC program. Likewise we are assuming that the network will consist of more than 50,000 pharmacies. We anticipate that OON utilization will be minimal. However, if an emergent situation arises whereby such service is required, we will work with the MA-PD to develop a Direct Member Reimbursement process for the unlikely and rare circumstance. The benefit design and cost share component for this access will be the decision of the MA-PD.

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FR Page #	*Excerpt*	*Comment/Question*
46663 46663 423.124 (a) C.5 P 119	*Incurred costs at out-of-network pharmacies* "When an enrollee purchases a covered Part D drug at an out-of-network pharmacy consistent with §423.124(a) of our proposed rule, the cost-sharing he or she pays relative to the plan allowance….counts as an incurred cost…." "…As with the price differential that a beneficiary could incur by purchasing an extended supply (for example, 90 days) of covered Part D drugs purchased at a retail pharmacy rather than a mail-order (discussed in section II.C.4.a of this preamble), the price differential between out-of-network pharmacies' U&C costs and the plan allowance would also be counted as an incurred costs against a beneficiary's annual out-of-pocket threshold." "Under this approach, plans would be required to explicitly account for such price differentials in the actuarial valuation of their coinsurance in their bids."	1. We can capture accumulator costs for TrOOP if network pharmacies are used. Patients going OON with a covered DMR will be providing us with the information needed to add to the TrOOP. However, there is beneficiary responsibility to provide the needed information. It is difficult if not impossible to forecast such OOP OON incurred costs to build into an actuarial forecast or valuation in a MA PD or PDP bid. To "explicitly account for such" suggests that we have OON data for an heretofore unmanaged population. We will need to make assumptions which may or may be financially fair to the MA-PD, PDP, or CMS as the payor for a segment of the risk. 2. We would ask that CMS consider beneficiary responsibility to use the defined network and to go OON only for emergent needs. If a beneficiary chooses OON for convenience, we would argue that these are costs that the beneficiary chooses to accept. It is not reasonable to have systems or costs incurred to manually track and capture such potentially not covered services for the incurred cost accumulator for annual OOP Threshold.
46663-64 46663-64 423.128 (a) C.6.a P 185	*Content of plan description* "The plan description would include information about …. How any formulary used by the plan works, the process for obtaining an exception to a prescription drug plan's or MA-PD plan's tiered cost sharing structure…..	1. The required information seems reasonable. However, we ask that CMS consider the adverse cost impact of suggesting to beneficiaries that exceptions are easily and readily granted. Physicians contracted to a MA-PD are not direct staff or employees and may be subjected to customer pressure to provide prescriptions for which there are equally efficacious and cost effective drugs. Physicians are under pressure and time constraints and wish to please and can yield easily to patient pressure, especially if they are not at risk for the drug cost. We need to have a balance in this arena to allow the MA PD, PDP, to assert a reasonable level of management on drug spend.

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466664 46664 423.128 (d)(1)(i)(ii) C.6.c P 188	*Call center access* "We strongly recommend, however, that plans provide some sort of 24-hour-a-day/7 day a week access to their toll-free customer call centers in order to provide timely responses to time-sensitive questions"	1. MedImpact STRONGLY opposes the notion of a mandated 24x7 standard for toll free call center access to time sensitive questions such as how to find an OON pharmacy. We are not convinced that finding an OON pharmacy merits the cost investment for such a service by every PDP, MA-PD, PBM. We would imagine such an emergent situation to be truly a medical emergency and may warrant a visit to an emergency department or 24 hour clinic. In that scenario, the patient would be provided the immediate drugs incident to that emergent need. 2. 3. The website strategy for providing information to beneficiaries for pharmacy access is most efficient. Likewise it is our expectation that beneficiaries need to take responsibility for managing their health and medication needs. True emergent needs may require 911 support.
46664 46664 423.128(d)(2)(ii) C.6.c P 189-190	*Website formulary update requirements and access* " In addition, per §§423.128(d)(2)(ii) and (iii) of our proposed rule, plans would have to post current versions of their formularies at least weekly…." "…Plan websites would have to be available both to current and prospective part D enrollees….	1. Our formularies usually change on a quarterly basis, although the P&T Committees do occasionally make formulary decisions outside of a regularly scheduled meeting. Would it be possible to modify this requirement to state that the website will be updated in conjunction with formulary changes? 2. We would request some flexibility on this issue. Theoretically, if formulary changes are prohibited during 21% of the year, no changes need to be posted during that time frame. 3. CMS clearly has concerns regarding deletions. We find that ADDITIONS are made sometimes on a more frequent basis and may occur weekly. New drug strengths and dosage forms are frequently released for existing formulary drugs. The new dosage forms need to be added. Likewise, release of new drugs may require emergent P & T meetings for approval of an advantageous essential new product. Are the rules structured to prevent changes including additions at designated points? There are the formularies which have the list of drugs available for review. There is the formulary used for adjudication which is constantly monitored by staff other than P& T.

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46664 46664 423.128(e)(6) C.6.d P 191	*Monthly explanation of benefits* "We would require, under §423.128(e)(6) of our proposed rule, that an explanation of benefits be provided at least monthly for those utilizing their prescription drug benefits in a given month."	1. The explanation of benefits includes individualized components, such as cumulative YTD cumulative incurred costs and applicable formulary changes. This requirement creates significant systems, operations, and cost issues. The current NCPDP 5.1 Transaction record from the pharmacy will not support the data described for EOB purposes. PBMs have not provided EOB reports prior. Monthly generation and mailing of such a report will create significant added administrative costs. The costs estimated for this requirement must far exceed $1 PMPM in materials, mailing, costs, and time. These dollars may be more effectively spent on drugs rather than reports which should be requested on-line or as information requested by telephone. 2. We would recommend that CMS allow MA PDs, PDPs, sub-contracted PBMs to make the prescription profile with use available on-line at the appropriate website for the plan sponsor. The website could provide access to the accumulator for TrOOP. Likewise, the beneficiary could view a current formulary on-line. Technology will allow the beneficiary to print such data as required. 3. Requirement to produce information about formulary changes is broad. Again, costs associated with generating such a document and mailing on a monthly basis may not be the most efficient use of tax payer dollars. 4. We would urge CMS to consider simplified processes or annualized reporting accessed through the network pharmacy where prescription service is provided. The systems at a pharmacy may be able to provide prescription utilization record for tax purposes and should likewise satisfactory as an EOB. 5. The right to receive an itemized statement may also be noted in the EOC at the time the beneficiary registers with a MA-PD, PDP, or other provider. 6. It would also make more sense to provide the drug use data with the EOB statements MA-PDs, PDPs, will be required to provide to beneficiary for medical and other Medicare costs. PBMs could provide a file of prescriptions filled, accumulator for TrOOP status, to the MCO MA-PD for generation of EOB data within existing infrastructure. It would be more cost effective for quarterly rather than monthly statements.

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	Monthly explanation of benefits *(Continued)*	7. The comprehensive information regarding cumulative, YTD amount of benefits relative to deductible, initial coverage limit, and the annual OOP thresholds creates added cost structures which ultimately increases administrative costs to the program and the taxpayer. This will require IT systems development between the MA and its PD subcontractor or provider. PBMs who are considering PDP strategies will have to construct this capability.
46665 46665 423.132 c C.7 P 193	*Disclosure of pricing for equivalent drugs* "…we are permitted to waive the requirement that information on differential prices between a covered Part D drug and generic equivalent covered Part D drugs be made available to prescription drug plan enrollees at the point of sale (or at the time of delivery of a drug purchased through a mail-order pharmacy.)	1. This regulation is currently in effect for DDC and network pharmacies should continue to abide by this codified section. Network agreements developed for the Part D networks will incorporate language re full compliance to 42 CFR 423.132. 2. We do not understand the rationale for waiving this requirement for those plans who employ a wide open unrestricted network. 3. We would recommend that LTC pharmacies disclose the drug price differentials in their contracts to the LTC facilitiy, to payers as well as to individuals responsible for the LTC resident.

Submitter : Ms. Mimi Haley **Date & Time:** 10/04/2004 08:10:37

Organization : Group Health Cooperative

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4068-P-1214-Attach-1.doc

Comments on the Proposed Rule on Establishment of the Medicare Advantage Program

CMS – 4068 – P

By

Group Health Cooperative
Seattle Washington

October 4, 2004

Contact: Eileen O'Donnell, odonnell.e@ghc.org, 206.448.6444
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I. Background on Group Health Cooperative

Group Health Cooperative ("Group Health") is a consumer-governed nonprofit healthcare system that integrates health coverage with medical care. About 540,000 residents in Washington State and Northern Idaho obtain medical care through Group Health Cooperative health plans. More than 70 percent of our members receive care in Group Health medical facilities.

Group Health was founded in 1947 by a community coalition dedicated to making quality healthcare available and affordable. As one of the few healthcare organizations in the country governed by consumers, the consumer elected board of trustees works closely with internal management and medical staff to ensure that the organization puts the needs of patients first.

Group Health was one of the original participants in the Medicare Risk Share program, contracting with the federal government since 1976 to provide prospectively paid, capitated, care to Medicare beneficiaries. We currently care for approximately 60,000 Medicare members.

Group Health, as an integrated delivery system, already has extensive experience designing, delivering and financing pharmacy benefit plans. Almost all of our 540,000 members, including almost half of our Medicare enrollees (approximately 30,000 members), currently receive their prescription medications through Group Health owned or contracted pharmacies.

II. Provisions of the Proposed Rule

Subpart B – Eligibility, Election and Enrollment

(Sec.423.34, p. 46639)
Dual eligibles. For full-benefit dual eligible individuals enrolled in MA plans, CMS proposes enrolling them in one of the MA-PD plans offered by their MA organization. CMS further proposes that if the basic premium of the MA-PD plan exceeds the low-income benchmark premium amount, CMS would not permit automatic enrollment in the MA-PD plan.

The regulations appear to drive dual eligibles into the lowest cost plan by limiting enrollment into MA-PDs or PDPs that bid at or below the low-income benchmark. We believe that continuity of care should be a paramount concern for CMS, especially for this patient population. Therefore, we request that dual eligibles currently enrolled in a MA plan be enrolled into that organization's MA-PD plan, regardless of that plan's bid amount.

The proposed rules do not contemplate individuals who are currently enrolled in MA plans at the time of initial eligibility for Medicare benefits. Such individuals should also

be auto-enrolled in a MA-PD plan offered by the MA organization in which the individual is enrolled at the time of initial Medicare eligibility. This ensures continuity of care for individuals and minimizes administrative confusion about enrollment.

Finally, it appears that MA-PDs will be excluded from receiving new enrollments of dual eligibles even if the MA-PD plan bid is at or below benchmark, if that individual was not previously enrolled in a MA plan. For purposes of level playing field and beneficiary choice, we believe that MA-PD plans that bid at or below benchmark should be an enrollment option for all dual eligible individuals.

We request that CMS clarify enrollment rules for full-benefit dual eligible individuals as noted above, with attention paid to administrative efficiency as well as enrollee health and continuity of care needs.

Subpart C – Benefits and Beneficiary Protections

(Section 423.100, p. 46646)
Dispensing Fees. CMS requests comments on the preferred option for dispensing fees.

We believe that Option 3 best represents the operational reality for integrated health systems where the financing and delivery of care are integrated. Group Health's clinical pharmacists perform both health plan functions and clinical functions in the course of performing their jobs on all patients regardless of Medicare eligibility status. For this reason, the total cost of providing both health plan and delivery system functions for integrated MA organizations need to be incorporated into the dispensing fees so that the total cost of care for MA-PD plans can be captured.

(Section 423.120(a)(1), p. 46655)
Assuring pharmacy access. PDPs and MA-PDs must have a contracted pharmacy network consisting of pharmacies, other than mail-order pharmacies, that meet certain access standards. These access standards apply differently to urban, suburban and rural areas under which a specified percentage of beneficiaries, on average, must live within specified miles of a network pharmacy. The access standards do not apply to an MA-PD plan that provides enrollees with access to Part D drugs through pharmacies owned and operated by the organization. MA private fee-for-service plans that provide coverage for drugs from all pharmacies without differentials in cost sharing are also not subject to the access standards.

(p.46656)
Long-term care pharmacy access. CMS is expecting that access to covered Part D drugs would be assured through MA-PD plan contracts with participating long term care facilities. CMS invites comments on a requirement for plan sponsors to contract with some or all LTC pharmacies in their areas, in particular how to balance access needs with reasonable dispensing costs associated with such pharmacies.

(p. 46658)
Any willing provider. A PDP sponsor or MA organization is obligated to contract with any pharmacy willing to meet its terms and conditions. PDP sponsors and MA organizations may not require a pharmacy to accept insurance risk as a condition of participation. CMS seeks comments on the idea of plans using a standard contract for such pharmacies.

We believe the draft regulations in these three areas appear overly prescriptive, calling for redundant systems that add cost but no real value to established MCOs. As such, we believe these provisions should be waived in instances where contracting plans can demonstrate adequate compliance with the intent of the law.

Group Health has a contracting process in place that is carefully crafted to meet customer demand, including a process to respond to both pharmacy and patient requests for network pharmacy expansion. Implementing provisions mandating a network for our population of patients would result in increased administrative costs, challenges in coordinating care, member confusion and potential risk to patients. MA organizations already have access standards in place to conform to existing regulations regarding medical care delivery; these standards should suffice for pharmacy access as well. Any willing provider provisions are antithetical to the essence of managed care systems, interfering with coordinated care and quality outcomes.

We strongly believe Tri-care and any willing pharmacy (AWP) provisions should be waived for MA-PD plans – both for plans with owned and operated pharmacies as well as contracted network pharmacies. We will investigate the need to supplement our existing long term care pharmacy with selected vendors as needed, based on quality, access measures and demand by enrollees in our MA-PD plan.

Group Health's current network of 225 pharmacies allows for appropriate quality review. AWP requirements, in principle, violate the basis of defined network, managed care delivery systems that are accountable for both cost- and medical-effectiveness. We would not endorse a standard contract for any participating pharmacy, as each contract would need to be individually structured to meet myriad market specific issues as well as reimbursement, digital connectivity and account administration requirements.

(Section 423.120, p. 46659)
P&T Committee membership. Under the proposed rules, the majority of members comprising the P&T Committee would be practicing physicians and/or practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician member would have to be experts in the care of elderly and disabled individuals.

This also provides that at least one practicing pharmacist and one practicing physician members on a plan's P&T Committee be independent experts, interpreted by CMS to be 'independent and free of conflict with respect to sponsor and plan' (having no stake, financial or otherwise, in formulary determinations).

CMS seeks comment on whether to limit such outside experts to one each, or to additional physician and pharmacy specialists. CMS also requests comment on whether the determinations of the P&T Committee should be binding on the MA-PD plan.

As with the pharmacy access standards, noted above, the draft regulations in this area are overly prescriptive and propose unacceptable expansion of one of the more troubling aspects of MMA: the composition and scope of MA organization's P&T committees. We believe the regulations should limit themselves to strict interpretation of the law as it is written, and not propose additional representatives to, or binding authority of, the MA organization's P&T Committee.

Group Health has a highly functioning physician led P&T Committee that includes actively practicing physicians and pharmacists from both our integrated group practice as well as our contracted network. It also includes a consumer representative. MMA proposes augmenting MA organization P&T committees with representatives who are independent of the plan and who have highly specialized backgrounds. We believe the degree of specificity related to these additional representatives is a troubling and unprecedented incursion by a payer into MA-PD plan operations. We question the benefit of broadening the current P&T committee composition, which has been an effective and functioning body for current Group Health pharmacy benefit plans and formularies for both commercial and Medicare members. We will seek legislative relief, requesting that this provision be waived for MA-PD plans that demonstrate a well functioning P&T committee with broad committee representation/composition.

In the interim, Group Health requests that the additional representatives proposed for the P&T committee be contracted physicians and pharmacists. Given that all P&T Committee members are compensated for their participation in the committee, we do not believe that "independence" as defined by CMS is operable or necessary for a well-functioning P&T Committee.

(Section 423.120, p. 46660)
Formulary Requirements. CMS seeks to solicit comments on the proposed USP Draft Model Guidelines.

Group Health agrees in principle with the therapeutic categories and classes released in the Draft Model Guidelines. They are an important first step to assist health plans develop formularies that comply with the Medicare Modernization Act. Overall, we believe these Model Guidelines:

1) Give plans the flexibility to drive industry competition and therefore improve affordability of the benefit by allowing either one drug (subdivisions) or two drugs (classes) on the formulary.
2) Allow Medicare beneficiaries a broader array of drugs than two within pharmacologic classes where therapeutics dictate a need for more than two drugs (e.g., insulins).

3) Create choice for both plans and patients choosing plans by allowing flexibility to choose MA-PDs or PDPs with a broader formulary than the model requires so long as the plans adhere to the minimum requirements.
4) Create a reasonable balance of incentives for affordability and choice of drugs available on plan formularies.

(Section 423.124, p. 46662)
Access to out-of-network pharmacies. CMS proposes to require that PDP sponsors and MA organizations offering MA-PD plans assure that their enrollees have adequate access to drugs dispensed at out-of-network pharmacies when they cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. CMS proposes to meet the requirements of this section by establishing a broader out-of-network access requirement.

We are troubled with such an expansion of out-of-network requirements and that CMS has precipitously abandoned the prudent layperson standard for MA enrollees obtaining medications under the Part D benefit. The out-of-network medical benefit for emergent and urgent care is well-established CMS policy, well understood by beneficiaries, and well managed by existing Medicare contracting organizations. We believe that MA-PD plans should be able to continue to apply this standard for purposes of receiving medications out-of-network. CMS should allow managed care organizations the flexibility to tie receipt of out-of-network emergency pharmacy benefits to receipt of emergent or urgent medical benefits, as those benefits are currently administered.

(Section 423.128, p. 46665)
Monthly explanation of benefits. CMS proposes to require that an explanation of Part D benefits be provided at least monthly for those utilizing their prescription drug benefits in a given month.

The explanation of benefits includes individualized components, such as year-to-date cumulative incurred costs and applicable formulary changes. Distributing this information through the dispensing process may be a preferred route, however we request that that the requirements be changed to allow patients to obtain the EOB at any time upon request rather than monthly. In addition, we support allowing MA organizations to use the required toll-free 1-800 number to supply enrollees with status updates on their true out-of-pocket costs.

In addition, we request elimination of the requirement to inform members of the availability of the lowest cost generic alternative when the prescribing physician or other licensed prescriber has requested that no generic be dispensed (i.e., dispense as written). We believe in such an instance that disclosure of the lower cost alternative would be without value, as it could not be dispensed, per the physician's order.

Subpart F – Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

(Section 423.265, p. 46678)
Specification of information (data, methodologies, assumptions, and data elements related to calculating actuarial equivalence, etc.). We concur with the detailed comments related to these proposed regulations made by AHIP, which encourage CMS to collect only information and data that are necessary to accomplish program objectives and requirements.

(Section 423.272, p 46679)
Review and negotiation of bid and approval of plans submitted by potential PDP sponsors or MA organizations planning to offer MA-PD – General Comments. We strongly concur with the detailed comments related to these proposed regulations made by AHIP on behalf of member plans.

(Section 423.272, p. 46680)
Rebate Reallocation for MA-PD Plans. The bid negotiation process will require resubmission of the bid once the outcome of the National Average is known, since it affects the beneficiary premium. After the rebate reallocation, the bid could either be excessive or insufficient to achieve the desired premium level.

While the bid process proposed in CMS regulations refers to it as a negotiation, it is unclear from the regulations whether this would be a two-way or one-way negotiation between MA organizations and CMS. Please clarify the extent of negotiations that would be allowed under these rules.

Part B Only Beneficiaries. The proposed regulations are silent on bid rules for Part B only enrollees in MA organizations. The eligibility rules for Medicare Part D could be interpreted to mean that Part B only beneficiaries are not eligible to enroll in MA-PD plans. Please clarify the enrollment and offering requirements for this subpopulation of grandfathered enrollees.

Subpart G – Payments to PDP Sponsors and MA Organizations offering MA-PD Plans

(Section 423.322, p. 46686)
Data elements and frequency. CMS requests comments on the content, format, and optimal frequency of data feeds for Part D administration, as well as for the risk-adjustment process, reinsurance subsidy payment, risk-sharing and program audit processes.

Similar to the data submission requirements originally contemplated for risk-adjustments that were significantly reduced based on discussion with M+C plans, we believe that CMS should limit data elements and frequency to those strictly required for reconciliation activities. The depth and breadth of new requirements, for both CMS and for participating PPO, MA or PDP-sponsor organizations, envisioned in toto (?) under MMA, beg for CMS to use expediency and minimalism as criteria for data submission. We believe these criteria should be used for both the data elements and the submission frequency requirements proposed by CMS.

(Section 423.343(a), p. 46693)
Retroactive Adjustment (i.e., reinsurance, low income cost-sharing). CMS is requesting comments on how best to make retroactive adjustments and reconciliations to PDP sponsors: in a lump sum or through monthly apportionment in the next year's payments.

We recommend that CMS pay or collect the difference through a lump sum payment, rather than through apportioning over the future payment year. This would be consistent with how CMS is administering retroactive adjustment for risk adjustment and would enable plans to more accurately track current cash flow. An additional option would be for CMS to allow plans an individual choice of making a lump sum adjustment or applying prospective adjustments through future payment year.

Subpart K – Proposed Application Procedures and Contracts with PDP Sponsors

(p. 46707)
Contracting requirements. We do not believe that the provisions specified in this subpart apply to MA-PDs, as they are inconsistent with terms, definitions and requirements of MA organizations in Title II. However, the proposed regulations of this Title I, Subpart K are so ambiguous and vague as to be unclear whether specific provisions apply to all PDP sponsors, including MA-PDs, or just to PDPs. We request clarification about the provisions, if any, in this subpart that apply to MA-PDs.

Subpart M – Grievances, Coverage, Reconsiderations, and Appeals

(Section 423.578, p. 46720)
Exceptions to tiered-cost sharing structure. CMS is considering a set of rules for exceptions to tiered cost-sharing arrangements that may be problematic to enrollees, including specific criteria that should be included in a PDP.

The proposed criteria would require development of a seemingly complex set of rules to manage these exceptions. In addition to adverse effects, a particular drug may be ineffective for a given patient, which would be another appropriate reason to use an alternative drug. The regulations already specify notification requirements and timelines for changes to the MA-PD plan formulary. Given these, we request a simple exception process for Part D members for exceptions to tiered cost sharing, consistent with the existing requirements for plan exceptions for medical benefits.

(p. 46723)
Employer-sponsored benefits and appeals. CMS is soliciting comments on the degree to which parallel appeal procedures under Part D and ERISA might pose a problem for plans, employers and enrollees.

Currently, MA organizations that contract with CMS have elaborate and functional procedures to process routine and urgent appeals from enrollees or their providers about

benefits and coverage determinations made by the plan. We urge CMS to allow MA organization to process appeals under an employer-sponsored plan as any other appeal. Parallel reviews by both CHDR and the employer group create costly redundancies and potential confusion and/or conflicting determinations.

Subpart P – Premium and Cost-Sharing Subsidies for Low-Income Individuals

(Section 423.800, p. 46732)
CMS seeks comment on the process of CMS notification to the PDP sponsor or MA organization that an individual is eligible for a subsidy and the amount of the subsidy. In addition, CMS requests comment on the process the PDP sponsor or MA organization should use to notify CMS that premiums or cost-sharing have been reduced, including the amount of the reduction.

CMS will be the entity tracking and assigning subsidy amounts for low-income individuals eligible for Part D benefits. In addition, CMS will already have on file each MA-PD or PDP plan available to enrollees in any given geography each year. Therefore, we request that CMS eliminate the requirement that MA-PDs and PDPs notify CMS of premium or cost-share reductions for individual enrollees. Instead, it would be administratively more efficient and less time-consuming if CMS retained the authority to track individual enrollee premium and subsidy amounts, and pay MA or PDP organizations accordingly at time of assignment.

In addition, it may be inferred from the proposed regulations that PDP sponsors, including MA-PDs, are required to calculate and submit separate bids for Low-Income Individuals. We strongly discourage such an idea as actuarially invalid and administratively cumbersome. We request, instead, one MA-PD plan and one bid for all enrollees, with premium discounts and subsidies applied to low-income eligibles as determined by CMS at the time of enrollment.

Subpart R – Payments to Sponsors of Retiree Prescription Drug Plans

(Section 423.884, p. 46743)
Data Reporting. CMS requests comments on the approach that employer group sponsors would be required to use for requesting a subsidy payment, including the timeframe for reporting and the proposed information list for submittal.

It is our experience that the timeframes proposed by CMS would be incompatible with the open enrollment season of most employer groups; however, we will defer to comments submitted by such employer sponsors for this proposed requirement.

It is likely that employer groups seeking subsidy payments for prescription drug benefit plans will require that data elements be supplied by the contracted MA-PD or PDP organization. Therefore, we request that CMS limit required data to those minimally necessary to calculate the subsidy amount, consistent with current requirements for risk-adjusters. In addition, we question the ability of employer groups to have access to many

of the proposed data elements without violation of HIPAA privacy and state patient confidentiality laws currently in force and request that CMS ensure compatibility between these proposed regulations and existing federal and state laws.

CMS-4068-P-1215

Submitter : Ms. lillian cardenas **Date & Time:** 10/04/2004 08:10:33

Organization : westchester independent living center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The disabled community has worked hard to get prescription coverage with the medicaid buy-in for working disabled. It's unfair that new laws want to take away prescription coverage for people on both medicare and medicaid. This would be a disincentive for people to go back to work. The disabled community is already at a disadvantage in life. You would be creating more obstacles in our struggle to better our living conditions. I hope you look at other options and help our community. Thank you

CMS-4068-P-1216

Submitter : Mr. Ronald Field **Date & Time:** 10/04/2004 08:10:11

Organization : Volunteers of America

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attached letter from Volunteers of America re: Medicare Prescription Drug Regulations

CMS-4068-P-1216-Attach-2.doc

CMS-4068-P-1216-Attach-3.doc

CMS-4068-P-1216-Attach-1.txt

Wednesday, October 20, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS File Code-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Medicare Program; Medicare Prescription Drug Benefit
Comments on Proposed Rule
69 Federal Register 46632

Volunteers of America welcomes the opportunity to provide comments on the proposed rule. Volunteers of America is a national, nonprofit, faith based housing and human services organization. Through our local affiliates and National Services Board, we serve thousands of low-income persons who rely on prescription drugs as part of their daily regimen, including older adults with chronic care needs and people with mental retardation and other developmental disabilities.

We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are six critical recommendations:

1. **Delay the implementation of the Part D program for dual eligibles.**

Dual eligibles (Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006.

CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the high improbability that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning of the enrollment period to January 1, 2006), we strongly recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

2. **Fund collaborative partnerships with organizations representing people with disabilities are critical to an effective outreach and enrollment process.**

Targeted outreach to Medicare beneficiaries with disabilities, especially those with low-incomes, is vitally important in the enrollment process. We strongly recommend CMS develop a specific plan for facilitating enrollment of beneficiaries with disabilities in each region that incorporates collaborative partnerships with state and local agencies and disability advocacy organizations.

3. **Designate special populations who will receive affordable access to an alternative, flexible formulary.**

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing bed rest, unnecessary hospitalizations and even death, on the other. Often, people with disabilities need access to the newest medications, because they have fewer side effects, and may represent a better treatment option than older less expensive drugs. Many individuals have multiple disabilities and health conditions making drug interactions a common problem.

Frequently, extended release versions of medications are needed to effectively manage these serious and complex medical conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects making it more important for the doctor to be able to prescribe the best medication for the individual. Often that process takes time since many people with significant disabilities must try multiple medications, and only after much experimentation, find the medication that is most effective for their circumstance. The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury, debilitating side effects, hospitalization, or other types of costly medical interventions.

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs, and the enormous potential for serious harm (including death) if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations:

- people who are dually eligible for Medicare and Medicaid;
- people who live in nursing homes, ICF-MRs and other residential facilities;
- people who have life threatening conditions; and

- people who have pharmacologically complex condition such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, and HIV/AIDS.

4. Impose new limits on cost management tools.

In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. We strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization.

We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications, which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

5. Strengthen and improve inadequate and unworkable exceptions and appeals processes.

We are also concerned that the appeals processes outlined in the proposed rule are overly complex, drawn-out, and inaccessible to beneficiaries with disabilities. We strongly recommend CMS establish a simpler process that puts a priority on ensuring ease of access and rapid results for beneficiaries and their doctors and includes a truly expedited exceptions process for individuals with immediate needs. We believe that the proposed rule fails to meet Constitutional due process requirements and fails to satisfy the requirements of the statute. Under the proposed rule, there are too many levels of internal appeal that a beneficiary must request from the drug plan before receiving an independent review by an administrative law judge (ALJ). Additionally, the timeframes for plan decisions are unreasonably long.

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs.

As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already

inadequate grievance and appeals process. We recommend that CMS revamp the exceptions process to:

- Establish clear standards by which prescription drug plans must evaluate all exceptions requests;
- Minimize the time and evidence burdens on treating physicians; and
- Ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

6. Require plans to dispense a temporary supply of drugs in emergencies:

The proposed system does not ensure that beneficiaries' rights are protected and does not guarantee beneficiaries have access to needed medications. For many individuals with disabilities such as epilepsy, mental illness or HIV, treatment interruptions can lead to serious short-term and long-term problems. For this reasons the final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

Thank you for your consideration of our views.

Sincerely,

Ronald H. Field
Vice President of Public Policy

Wednesday, October 20, 2004

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Department of Health and Human Services
Attention: CMS File Code-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Medicare Program; Medicare Prescription Drug Benefit
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CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the high improbability that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning of the enrollment period to January 1, 2006), we strongly recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

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We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs, and the enormous potential for serious harm (including death) if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations:

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Thank you for your consideration of our views.

Sincerely,

Ronald H. Field
Vice President of Public Policy

CMS-4068-P-1217

Submitter : Mrs. Nicole Antonson **Date & Time:** 10/04/2004 08:10:42

Organization : Highmark, Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4068-P-1217-Attach-1.doc

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244 – 8014

Re: Comments on Medicare Prescription Drug Benefit

Highmark Inc. and its wholly owned subsidiary, Keystone Health Plan West, Inc. (collectively referred to herein as "Highmark"), are submitting the following comments on the proposed rule implementing provisions of the Medicare Program: Medicare Prescription Drug Plan.

Highmark is uniquely qualified to comment on the proposed rule. We have been offering MA (formerly Medicare+Choice) products with prescription drug benefits to Medicare eligibles in western Pennsylvania for almost 10 years. Highmark's MA Health Maintenance Organization (HMO), SecurityBlue, is currently one of the largest MA plans in the country with over 180,000 members. Given our experience and success offering seniors prescription drug coverage, we believe that we can provide valuable comments on the proposed rule.

Finally, while we largely agree with the comments the Blue Cross Blue Shield Association and America's Health Insurance Plans have submitted, we feel it is important to comment further in a few key areas.

Subpart B – Eligibility and Enrollment

§423.34 Part D Enrollment Process (§423.34; P: 46638; R: 46811)

Highmark Comment: Dual eligibles should be assigned randomly by CMS, if an eligible does not select a Part D carrier. In addition, if a partnership exists between a PDP and a Medicaid HMO, the PDP should be permitted to provide a smooth transition into its plan for any willing dual eligible.

§423.44 Disenrollment by the PDP (§423.44; P: 46641; R: 46812)

Highmark Comment: Highmark agrees with AHIP concerning members who change their permanent address. If a member permanently moves outside of a region, the member should be allowed to stay with their original plan for a specified amount of time.

However, if the plan does not have the capabilities to provide the member with Part D benefits outside the region, the plan should be permitted to disenroll the member. If the plan decides to disenroll, it must provide the member with 60 days notice.

Subpart C – Benefits and Beneficiary Protections

§423.120 Access to Covered Part D Drugs; Pharmacy Access Standards (§423.120; P: 46655; R: 46818)

Highmark Comment: Contracts with pharmacies cannot be uniform as some pharmacies specialize in particular drugs (i.e., injectables) and are able to offer much lower prices than retail pharmacies. Furthermore, specialty pharmacies are able to deliver additional services such as prior authorizations for these drugs. Because a PDP often only wants to coordinate with one entity for such services, contracting with any willing provider would be administratively burdensome and costly for a PDP. Highmark recommends that contracts with pharmacies do not have to be uniform and available to all willing pharmacies.

§423.128 Dissemination of Plan Information; Disclosure of Information upon Request (§423.128; P: 46663; R: 46819)

Highmark Comment: Highmark agrees that description information regarding Part D plans should be available on a website; however, online application and enrollment should not be mandatory. Until seniors, PDPs, and CMS become more familiar with Part D, mandatory online enrollment may be more burdensome than efficient. In addition, the majority of seniors do not use the Internet.

Subpart D – Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

§423.159 Electronic Prescription Program (§423.159; P: 46670; R: 46821)

Highmark Comment: There is not adequate industry experience to waive the ePrescribing pilot. Until systems in local communities can communicate, ePrescribing should be supported on a voluntary basis. This support could be in the form of incentives and/ or federally funded activities such as educational ad campaigns and pilots.

CMS also requested comments for determining metrics to track the success of ePrescribing. Highmark believes progress should be noted by the number of electronic prescriptions per provider, the amount of increase in generic fill rate and formulary compliance.

Finally, ePrescribing will help CMS mitigate rising drug costs by increasing formulary adherence, increasing generic fill rate, increasing patient compliance where in turn should

decrease hospital admissions, and increase opportunities for patient care coordination through shared data.

Subpart I – Organization Compliance with State Law and Preemption by Federal Law

§423.440 Preemption of State Laws and Prohibition of Premium Taxes (§423.440; P: 46696; R: 46831)

Highmark Comment: Title II of the MMA (Part C, Medicare Advantage) provides for a sweeping federal preemption of state law, replacing the old narrow provision with a broader preemption providing that "State laws are presumed to be preempted unless they fall into two specified categories [state licensing laws or state laws relating to plan solvency]." (Preamble 46904). In contrast, the guidance for the Title I (Part D, drug benefit) preemption provision limits federal preemption, even though the preemption provisions in both Title I and Title II are virtually identical. Title I guidance states that "to the extent there are Federal standards, those standards supersede any State Law." (Preamble 46696). Under Title I, the preemption authority only applies if there is an extant federal rule that trumps an analogous state rule, rather than having all relevant state laws preempted unless they relate to licensing or solvency. This drastically limits the federal preemption on the Title I side as compared to that on the Title II side.

Nothing in the guidance for Title I suggests that Congress intended the preemption under Title I to be narrower than that under Title II. As Congress intended both MA programs and Part D drug programs to operate as federal programs under federal rules, we ask CMS to conform the Title I guidance to that in Title II to support a broad federal preemption in both Title I and Title II.

Subpart J – Coordination Under Part D Plans with Other Prescription Drug Coverage

§423.464 Coordination of Benefits with Other Providers of Prescription Drug Coverage (§423.464; P: 46700; R: 46832)

Highmark Comment: Currently many Health Plans do not include coordination of benefits (COB) within the scope of managing the prescription drug benefit. This is primarily due to the lack of adequate "other insurance data" collected/exchanged/updated from business partners (groups).

While most PBM's can perform COB at the point-of-sale, they need complete/accurate data. Because this is not readily available (e.g., PACE information is only available monthly), implementing such a process would be challenging on a real time basis. Therefore, Highmark supports Option 2 whereby CMS contracts with a TrOOP facilitator. We also support the comments provided by Medco, our PBM, on this matter. In summary, the facilitator would act as the single point of contact for several purposes, such as: matching claims, helping to determine final beneficiary costs. Finally, because

this will be difficult to achieve, plans should be permitted to conduct COB on a monthly or yearly basis.

Subpart M – Grievances, Coverage Determinations and Appeals

§423.590 Appeals; Redeterminations (§423.580; P: 46721; R: 46845)

Highmark Comment: The proposed regulations allow for oral standard appeals. This is a change from current MA regulations and could pose an administrative burden on the PDPs by increasing the number of appeals and also making it difficult to distinguish between appeals and questions. We recommend that appeals be made in the same manner MA appeals are currently handled.

Subpart R– Payments to Sponsors of Retiree Prescription Drug Plans

§423.882 Definitions (§423.882; P: 46737; R: 46858)

Highmark Comment: Highmark receives drug rebate payments an average of 8 months after the incurred date of the claim. Approximately 10% of rebates are paid more than a year after the incurred date of the claim.

The most straightforward solution would be to:

1. Calculate the actual drug payments between the cost limit and threshold for each member and add these amounts at the group level.
2. Calculate a good faith anticipated rebate (percentage of allowances) across the entire book-of-business based on historical data.
3. Calculate the group level subsidy-eligible payments by reducing the aggregate group payment amount by the anticipated rebate.

Although a true-up calculation at a later date may be possible, it is not recommended. A true-up based on actual rebates at the member level is not possible under current rebate arrangements since rebates are not tracked at the member level. A true-up based on actual rebates at the group level would be more costly in terms of administrative expenses, but (assuming the aggregate rebate estimate was accurate) represent a zero-sum gain to the system as a whole. Any reductions in the estimated rebates for some groups would be offset by increases in the estimated rebates for other groups. There would be no net effect on the level of total government subsidies. If the aggregate rebate estimate was incorrect, there are 3 likely scenarios:

1. The aggregate rebate is fluctuating. In this case, overpayments in some years will (for all practical purposes) balance out against underpayments in other years.
2. The aggregate rebate is increasing. In this case, the government will save a small amount of money by paying lower subsidies than it would pay if the aggregate rebate estimate had been more accurate.

3. The aggregate rebate is decreasing. In this case, the government will lose a small amount of money by paying higher subsidies than would have been paid if the aggregate rebate estimate had been more accurate. This problem is self-solving since, unless the downward trend ceases or is reversed, rebates and the problem of how to account for them would eventually disappear.

If the government believes that a true-up is absolutely necessary, then the true-up should be based on an aggregate rebate (percent of allowances) calculated at least 2 years after the incurred date of the claim. This would, however, add significant administrative expenses to the system without adding much value. If a true-up is required, we recommend that it occur infrequently to limit administrative expenses.

§423.888 Payment Methods, Including Provision of Necessary Information; Payment Methodology (§423.888; P: 46745; R: 46859)

Highmark Comment: CMS is seeking comments on the Payment Methodology for disbursing subsidies to plan sponsors. We suggest that Option 3 be removed, as a monthly process creates a significant burden both on plan sponsors and MA organizations assisting them. Option 2, making interim payments throughout the year, is acceptable if payment is quarterly. Option 1 is most preferable, as it would significantly reduce administrative costs and data collection burdens. Regarding periodicity, we suggest that quarterly disbursement be the standard if Option 2 is chosen, as plan sponsors would still be able to receive regular subsidy payments but the administrative burdens would be more reasonable for smaller businesses with fewer employees.

Thank you for your consideration of these comments. We look forward to working with you to determine the most efficient way to roll out Part D. If you need any further explanation or assistance, please contact me at **sandra.tomlinson@highmark.com** or 412-544-7646.

Sincerely,

Sandra Tomlinson
Senior Vice President, Provider Services and Pharmacy Affairs
Highmark, Inc.

Cc: Kenneth Melani, M.D., CEO and President, Highmark Inc.
David O'Brien, President, Keystone Health Plan West, Inc.
James Klingensmith, Executive Vice President, Highmark Inc.
Anne Crawford, Medicare Advantage Compliance Officer, Highmark Inc.
Jane Galvin, Director of Regulatory Affairs, Blue Cross Blue Shield Association

CMS-4068-P-1218

Submitter : Dr. Dean Hakanson **Date & Time:** 10/04/2004 08:10:39

Organization : GlaxoSmithKline

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

GlaxoSmithKline's comments to the Proposed Rule are attached, plus a copy of our comments to the USP Model Guidelines.

CMS-4068-P-1218-Attach-2.doc

CMS-4068-P-1218-Attach-1.doc

October 4, 2004

BY HAND DELIVERY

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-4068-P (Medicare Program; Medicare Prescription Drug Benefit)

Dear Dr. McClellan:

GlaxoSmithKline ("GSK") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Proposed Rule regarding the establishment of a Medicare Prescription Drug Benefit, published in the Federal Register on August 3, 2004 (the "Proposed Rule"),[1] pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").[2] GSK is a world leading research-based pharmaceutical company with a mission to improve the quality of human life by enabling people to do more, feel better, and live longer.

GSK applauds CMS for acting quickly to implement the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"). We are well aware that the MMA has placed an enormous responsibility on the agency to make complex changes to the Medicare program in a short period of time. We appreciate CMS's efforts to appropriately implement the Part D prescription drug benefit. As CMS continues to refine its implementation of the MMA, we hope that it will remain open to comments and dialogue with affected entities and continue to provide clear written guidance to manufacturers on its website or through other means.

Most of our comments focus on protecting patient access to prescription drugs. While the new Medicare prescription drug program holds the potential to greatly increase Medicare enrollees' access to prescription drugs, we are concerned that this access may not be fully realized because of limitations in how the Part D is implemented, most particularly with respect to the design of plan formularies and the limits of a burdensome appeals process.

Following are GSK's detailed comments to the Proposed Rule.

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[1] 69 Fed. Reg. 46632 (Aug. 3, 2004).

[2] GSK also is a member of both the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Industry Organization ("BIO") and fully supports those associations' comments to the Proposed Rule.

I. Subpart C -- Evaluation of a Plan's Design and Formulary Review -- § 423.272(b)(2)

CMS needs to carefully scrutinize formularies and formulary design to ensure that certain groups of Medicare enrollees are not discouraged from enrolling in part D plans.

- **GSK recommends that CMS revise §423.272(b)(2) to establish the two separate types of reviews required by statute—one establishing the general review of plan design for risk avoidance characteristics and the second based on criteria for formulary categories and classes.**

- **Also, CMS needs to clarify that the access criteria in section 423.120 are of no relevance for the general risk selection review of plan design under 423.272(b)(2).**

- **Lastly, GSK urges CMS to establish guidelines to be used for its general risk avoidance review of a plan's design that considers, among other things, clinically recognized treatment guidelines for particular diseases or conditions.**

Congress deemed it critical to the structure and success of the Part D benefit that Part D plans not be able to engage in risk selection. The market mechanism being created for part D will not work either to attract beneficiaries to enroll in this optional benefit or to fairly apportion risk among participating Part D plans if entities are able to explicitly or implicitly discourage enrollment by individuals whose care requires specific and/or multiple medications. Under the plain language of the statute, CMS review of a "plan benefit design" not only must encompass the "design of categories and classes" but also must identify **any** feature that would tend to explicitly or implicitly serve as a risk avoidance mechanism by discouraging patients with specific medical conditions from enrolling in that plan. This means that CMS review must also include the plan's formulary management interventions, including formulary tiers, prior authorization, step therapy, and cost sharing.

In our view, the Proposed Rule does not adequately protect against the risk that certain populations of Medicare enrollees will be discouraged from enrolling in Part D plans. CMS has stated that the agency will evaluate a Part D plan's formulary to ensure that the plan has not designed its formulary to discourage the enrollment of certain groups of Medicare beneficiaries[3] – for example, those with diseases or conditions that require significant prescription drug therapies. However, the Proposed Rule at section 423.272(b)(2) can be read as combining the CMS review of risk avoidance as a general matter, with the criteria for meeting but one of many of the elements to be reviewed, i.e., the single characteristic of plan design (categories and classes).

[3] Proposed 42 C.F.R. § 423.272(b)(2).

GSK recommends that the regulation be changed to conform to the statute by separating out measures that may be used by Part D plans to satisfy the "category and class" element from the general requirement that plan design (including formulary management interventions and formulary tiers) cannot discourage enrollment. CMS must clearly separate the general risk avoidance review and any criteria that CMS may apply from guidelines developed pursuant to the statute (i.e. USP Model Guidelines) for ensuring that the formulary categories and classes satisfy the nondiscrimination requirement. This distinction requires that section 423.272(b)(2) be rewritten to establish the two separate types of review required by the statutory authority – one establishing the general review of plan design for risk avoidance characteristics and the second based on criteria for formulary categories and classes.

The MMA explicitly states:

> "The Secretary may approve a prescription drug plan only if"[4] (among other things) "[t]he Secretary does not find that the design of the plan and its benefits … are likely to substantially discourage enrollment by certain part D eligible individuals."[5]

The statutory language is clear that the "design of the plan" being reviewed by CMS under MMA clause 1860D-11(e) (2) (D) (i) of the law is not limited to a list of covered drugs. The statute explicitly states that the review is of the *plan benefit design*, which may include prior authorization, step therapy, and clinical limitations on coverage of specific drugs, as well as the formulary, its categories and classes, *and* any "tiered formulary structure" for co-payments by beneficiaries. It is an entirely *separate* clause of the statute which provides that "the design of categories and classes within a formulary" cannot be the basis for finding that a formulary and its tiered structure discourage enrollment, if the categories and classes used by the Part D plan are "consistent with" the United States Pharmacopeia ("USP") guidelines.[6] Thus, the language of the statute is clear that the use of USP categories and classes under MMA clause 1860D-11(e)(2)(D) (ii) will satisfy merely one of the multiple points of review that the Secretary is required to make under clause (D)(i).

The explicit requirements of the MMA notwithstanding, the reasons for our recommended clarification to Proposed Rule section 423.272(b)(2) are straightforward and will further Congressional intent. First, formularies are clinical tools that must reflect the current state of science and clinical practice for the diseases that physicians treat. The MMA explicitly requires Part D plans to provide information to prospective enrollees about the plans' formularies prior to enrollment. Thus, the statute clearly contemplates that for a person already receiving

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[4] SSA § 1860D-11(e)(2).

[5] SSA § 1860D-11(e)(2)(D)(i).

[6] SSA § 1860D-11(e)(2)(D)(ii).

medical care for a medical condition, a plan whose design (including formulary, formulary tiers, authorization, and step therapy) does not provide access to drugs consistent with up-to-date medical practice is not a viable option for enrollment. It would be inconsistent with Congress's intent, therefore, to allow a plan to satisfy the requirement that it not be designed "to discourage enrollment by certain part D eligible individuals" simply by using the formulary categories and classes designed by the USP and ensuring that there are a specified number of drugs in each of those categories.

Second, unless CMS clarifies Proposed Rule Section 423.272(b)(2) as recommended above, prospective bidders are likely to be misled about the nature of the risk avoidance review, particularly in light of statements in the commentary to the Proposed Rules[7] and section 423.120(b)(2) of the regulation relating to minimal formulary criteria for assuring access to drugs.[8] For example, in the minimum formulary access provisions (discussed below), CMS has said that it is possible for an adequate formulary to include *only* two drugs per class. If a simple numerical criterion together with use of the USP categories and classes would assure passage of this review, the Proposed Rule would be inconsistent with the statute as a legal matter and would not achieve the stated objective of avoiding the risk that certain populations of Medicare enrollees will be discouraged from enrolling in Part D plans.

Another concern with the current draft of the Proposed Rule is that combining the requirements of sections 423.272(b) (2) and 423.120(b) (3) does not assure clinically sound formularies. The USP categories and classes that are being developed for use by CMS for the review of this one element of plan design may or may not be an appropriate clinical foundation for assuring access to medically appropriate care under part D. GSK understands that the evaluation of the adequacy of the model categories and classes designed by USP is ongoing, and we have urged USP to substantially revise its model guidelines to better reflect accepted medical practice and nationally recognized treatment guidelines. (GSK's comments filed with USP on September 17, 2004, are attached.) Even if there could be agreement on the structure of categories and classes to be used in formulary design, it would not be clinically valid to decide a priori that a specific number of drugs – and the same number for each class – will always be sufficient to provide access to care. Rather, Congress's use of the plural form "drugs" in referring to formulary access is meant to ensure that physicians and patients always have a choice of therapy options, in recognition that medical care in the 21st century is increasingly personalized to meet the specific characteristics of the disease, the patient, and his or her current condition.

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[7] 69 Fed. Reg. at 46660. This portion of the commentary states, "The USP listing would simply serve as a model set of guidelines. As specified in 1860D-11(e)(2)(d)(ii) of the Act, if the therapeutic classifications within a plan's formulary conform to the USP classifications, we could not determine, based on the formulary's therapeutic classifications, that the plan violates the provision at 1860D-11(e)(2)(d)(i) of the Act and section 423.272(b)(2) that prohibits the design of the plan and its benefits (including any formulary and tiered formulary structure) that substantially discourages enrollment by certain Part D eligible individuals."

[8] 42 C.F.R. § 423.120(b)(2).

CMS should clarify in the final rule that the access criteria in section 423.120 are of no relevance for the general risk selection review of plan design under 423.272(b) (2). Rather, the criteria in section 423.120 are minimal guidelines for ensuring a choice of therapy alternatives when developing a formulary. A Pharmacy and Therapeutics Committee should use sound clinical judgment to create the list of drugs covered by the plan, taking into account authorization requirements, clinical guidelines and step therapy, as well as the categories and classes that are used to sort and create preferential coverage and co-payment for the drugs available for treating specific diseases and conditions. Accordingly, we recommend below in our comments regarding section 423.120(b) (Pharmacy and Therapeutics Committees) that CMS clarify that Pharmacy and Therapeutics Committees should take into account clinical guidelines as well as the therapeutic categories and classes when creating preferential coverage and co-payment for the specific drugs.

GSK urges CMS to establish guidelines to be used for its general risk avoidance review of a plan's design that considers, among other things, clinically recognized treatment guidelines for particular diseases or conditions. Specifically, CMS should establish two types of guidelines for evaluating risk avoidance:

(a) Where there are treatment guidelines and protocols established by recognized entities for use in treating the disease or condition, the formulary design must allow for coverage of the full range of drugs needed to use the treatment guideline or protocol and to provide the doctor and patient with therapeutic options and alternatives.

Many among the elderly and disabled population served by Medicare have conditions for which drug treatments may be especially effective, such as Chronic Obstructive Pulmonary Disease (COPD), diabetes, asthma, heart failure, HIV, cancer and depression. Medications for these conditions must be taken for extended periods, and enrollees with multiple problems may require simultaneous administration of multiple medications. [9] In 2001 for example, people 65 and over who reported a prescribed medication expense purchased an average number of 26.5 medications.[10] The elderly population struggles with medication adherence, and their vulnerability is increased by the creation of extremely limited formularies. Such formularies will disproportionately affect the economically disadvantaged elderly and the sickest members.

Nationally and internationally recognized evidence-based clinical guidelines for chronic diseases such as COPD, asthma, HIV, and diabetes, routinely include combination therapies as

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9 Report to the President, "Prescription Drug Coverage, Spending, Utilization, and Prices," From Department of Health & Human Services, April 2000, available at http://aspe.hhs.gov/health/reports/drugstudy/.

10 Pancholi M, Stagnitti M. Outpatient Prescribed Medicines: A Comparison of Use and Expenditures, 1987 and 2001. *Statistical Brief #33.* June 2004. Agency for Healthcare Research and Quality, Rockville, MD. http://www.meps.ahrq.gov/papers/st33/stat33.htm

part of their management recommendations and treatment options.[11,12,13,14] Such recommendations include the simplification of therapy by reducing the number of pills and frequency of dosing, and frequently, a discussion of the potential benefits of such strategies relative to medication adherence, drug interactions and side effects.[14, 16]

Additionally, the effectiveness of combination therapies as a means of simplifying treatment regimens and promoting adherence and compliance has been well documented in the literature.[15,16,17,18,19] Using respiratory tract diseases as an example, combination therapies such as Advair® (fluticasone proprionate and salmeterol) are included in both the NIH/NHLBI guidelines for the treatment of asthma, and the ATS/ERS guidelines for managing COPD.[12, 13,14] Supporting evidence from clinical studies, such as Stoloff et al, demonstrate greater refill persistence with the combination therapy Advair® (fluticasone proprionate and salmeterol) compared with the individual components administered seperately.[18] Based on the consistency of such findings and guideline recommendations, CMS's review of plan design for impermissible risk avoidance issues should consider the importance to Medicare enrollees' of having appropriate access to necessary combination therapies.

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[11] Report to the President, "Prescription Drug Coverage, Spending, Utilization, and Prices," From Department of Health & Human Services, April 2000, available at http://aspe.hhs.gov/health/reports/drugstudy/.

[12] Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: Executive Summary—Updated 2003. Bethesda, Md: NIH, NHLBI; 2003.

[13] National Institutes of Health National Heart Lung and Blood Institute. National Asthma Education and Prevention Program. Executive summary of the NAEPP expert panel report. Guidelines for the diagnosis and management of asthma- update on selected topics 2002. NIH Publication No. 02-5075. June 2002.

[14] . Panel on Clinical Practices for the Treatment of HIV Infection. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. February 2001. Department of Health and Human Services, and the Henry J. Kaiser Family Foundation. Available at http://www.hivatis.org. Accessed November 26, 2001

[15] Celli B, MacNee W, et al. Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. Eur Respir J 2004;23:932-946.

[16] Gurwitz JH et al. Incidence and Preventability of Adverse Drug Events Among Older Persons in the Ambulatory Setting. *JAMA*. March 5, 2003. Vol 289 (9).1107-1116.

[17] Inzzucchi, SE. Oral antihyperglycemic therapy for type 2 diabetes. JAMA.2002; 287; 360-372.

[18] Stoloff SW et al. Improved refill persistence with fluticasone propionate and salmeterol in a single inhaler compared with other controller therapies. *J Allergy Clin Immunol* 2004;113:245-51.

[19] Taylor AA, Shoheiber O. Adherence to Antihypertensive Therapy With Fixed-Dose Amlodipine Besylate/Benazepril HCl Versus Comparable Component-Based Therapy. *CHF* 9(6):324-332, 2003.

(b) CMS should ensure that the cost sharing imposed under any tiered formulary structure that does not prefer drugs integral to treatment protocols or guidelines for a disease or condition does not impermissibly shift costs to any specific patient population.

In other words, CMS must ensure that the actuarial value of the Part D benefit does not selectively reward persons with lower aggregate drug costs while imposing higher costs on persons with a particular disease or condition, such as HIV, cancer, COPD, diabetes, or asthma. Such cost shifting is unfair to most enrollees and inconsistent with the risk selection prohibition in the statute. It also unfairly shifts costs to the federal government because such costs are paid by the government for enrollees under 135% FPL and also count toward TrOOP for purposes of "catastrophic coverage." Furthermore, such cost shifting may unduly burden SPAPs, which may pick up the higher cost-sharing amounts through their supplemental coverage or benefits.

Evidence is mounting that good health and good pharmacoeconomics go hand in hand. Dr. Avi Dor from Case Western and William Encinosa from AHRQ recently demonstrated the profound impact of increasing out-of-pocket costs on adherence and overall medical spending in a working paper prepared for the National Bureau of Economic Research.[20] They demonstrated that, as out-of-pocket costs for medications rise, medication adherence decreases, and anticipated savings to the payor are greatly offset by the increase in costs related to hospitalizations and other medical complications.

Many recent studies using analyses of claims databases linked to benefit design across different populations (private pay and government) consistently have noted that as out-of-pocket costs increase, adherence to essential medications decreases. Since out-of-pocket costs could be a barrier to obtaining recommended and appropriate non-formulary medications, overall health care spending could significantly increase. Most notably, thought leaders from RAND,[21] Harvard University,[22] Case Western Reserve University,[23] the Agency for Healthcare Research and Quality,[24] Cleveland Clinic,[25] and the University of Michigan[26] are adding to the body of evidence

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[20] Dor A, Encinosa WE. NEBR Working Paper Series. Does Cost Sharing Affect Compliance? The Case of Prescription Drugs. National Bureau of Economic Research. http://papers.nber.org/papers/w10738.pdf

[21] Joyce GF, Escarce JJ, Solomon MD, Goldman DP. Employer drug benefit plans and spending on prescription drugs. JAMA. 2002;288(4):1733-1739. - Multi-year study of 25 companies.

[22] Huskamp, HA, Deverka PA, Epstein AM, et al. et al. The Effect of Incentive-Based Formularies on Prescription –Drug Utilization and Spending. N ENJ J MED 2003;2224-32.

[23] Dor A, Encinosa WE. NEBR Working Paper Series. Does Cost Sharing Affect Compliance? The Case of Prescription Drugs. National Bureau of Economic Research. http://papers.nber.org/papers/w10738.pdf

[24] *Id*

[25] Ellis JJ, Fendrick M et al. Suboptimal Statin Adherence and Discontinuation in Primary and Secondary Prevention Populations. Should We Target Patients with the Most to Gain? J Gen Intern Med 2004;19:638-645.

supporting the conclusion that financial barriers (increasing out-of-pocket costs) to essential medications in chronic diseases leads to an overall increase in morbidity and downstream health care costs. [27,28,29,30,31,32,33,34,35,36,37,38,39]

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[26] *Id*

[27] Dor A, Encinosa WE. NEBR Working Paper Series. Does Cost Sharing Affect Compliance? The Case of Prescription Drugs. National Bureau of Economic Research. http://papers.nber.org/papers/w10738.pdf

[28] Joyce GF, Escarce JJ, Solomon MD, Goldman DP. Employer drug benefit plans and spending on prescription drugs. JAMA. 2002;288(4):1733-1739. - Multi-year study of 25 companies.

[29] Berman C. Pitney Bowes: Prescription Drug Value-Based Purchasing. Presented at National Business Coalition on Health; January 22, 2004; Las Vegas, NV.

[30] Cramer JA, Glassman M, Rienzi V. The relationship between poor medication compliance and seizures. Epilepsy and Behavior. 2002;3(4):338-342.

[31] Cranor CW, Bunting BA, Christensen DB. The Asheville Project: Long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc. 2003;43:173-84.

[32] Ellis JJ, Fendrick M et al. Suboptimal Statin Adherence and Discontinuation in Primary and Secondary Prevention Populations. Should We Target Patients with the Most to Gain? J Gen Intern Med 2004;19:638-645.

[33] Goldman, DP, Joyce, GF, Escarce,EJ, Pace, JE, Solomon,MD, Laouri, M, Landsman, PB, Teutsch, SM, Pharmacy Benefits and the Use of Drugs by the Chronically Ill. JAMA. 2004;291:2344-2350.

[34] Huskamp, HA, Deverka PA, Epstein AM, et al. et al. The Effect of Incentive-Based Formularies on Prescription –Drug Utilization and Spending. N ENJ J MED 2003;2224-32.

[35] Pharmaceutical Research and Manufacturers of America. Focus on Health Policy, Winter 2004, pg 1-7. Medicare Beneficiaries Cared for with Prescription Medicines. Available at: http://www.phrma.org/publications/policy//2004-03-23.921.pdf . Accessed May 17, 2004.

[36] Rand Study Finds Patients with Chronic Conditions cut use of Preventive Drugs when Drug Co-Payments Double. Press Release May 18, 2004. Available at: http://www.rand.org/news/press.04/05.18.html. Accessed May 19,2004.

[37] Rundall, T, As good as it gets? Chronic care management in nine leading U.S. physician organizations. Br. Med. J., 2002; 325:

[38] The Hidden Epidemic: Finding a Cure for Unfilled Prescriptions and Missed Doses. December, 2003. The Boston Consulting Group and Harris Interactive. Available at http://www.bcg.com/publications/files/TheHiddenEpidemic_Rpt_HCDec03.pdf. Accessed August 16, 2004.

[39] Wye River Group on Healthcare. An Employer's Guide to Pharmaceutical Benefits. 2003. Available at: http://www.wrgh.org/docs/Book.pdf Accessed May 21, 2004.

II. Comments on Subpart C -- Other Formulary Issues -- § 423.120

a. Inclusion of New Drugs and New Uses – 423.120(b) (3).

GSK recommends that CMS require Part D plans to use the Pharmacy and Therapeutics Committee process to evaluate their formularies at least once each quarter to reflect new drugs and new uses of existing drugs.

GSK strongly supports the provisions in the Proposed Rule that would allow plans to change categories and classes during a calendar year to take into account new therapies or new uses for existing therapies.[40] GSK continually strives to develop new medicines that will fulfill our mission of improving the quality of human life. Because the FDA approves new medicines and new uses for existing therapies throughout the year, the full benefits of continuous medical innovation can be realized only if patients have timely access to innovative treatments. CMS' proposal will help ensure timely patient access to critical therapies by allowing plans to adjust their formularies as medical technology evolves, and it should be implemented in the final rule.

Additionally, we recommend that CMS take further steps to ensure that Part D plans' formularies keep up with the pace of pharmaceutical innovation. Some plans might not take advantage of the opportunity to update their formularies unless CMS requires them to do so. Patient access to life-saving or life-extending therapies could be delayed by plans that fail to update their formularies on a regular basis. *We therefore urge CMS to require Part D plans to evaluate their formularies at least quarterly, using the Pharmacy and Therapeutics Committee process, to reflect new drugs and new uses of existing drugs.*

b. Removal of Drugs from a Formulary and Changes to Cost-Sharing Status – 423.120(b) (5).

CMS should modify the regulation to provide that, upon ninety days notice to physicians, pharmacies, the Secretary, and other financially responsible parties as well as enrollees not yet prescribed a drug, a plan may change the formulary or preference status of a drug. However, such change is not effective as to enrollees with an active prescription for such drug – these enrollees must be ensured continued access to an ongoing therapy during the course of their disease.

The MMA allows Part D plans to remove a drug from a formulary or change its cost-sharing status with "appropriate notice" to certain parties, including affected enrollees, providers

[40] Proposed 42 C.F.R. § 423.120(b)(3).

and the Secretary.[41] In the Proposed Rule, CMS has interpreted this "appropriate notice" provision as permitting a plan to remove a drug from its formulary or change its cost-sharing status with only thirty days notice.[42] We think that this proposal inappropriately confuses appropriate notice to practitioners using the formulary in making treatment decisions for their *new* patients with appropriate notice to Medicare enrollees who have relied on a plan's formulary in making treatment decisions and/or decisions regarding the selection of a Part D plan. Furthermore, we believe that, even for enrollees not currently taking a drug, a thirty day notice is inadequate. As such, the Proposed Rule fails to implement the provisions of the MMA and ultimately ensures a high probability that the Part D benefit will devolve to substandard quality unlikely to meet the medical needs of enrollees

Medical care for the chronic conditions that affect elderly and disabled Medicare beneficiaries is ongoing. For many conditions, care spans many months and even years. Although scientists and clinicians may dispute which of several therapeutic alternates is "best" for *starting* treatment for a patient who has been just diagnosed, there are no principles of good medical practice that would support changing a patient's medications every thirty days if the medication is effectively managing the patient's condition. Yet this is precisely what CMS's proposal would permit.

The entire structure of the Part D benefit depends on enrollees evaluating a plan's design, including its formulary, and through the exercise of choice during each open enrollment period, encouraging plans to improve in quality and coverage to compete for beneficiaries. In fact, CMS has expressly noted that it will be important for beneficiaries to "have the most current formulary information by the time of the annual enrollment period…in order to enroll in the Part D plan that best suits their particular covered Part D drug needs."[43] Yet the Proposed Rule virtually guarantees that this cannot occur. By permitting Part D plans to change which drugs are on its formulary at any time, as many times as it likes, so long as "affected parties" have thirty days notice, CMS would severely undermine the enrollee's plan selection process and the structure of the Part D benefit.

More ominously, the criteria CMS has established would permit a plan to market a clinically rich formulary, modest authorization requirements and clinical guidelines during open enrollment season, and then drop drugs or increase cost-sharing on all drugs after the first 30 day protected period to meet cost containment objectives,[44] so long as the two-drug minimum access

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[41] SSA § 1860D-4(b)(3)(E).

[42] Proposed 42 C.F.R. § 423.12f0(b)(5). CMS has proposed that plans would not be permitted do make such changes during the annual open enrollment period and at the beginning of each enrollment year.

[43] 69 Fed. Reg. at 46661.

[44] Proposed 42 C.F.R. § 423.120(b)(6).

criterion is met.[45] Thus, the 30-day formulary change criterion established by the Proposed Rule not only fails to meet the statutory criterion of "appropriate" notice established by the MMA, but also fails to protect beneficiaries against the very "bait-and-switch" tactics that have been a major focus of concern and action by CMS in connection with implementation of the Medicare Drug Discount Card. Utilizing these tactics, a plan might seek to attract beneficiaries whose condition is stabilized on popular drugs; and, once the patient is locked in and the premium revenue guaranteed for a year, switch the formulary preference. Such bait-and-switch tactics are prohibited under the consumer protection laws of the United States and the States individually as unfair and deceptive to consumers. The Congress established a market-based system to provide a cost-effective drug benefit for Medicare beneficiaries; it did not intend to permit commercial practices that cause beneficiaries to pay a premium and face administrative hassles and confusing messages about the medical care prescribed by their doctors.

We recommend that because the Congress has established a system in which beneficiaries select plans based on their formularies and because beneficiaries are (except in rare circumstances) not permitted to switch from one plan to another more than once in a year, "appropriate notice" to affected parties cannot be a fixed thirty day period. Rather, we urge CMS to require plans to provide *all* enrollees – whether or not they are taking the affected drug – with a 90 day notice before removing a drug from a formulary or increasing the cost-sharing for a drug. Where a patient had an active prescription for a drug for an ongoing or episodic condition when she or he enrolled in a Part D plan or was first prescribed a drug after enrollment in the plan, the Part D plan should not be permitted to exclude the drug or increase its cost sharing for that patient during the course of the patient's disease.

Thus, we recommend that CMS modify the regulation to provide that, upon ninety days notice to physicians, pharmacies, the Secretary and other financially responsible parties as well as enrollees not yet prescribed a drug, a plan can change the formulary or preference status of a drug. However, such change is not effective as to enrollees with an active prescription for such drug – these enrollees must be ensured continued access to an ongoing therapy during the course of their disease.

c. Special Populations -- § 423.120

We recommend that special populations – such as HIV/AIDS, cancer, mental health conditions, long-term care residents, and dual eligibles – be given access to open formularies.

As CMS has acknowledged, Part D enrollees with serious and chronic disease have special needs that may not adequately be met through a restrictive formulary.[46] In addition,

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[45] *See* 69 Fed.Reg. at 46661.

[46] 69 Fed.Reg. at 46661

CMS is concerned that plans might inappropriately discriminate against select Medicare populations. These enrollees – among Medicare's most fragile – tend to require multiple medications and are likely to require individualized treatment plans and specific therapies. Also, because of the nature of the diseases and of the complexity of the pharmaceutical therapies available, the patients will tend to incur high plan costs. It is possible that plans might want to restrict access to select therapeutic areas to discourage these patients from enrollment.

GSK urges CMS to provide these enrollees with access to an open formulary requiring plans to institute special formulary standards for these enrollees that reflect their special medical needs. Such standards may include broad access to the range of therapies required by individuals with serious and chronic illnesses, including access to special dosage forms and a special exceptions process should an open formulary not be implemented.

Below we have identified some reasons why certain Medicare populations – those with AIDS, cancer, or mental health conditions, those in long-term care, and those dually eligible for Medicare and Medicaid – may need these special formulary rules.

Part D Enrollees with HIV/AIDS:

GSK recommends that people with HIV/AIDS be given broad access to a full range of therapeutic and supportive care options based on available scientific evidence.

The standard of care in HIV therapy requires at least three HIV drugs, which are typically in the same class.[47] For example, many HIV patients take two drugs from the nucleoside/nucleotide reverse transcriptase inhibitor category. These drugs are in the same pharmaceutical class and have the same general mechanism of action; yet a specific mutation in the HIV virus may render some of these drugs ineffective. Because several such mutations exist, it is not possible to identify two drugs that would be effective in all patients.[48] Further, changing patterns of viral resistance to the antiviral agents used for HIV treatment mandate an opportunity for the treating physician to readily make changes in the treatment regimen without a burdensome exception process.[49] Transmitted human immunodeficiency virus type 1 carrying the D67N or K219Q/E mutation evolves rapidly to zidovudine resistance in vitro and shows a high replicative fitness in the presence of zidovudine.[50]

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[47] *See, e.g.,* DHHS, Panel on Clinical Practices for Treatment of HIV Infection, "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents," (March 23, 2004) at 13.

[48] *See id.* at 19.

[49] (2004: which HIV-1 drug resistance mutations are common in clinical practice? AIDS Rev. 2004 Apr-Jun;6(2):107-16

[50] J Virol. 2004 Jul;78(14):7545-52.)

Thus, the minimum two drugs per class will not be sufficient to meet the needs of HIV patients. These individuals will need broader access to drugs under Part D to obtain appropriate medical care; the appeals and exceptions process will not be adequate to ensure sufficient access to necessary therapies for this population.

Part D Enrollees with Cancer:

GSK recommends that cancer patients be given broad access to a full range of therapeutic and supportive care options based on available scientific evidence.

We are particularly concerned about whether cancer patients will be able to access the therapies they need through Part D formularies. This will depend in part on whether the USP properly revises its model guidelines to reflect the range of necessary cancer therapies and whether CMS appropriately considers the specific needs of cancer patients in scrutinizing plan formularies.

Current treatment guidelines for cancer management clearly reflect the need for oncologists and cancer patients to have broad access to a full range of therapeutic and supportive care options based on available scientific evidence. These guidelines are frequently updated based on the rapidly evolving nature of the scientific evidence.[51]

It is particularly difficult to provide appropriate cancer treatment within the confines of a plan formulary. Cancer is actually a wide range of diseases requiring therapies from multiple pharmacological classes depending on factors such as tumor type, stage of disease, available biomarkers, proven combination regiments, and patient tolerability. Appropriate cancer treatments may include antineoplastics, hormone suppressants, immune suppressants, and other immunological agents -- as well as supportive therapies for the management of the severe side effects of chemotherapy or radiation therapy. These therapies include antiemetics and treatments for anemia, neutropenia, and thrombocytopenia.

Cancer patients cannot afford the time lost in a lengthy appeals process that may be required to access the care they need. So this population could face significant risk of being discriminated against by Part D plans seeking to contain drug costs

Part D Enrollees with Mental Health Conditions:

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[51] NCCN/ACS Treatment Guidelines for Patients. National Comprehensive Cancer Network. 2004. http://www.nccn.org/professionals/physician_gls/f_guidelines.asp#site

GSK recommends that patients with mental health conditions be given broad access to a full range of therapeutic and supportive care options based on available scientific evidence.

Prescription drugs play a critical role in treating and managing mental illnesses such as depression, schizophrenia, and bipolar disorder. For these conditions, a patient typically must try several drugs in the same class before finding the proper drug and dose. In the Conference Report to the MMA, Congress recognized the special needs of the mentally ill, stating its intent that these Part D enrollees have clinically appropriate access to pharmaceutical treatments for mental illnesses[52] and noting that this is a "unique population with unique prescription drug needs as individual responses to mental health medications are different."[53] There are many legitimate reasons for multiple drug therapy in this population.[54] To fully comply with the MMA, the Part D implementing regulations must appropriately reflect the needs of this population to have broader access to medications. *GSK recommends that patients with mental health conditions be given broad access to a full range of therapeutic and supportive care options based on available scientific evidence.*

Part D Enrollees in Long-Term Care Facilities:

GSK recommends that residents of LTC facilities be considered a "special population" with respect to Part D plan formularies and be granted access to an open formulary that supports their unique medical needs.

Residents of long-term care ("LTC") facilities will be especially vulnerable to adverse consequences that inevitably arise from therapeutic substitutions and administrative inefficiencies in the formulary process. *GSK urges CMS to grant this population access to formularies that include a wider range of drugs than may be offered under the restricted or closed formularies of Part D plans.*

The elderly population, which represents the largest group of patients in LTC facilities, typically requires multiple medications across multiple therapeutic categories and classes; and these drugs often are not interchangeable with other drugs within the class without risking drug interaction and/or other substantial complications. Restricting formulary access to medications will force some of these Part D enrollees to seek approval through the exceptions and appeals processes for the therapies they need. Yet because of their unique needs, many of these

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[52] Conf. Rep at 769-770.

[53] Conf. Rep. at 770.

[54] "Reasons for polypharmacy among psychiatric patients." Pharm World Sci. 2004 Jun;26(3):143-7.

vulnerable enrollees will be unable to meaningfully access the appeals and exceptions processes to appeal the denials and other barriers to access they encounter.

To meet the special needs of this population, GSK recommends that residents of LTC facilities be considered a "special population" with respect to Part D plan formularies and be granted access to an open formulary that supports their unique medical needs.

For a more thorough analysis of these risks and issues, we recommend that you reference the September 17, 2004, Comments to the Draft Model Guidelines submitted by the American Society of Consultant Pharmacists.

Part D Enrollees Dually Eligible for Medicaid:

GSK recommends that CMS establish special formulary rules to provide dual eligibles with continued access to a formulary that is consistent with their current access to prescription drugs under Medicaid.

Dual eligibles are likely to have significant difficulty adjusting to the Part D benefit. Currently, these individuals have access to drugs through Medicaid programs, which generally provide access to medically necessary drugs. Once the Part D benefit begins, these individuals will have access only to those prescription drugs available on their Part D plan's formulary.

It will be critical that CMS establish special formulary rules to provide this population with continued access to a formulary that is consistent with their current access to prescription drugs under Medicaid. Many of these enrollees have special medical needs such as mental health conditions and/or are in long-term care facilities, group homes or other community-based programs that provide long-term care in a setting more conducive to maintaining activities of daily living.

We urge CMS to ensure that these enrollees continue to receive the medications they need by providing them access to medically necessary drugs. Because individuals receiving long-term care in facilities and community settings depend heavily on caregivers for advice and assistance, any transition of these enrollees that requires en masse switching or discontinuation of medicines will be particularly burdensome for physicians (who must participate in exceptions requests and appeals), destructive of the quality of care provided by these community providers, and detrimental to this vulnerable population.

III. Subpart C -- Covered Part D Drugs -- § 423.100

a. Obesity -- § 423.100

Given that numerous Medicare enrollees suffer from health disorders where obesity is a modifiable risk factor, GSK urges CMS to clarify that Part D plans may include in their formularies therapies whose mechanism of action is weight loss when the therapy is medically necessary to improve the outcomes of co-morbid diseases for which obesity is a modifiable risk factor.

Obesity is a modifiable risk factor for a host of diseases including diabetes, heart disease, dyslipidemia, sleep apnea, gallstones, bladder control problems, uric acid nephrolithiasis, psychological disorders, osteoarthritis, and certain cancers.[55] For example, central obesity is one of the risk factors for Metabolic Syndrome – a condition that affects an estimated 20 percent of adults in the U.S., with the prevalence approaching 50% in the elderly.[56] The syndrome is also characterized by dyslipidemia, hypertension, and insulin resistance. Although these combined risk factors do not necessarily manifest in overt symptoms, they are warning signs for increased risk of atherosclerosis, heart disease, stroke, diabetes, kidney disease, or premature death.[57]

Given the recognition and significance by various agencies within HHS of the significance of obesity with regard to health, the number and extent of diseases associated with obesity, and the impact obesity and co-morbidities have on the Medicare population, GSK recommends the following:

GSK urges CMS to consider the significance of obesity and its relation to other co-morbid conditions in the Medicare population and clarify that Part D plans are not prohibited from covering therapies whose mechanisms of action are primarily aimed at obesity, when therapy is medically necessary to improve the outcomes of co-morbid diseases for which obesity is a modifiable risk factor.

Other agencies within HHS recognize the need to combat obesity with regard to improving health. The Food and Drug Administration's ("FDA's") Endocrinologic and Metabolic Drugs Advisory Committee recently held an open meeting to consider changes to the FDA's 1996 guidance document for the clinical evaluation of weight-control drugs and unanimously recommended that indications for the treatment of co-morbidities should not be disqualified simply because the primary mechanism of action was weight loss.

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55 http://www.cdc.gov/nccdphp/dnpa/obesity/consequences.htm

56 http://www.labtestsonline.org/understanding/conditions/metabolic.html.

57 Id.

CMS has revised a long-standing national coverage policy and indicated that "[s]ervices in connection with the treatment of obesity are covered services when such services are an integral and necessary part of a course of treatment for one of these medical conditions."[58] Not only is coverage of therapies that treat obesity clinically sound, but it also translates into cost-savings. According to the 2001 Surgeon General's Call to Action on Prevent and Decrease Overweight and Obesity, the total direct and indirect costs were estimated at $177 billion nationally in 2000.

GSK applauds the agency's recognition that coverage of obesity treatments is warranted when interrelated to other diseases.

b. Vaccines -- § 423.100

GSK is concerned that Part D plans may interpret § 423.100 in a manner that allows them to exclude coverage of certain vaccines that are reasonable and necessary for prevention. Therefore, we recommend that CMS

1. **specify that plans are required to offer coverage for vaccines and**

2. **actively communicate the value of immunizing Medicare enrollees.**

The MMA defines "covered Part D drugs" to expressly include vaccines.[59] CMS mirrors this definition in the Proposed Rule.[60] However, the potential for confusion exists due to other sections of the MMA.

In addition to the express mention of vaccines as covered Part D drugs, the MMA also allows a Part D plan to exclude a covered Part D drug if payment for that drug "would not be made if section 1862(a) applied to this part."[61] Section 1862(a) of the Social Security Act excludes, among other things, from Part B coverage items and services that are not "reasonable and necessary" for the "diagnosis or treatment of illness or injury or to improve the functioning

[58] Medicare Coverage Issues Manual, § 35-26.

[59] SSA §1860D-2(e)(1).

[60] Proposed 42 C.F.R. § 423.100.

[61] SSA § 1860D-2(e)(3).

of a malformed body member."[62] Yet, Part B also covers certain vaccines, including their administration costs, that are reasonable and necessary for prevention.[63]

By explicitly including vaccines in the definition of "covered Part D drugs," Congress clearly contemplated that Part D plans would provide coverage for vaccines. The provision allowing plans to exclude coverage where § 1862(a) would apply was intended to protect plans from being forced to cover drugs that are not "reasonable and necessary." There is no indication Congress intended to allow plans to exclude preventative therapies such as vaccines from the Part D benefit. In fact, the Conference Report for the MMA describes the covered Part D drugs that plans may exclude from coverage as "any drug which would not meet Medicare's definition of medically necessary or was not prescribed in accordance with the plan or Part D,"[64] thus clarifying the intent of the reference to § 1862(a). *Accordingly, GSK urges CMS to specify that Part D plans are required to offer coverage for vaccines.*

Some adult immunizations are already provided under Medicare Part B (e.g., influenza, pneumococcal, hepatitis B to select populations). However, senior adults may need immunizations not currently covered by Part B. For example, Healthy People 2010 includes an objective of reducing levels of hepatitis A from the 1997 baseline of 11.3 new cases per 100,000 people to 4.5 new cases per 100,000 by 2010.

One of the strategies is to target high risk adults over age 40. The availability of hepatitis A vaccine from a plan offering a Part D benefit would make it easier to meet that objective. In addition, Healthy People 2010 contains an objective to reduce cases of hepatitis B from the 1997 baseline of 15.0 cases per 100,000 to 3.8 cases per 100,000 by 2010. Universal immunization of children will go a long way to reaching that objective, but there are many seniors outside of the traditional high risk groups currently eligible for Medicare covered hepatitis B immunization who have never been immunized. This additional population may still be at risk because hepatitis B is a blood-borne pathogen that may be contracted in a variety of circumstances. In fact, hepatitis B can be easier to contract than HIV.[65] Another category of enrollees who should be vaccinated, according to the CDC, are travelers to selected countries. *GSK urges CMS to actively communicate the value of immunizing Medicare enrollees.*

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[62] SSA § 1862(a)(1).

[63] *See* SSA § 1861(s)(10).

[64] H.R.1, Conf.Rep. 108-391 at 442.

[65] Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures. CDC. MMWR, 1991; 40 (RR-8): 1-9.

IV. Subpart C -- Pharmacy and Therapeutics Committees – § 423.120(b)

Under the MMA and the Proposed Rule, plan formularies must be reviewed by Pharmacy and Therapeutics ("P&T") committees.[66] In general, GSK supports CMS's efforts to utilize the P&T committee process in a manner that ensures that plan formularies are designed with appropriate emphasis on clinical considerations. We also appreciate CMS's efforts to make this process more transparent. We have commented on particular P&T committee functions below.

a. P&T Committee Decisions as Binding -- § 423.120(b).

P&T Committee decisions should be binding with respect to the list of drugs on the formulary.

CMS proposes that P&T committee decisions be binding on a plan[67] and suggests that the P&T committee be involved in designing any tiers within a formulary.[68] GSK agrees that P&T committee decisions should be binding, but only with respect to which drugs should be placed on the formulary.

Making these decisions binding on the plan will help to ensure that the formulary represents a clinically appropriate range of drugs that will meet the needs of the Medicare population. These decisions should be binding on the Part D plan even where the plan uses an outside subcontractor as its P&T committee. The plan should be permitted greater participation, however, in the process of assigning formulary tiers to specific drugs. This will appropriately reflect the market-based nature of the Part D benefit and will allow plans to consider their negotiations with manufacturers, while also allowing the P&T committee to have appropriate input to ensure that clinical concerns are properly incorporated.

b. Specialists on P&T Committees – Proposed 42 C.F.R. § 423.120(b)(1)(ii).

Committees should include specialists knowledgeable in the diseases facing the elderly.

P&T committees should include specialists that reflect the prevalent diseases of the elderly such as cardiovascular disease, depression, cancer, and diabetes. We appreciate that CMS is encouraging plans to include such specialists,[69] and *we urge CMS to formalize this by requiring plans to include a range of specialists.*

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[66] Proposed 42 C.F.R. § 423.120(b)(1).

[67] 69 Fed.Reg. at 46659.

[68] Proposed 42 C.F.R. § 423,120(b)(1)(iv); 69 Fed.Reg. at 46659.

[69] 69 Fed.Reg. at 46659.

As a related requirement, the Proposed Rule requires that P&T committees include at least one member who specializes in treatment of the "elderly or disabled."[70] *We urge CMS to clarify what is meant by "disabled" and encourage the adoption of a broad definition to ensure that the needs of Medicare populations with physical disabilities and mental illness are appropriately considered in developing a plan's formulary.*

c. P&T Committee Members Independent and Free of Conflict -- § 423.120(b)(1)(ii).

CMS's proposed extension of the independence requirement to pharmaceutical manufacturers is inconsistent with the intent of the statutory provisions. However, safeguards can be implemented to ensure that physicians or pharmacists with a clear conflict of interest are recused from P&T decisions directly impacted by such conflict.

The MMA requires that at least one practicing physician and one practicing pharmacist on the P&T committee be independent and free of conflict with respect to the Part D plan.[71] CMS proposes to extend this requirement to require these members to be independent and free of conflict not only with respect to the plan[72] but also with respect to pharmaceutical manufacturers.[73] This extension is inconsistent with the intent of the statutory provision, and we are concerned about how this will work in practice.

Congress enacted a number of provisions that seek to ensure that Part D plans will establish formularies that provide a meaningful range of prescription drugs on which elderly patients tend to rely. Congress's apparent intent in setting forth this particular requirement was to provide enrollees with some protection against the possibility that a plan would design its formulary with too much self-interest. In the private market, P&T committees often include members that are independent and free of conflict with respect to the plan. In fact, the recent Merck-Medco consent agreement requires that a majority of P&T committee members be independent of the plan, and members who are not deemed independent have no vote in P&T committee decisions.[74]

CMS's proposed requirement that these members be independent and free of conflict also with respect to pharmaceutical manufacturers will eliminate many of those clinical experts most focused on treatment of the elderly. It is critical to the appropriate development of Part D

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[70] Proposed 42 C.F.R. § 423.120(b)(1)(ii).

[71] SSA § 1860D-4(b)(3)(A)(ii)(I).

[72] Proposed 42 C.F.R. § 423.120(b)(1)(ii).

[73] 69 Fed.Reg. at 46659.

[74] *U.S. et al v. Merck-Medco Managed Care LLC, (Civ. Act. No. 00-737) 2004 WL 977196 (E.D. Penn).*

formularies that P&T committees include members who are engaged in research on new therapies for the elderly. These are exactly the kinds of experts and specialists who should participate in P&T committee decisions regarding a list of drugs that is clinically appropriate for senior citizens. Many physicians and pharmacists participate in some manner in clinical research related to drug development. *We urge CMS to adopt an approach that would not broadly eliminate all physicians or pharmacists previously or currently engaged in such research.*

Safeguards can be implemented to ensure that physicians or pharmacists with a clear conflict of interest are recused from P&T decisions directly impacted by such conflict. For example, CMS could require that P&T committee members with a conflict regarding a particular drug not participate in P&T committee decisions regarding that drug. CMS also could establish a framework for developing criteria to identify those experts who may have a conflict that would be likely to interfere with objective P&T committee decisions. Such criteria could include financial thresholds or other means of determining when members may have a conflict. These types of measures, along with a requirement that a majority of P&T committee members are independent and that each voting member has an equal vote, will help to ensure that the P&T committee process is designed to best consider the prescription drug needs of the Part D enrollee population.

d. P&T Committees and Drug Utilization Management -- § 423.120(b)(iii).

GSK recommends that robust safety and efficacy data be the primary information considered by P&T committees making formulary decisions. If supplemental information is considered, CMS should ensure such information is critically and appropriately assessed.

The Proposed Rule requires that P&T committees base formulary decisions on clinical considerations such as scientific evidence and standards of practice, including but not limited to peer-reviewed medical literature, randomized clinical trials, pharmacoeconomic studies, outcomes research data and other information as it deems appropriate.[75]

Robust safety and efficacy data should be the primary information considered by P&T committees that are making formulary decisions. While other data can be used, it should supplement the primary information. If supplemental information is considered, CMS should ensure such information is critically evaluated.

In particular, information derived from outcomes, pharmacoeconomic, and database studies can be helpful in assessing the effectiveness of a medicine in real world practice and its place within disease/illness management. Pharmacoeconomics is the scientific discipline that assesses the overall value of pharmaceutical health care products, services, and programs. It

[75] Proposed 42 C.F.R. § 423.120(b(iii).

addresses the clinical, economic, and humanistic aspects of health care interventions in the prevention, diagnosis, treatment, and management of disease. Data to conduct pharmacoeconomic evaluations are obtained from clinical trials, databases, outcome studies, health care and insurance data, epidemiology studies, and patients. Pharmacoeconomic studies often assess important patient driven data such as medication tolerability, as well as quality of life and compliance effects.

Results from pharmacoeconomic studies, however, are dependent on the type of evidence and study design that is used; thus the external and internal validity of the study must be critically assessed. *To this end, we urge CMS to take steps to ensure that P&T committees utilize well accepted economic research practice guidelines, such as those provided in the Academy of Managed Care Pharmacy Format for Formulary Submission, developed specifically to assist managed care organizations to appropriately consider pharmacoeconomic studies, outcomes research data, and other such economic information as a basis, in part, for their formulary decisions.*

This document provides guidance on the use of clinical and economic information in the formulary decision-making process, the transparency of study sponsorship, and the use of accepted standards and methods in conducting pharmacoeconomic research. *In addition, GSK recommends that CMS set standards for the education and experience of P&T committee staff to ensure they have the training necessary to review pharmacoeconomic studies.*

In sum, while scientific evidence of safety and efficacy should be the primary driver for formulary decisions, information on the cost-effectiveness or "value" of a medicine can be extremely helpful in considering the impact of a therapy on the total health care system. Pharmacoeconomic studies can help P&T committees assess the value of a medicine and the impact of utilization on the total health care budget, which is much more critical than a narrow focus solely on the impact a drug budget. *CMS should take steps, to ensure that pharmacoeconomic studies are critically and appropriately assessed.*

V. Subpart D -- Drug Utilization Review and Medication Therapy Management Programs -- § 423.153

a. Cost-Effective Drug Utilization Management -- § 423.153(b)

CMS should define the terms necessary to ensure that drug utilization programs are designed to improve health outcomes and total health care costs rather than to limit enrollee access to important drug therapies.

Under the MMA, a Part D plan sponsor or MA-PD plan must establish a cost-effective drug utilization management program. The Proposed Rule describes cost-effective drug utilization management as including incentives to reduce costs when "medically appropriate"[76] through the use of various cost containment tools. The Proposed Rule does not, however, define "costs," "cost-effective," or "medically necessary" – terms central to understanding how a drug utilization management program should work

GSK recommends that CMS clearly define the terms "costs," "cost-effective," and "medically necessary" in a manner that will ensure that drug utilization management does not impair enrollee access to critical drugs.

"Cost" and "cost-effective" are important concepts in designing a drug utilization management program. Although a Part D plan may bear some of the costs of providing prescription drugs to enrollees, other parts of the Medicare program will reap the benefits of appropriate prescription drug use, including decreased spending on hospitalizations, physicians' services, and nursing home care. "Cost" and "cost-effective" should be defined, therefore, to recognize the effect of appropriate use of drug therapies on total health care spending, not just the cost of the drugs themselves

We recommend that CMS define "cost" and "cost-effective" to include all of the expenses and savings for Medicare and the enrollee. To help stand-alone Part D plans with this assessment, we suggest that CMS provide these plans with information on all Medicare costs incurred by their enrollees.

We understand that a single definition of "medically appropriate" is difficult to form, given the constantly changing nature of medicine and the particular needs of an individual patient. The only way to ensure that drug utilization management fully and accurately considers the needs of the patient is to allow the enrollee's physician to determine what is "medically appropriate."

GSK urges CMS to define "medically appropriate" to mean "medically appropriate, as determined by the beneficiary's physician."

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[76] Proposed 42 C.F.R. § 423.153(b)(1).

b. Cost Containment Tools -- § 423.153(b)

Drug utilization programs should not be used to discriminate against certain classes of Part D enrollees. CMS should monitor plans' use of cost containment tools to ensure that such tools are not used to negatively affect beneficiary enrollment or health outcomes.

CMS proposes that cost-effective drug utilization management programs use cost containment tools such as requiring use of multiple source drugs, prior authorization, step therapy, and tiered cost-sharing.[77] GSK appreciates the use of private-sector cost-control devices, but we urge CMS to monitor carefully their use in Part D plans.

We are concerned that cost containment efforts, particularly by stand-alone plans, may lead to underutilization of drugs and increased spending for other types of health care services. For example, a stand-alone plan might seek to control costs by requiring enrollees to use an older, less costly therapy before a newer, more advanced drug would be covered. If the older drug is ineffective or causes unpleasant side effects, the patient may stop taking the drug, prolonging his or her illness and requiring more physician and hospital services. In such a case, a cost containment tool may reduce the plan's expenditures, but increase spending in other parts of Medicare. As we discussed above, Part D plans should take into account all costs and savings associated with appropriate drug use when designing their drug utilization management programs.

To this end, we urge CMS to ensure that cost containment efforts do not impair beneficiary access to appropriate drug therapies.

GSK commends CMS for recognizing that "appropriate drug utilization management programs would have policies and systems in place to assist in preventing over utilization and underutilization of prescribed medications."[78] Part D plans should dedicate as much attention to underuse as to overuse. When patients fail to adhere to their prescribed drug regimens by not taking all of their medications or by reducing their doses, they risk serious consequences to their health. These risks are particularly great for patients with chronic conditions such as congestive heart failure, diabetes, hyperlipidemia, asthma, COPD, and hypertension, which often require costly care in hospitals and nursing homes if not controlled through medications.

We encourage Part D plans to design drug utilization management programs to prevent underutilization of important prescription drugs and to help enrollees avoid painful and costly illnesses.

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[77] 69 Fed. Reg. at 46666-7.

[78] 69 Fed. Reg. at 46667.

Although we generally support drug utilization management programs, we are concerned that they may be used to discriminate against certain classes of Part D enrollees. Plans that direct their cost containment tools toward certain classes of drugs could discourage enrollees who need those therapies from enrolling or remaining in their plans.

GSK urges CMS to monitor plans' use of cost containment tools and direct plans to change their programs if their use affects beneficiary enrollment and health outcomes.

c. Medication Therapy Management Programs (MTMP)

CMS must (i) carefully define targeted populations, (ii) establish clear guidelines to ensure that these programs are used to promote appropriate use of medications and not simply as a cost containment tool, and (iii) ensure that neither program design nor reimbursement structure discourages the enrollment of certain groups of Medicare enrollees or negatively impacts health outcomes.

Under the MMA, a Part D plan must establish a medication therapy management program.[79] CMS proposes to use these programs to "provide services that will optimize therapeutic outcomes for targeted enrollees."[80] GSK supports the suggested uses of MTMPs: to promote the appropriate use of medications and reduce the risk of adverse events, increase enrollee adherence to prescription medication regimens, and detect adverse drug events and patterns of overuse and underuse. [81]

MTMPs are relatively new, and neither CMS nor many private insurers have extensive experience using or reimbursing for their services.[82] *GSK therefore urges CMS to carefully define the targeted populations and establish standards and guidelines for these groundbreaking programs.*

We agree with the Proposed Rule that MTMPs should be targeted toward enrollees with multiple chronic diseases who take multiple Part D covered drugs and who are likely to incur annual costs exceeding a fixed level.[83]

A well designed and implemented MTMP can be very valuable to enrollees with complex conditions. Studies have found that the majority of aged Medicare enrollees have one or more

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[79] SSA § 1860D-4(c).

[80] 69 Fed. Reg. at 46668.

[81] *Id.*

[82] *Id.*

[83] *Id.*

chronic conditions[84] and take more than eight outpatient prescription medications.[85] *Given the complexity of managing the many Medicare enrollees with co-morbidities and multiple medications, we suggest that CMS adopt a "more than one" approach in defining the multiple chronic diseases necessary to be eligible as a "targeted beneficiary."*

This approach is consistent with MMA's use of the term "multiple" to mean more than one. In addition, any other approach may mean that a significant number of enrollees who need medication therapy management services might not be able to take advantage of these programs. For example, based on CMS's own studies, on average, a beneficiary with one or two chronic conditions has approximately 19 filled prescriptions, whereas a beneficiary with three or four chronic conditions has approximately 32 filled prescriptions.[86] *By defining "multiple" chronic diseases to mean more than one chronic condition, CMS will help to assure that MTMP services are available to the enrollees who need them.*

In addition, when providing guidance on MTMPs, CMS should consider that targeted enrollees with multiple chronic diseases may be receiving care through a number of different physicians, any number of whom who may be providing prescriptions for multiple drugs. For example, enrollees with two chronic conditions have, on average, five physicians, while enrollees with four chronic conditions have eight physicians.[87] Effective MTMPs factor in the multiple prescribers and should educate enrollees about the need for effective communication among the enrollee's physicians.

Establish clear guidelines: These patients' health depends on appropriate use of their prescription medications. We recommend that MTMPs provide these patients with one-on-one education and counseling to help them adhere to their drug regimens and prevent harmful underutilization.

Medication adherence is a significant health care dilemma. Research indicates approximately 50% of patients never fill their initial prescription.[88] Twenty to eighty percent make errors in taking their medications.[89] Additionally, thirty to sixty percent of patients stop

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[84] Copeland C, *Prescription Drugs: Issues of Cost, Coverage, and Quality*, EBRI Issue Brief, 1999 Apr; (208):1-21

[85] Wolff JL, et al., "Prevalence, Expenditures, and Complications of Multiple Chronic Conditions In the Elderly," Arch Intern Med. 2002 Nov 11; 162(20):2269-76.

[86] Centers for Medicare and Medicaid Services, CMS Chart Series, *Medicare Program Information: Profile of Medicare Beneficiaries*, found at http://www.cms.hhs.gov/charts/series/sec3-b1-9.pdf

[87] *Id.*

[88] World Health Organization: Adherence to Long-Term Therapies: Evidence for action. Available at http://www.who.int/chronic_conditions/en/adherence_report.pdf

[89] Gotlieb H. Medication nonadherence: finding solutions to a costly medical problem. *Drug Benefit Trends*. 2000;12(60:57-82

taking their medications too soon.[90] Furthermore, eighty-eight percent of prescriptions are filled for chronic conditions, but only twenty percent take the medication as prescribed.[91]

As the *Journal of Clinical Psychiatry* cautions,:

"The consequences of drug noncompliance may be serious in older patients. Estimates of the extent of noncompliance in the elderly vary, ranging from 40% to a high of 75%. Three common forms of drug treatment noncompliance are found in the elderly: overuse and abuse, forgetting, and alteration of schedules and doses. Some older patients who are acutely ill may take more than the prescribed dose of a medication in the mistaken belief that more of the drug will speed their recovery. Such overuse has clearly been associated with adverse drug effects. Forgetting to take a medication is a common problem in older people and is especially likely when an older patient takes several drugs simultaneously. Data suggest that the use of three or more drugs a day places elderly people at particular risk of poor compliance. The use of at least three drugs, and often more, is common in the elderly, with estimates of as many as 25% of older people taking at least three drugs. Averages of drug use among elderly hospitalized patients suggest that eight drugs taken simultaneously may be typical. Problems may also arise when dementia or depression is present, which may interfere with memory. The most common noncompliant behavior of the elderly appears to be underuse of the prescribed drug. Inappropriate drug discontinuation, furthermore, may occur in up to 40% of prescribing situations, particularly within the first year of a chronic care regimen. As many as 10% of elderly people may take drugs prescribed for others; more than 20% may take drugs not currently prescribed by a physician ."[92]

Ensure that neither program design nor reimbursement structure discourages enrollment: GSK recommends that CMS provide clear instructions to Part D plans on reimbursement for MTMP services. We urge CMS to prohibit plans from using reimbursement for MTMP services to direct patients to or away from specific plans or drugs. We also recommend that a plan's reimbursement for MTMP services be included in CMS's review of whether a plan substantially discourages enrollment of certain groups of Medicare enrollees. Finally, although CMS states that it believes payment for MTMP services is separate and distinct from dispensing fees,[93] we recommend that CMS explicitly prohibit any linkage between these payments.

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[90] NACDS and Drug Topics archives (3/3/97).

[91] *Id.*

[92] Salzman C. Medication compliance in the elderly. J Clin Psychiatry. 1995;96 Suppl 1:18-22; discussion 23

[93] 69 Fed. Reg. at 46669.

d. **Cost Control and Quality Improvement (QI) Requirements for Prescription Drug Plans**

GSK recommends that QI standards and systems used by Part D plans

- **include a focus on potential underutilization,**
- **focus on clinical contraindications and adverse drug-to-drug interaction, and**
- **be subject to oversight by the Part D plan's P&T committee**

Due to the specific characteristics of the Medicare population, it is essential that QI standards and systems designed specifically for this population be utilized by Part D plans. The higher rate of physical morbidity and greater chance of receiving multiple prescription drugs[94] increases the risk that older adults will suffer from adverse drug reactions. In addition, biologic and physiologic changes caused by aging may lead to increased sensitivity to differing drug dosages or altered pharmacokinetics.[95] Finally, when examining the patient's perspective in taking prescribed medicines, it is found that physical, psychological, and economic considerations often interfere with their ability to obtain and comply with their medication regimens.[96]

We support the efforts of CMS in evaluating the status of existing QI programs and considering how to modify such programs for the Medicare population. We encourage CMS to update program requirements on an ongoing basis as best practices for this population are identified. We provide some recommendations for consideration below.

1. CMS's proposal to link the QI programs and DUR is an important one. Cost containment mechanisms must be a component of the Part D program. However, there is the potential for underutilization of necessary medications when DUR is applied and only drug costs are considered. *The QI program should include a focus on potential underutilization, providing a necessary balance between the need for cost containment mechanisms and the dangers of underutilization.*

For example, depressive disorders are estimated to affect nearly 1 in 10 adults in America. NCQA's Antidepressant Medication Management HEDIS measure clearly shows that pharmacological management of depression is far below guideline recommendations, particularly for the Medicare population (Acute Phase = 55.3%,

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94 Katona CL, "Psychotropic and Drug Interactions in the Elderly Patient," *Int. J. Geriatr Psychiatry*, 2001 Dec.; 16 Supp I:S86-90

95 Reidenberg, MM, "Drug Interactions and the Elderly," *J Am Geriatr Soc*. 1982 Nov; 30 (11 Suppl): S67-8 [1982]

96 Morris LS, Schulz RM, Medication Compliance: The Patient's Perspective. *Clinical Therapeutics* 1993; 15 (3): 593-606.

Continuation Phase = 39.2%).[97] The State of Health Care Quality 2004 reports there has been no improvement in the Medicare rate for the measure from the previous year. Average Medicare scores continue to lag 5 to 10 points below those reported by commercial health plans.

2. *The quality improvement programs should be subject to oversight by the Part D plan's P&T Committee.* This design would allow the P&T Committee to ensure appropriate access and clinical efficacy while allowing the plans autonomy to determine their best organizational structure.

3. *QI programs should focus on clinical contraindications and adverse drug-to-drug interactions would particularly benefit special needs Medicare beneficiaries and Medicare dual-eligibles*.

[97] National Committee for Quality Assurance; 2004 *The State of Health Care Quality*;©2004 by NCQA.

VI. Subpart C – Patient Assistance Programs and TrOOP -- § 423.100

GSK urges CMS to provide specific guidance in the final rule regarding whether pharmaceutical manufacturers' patient assistance programs ("PAPs") may provide assistance in paying enrollees' out-of-pocket cost-sharing obligations during the doughnut hole, and if so, whether that assistance would count towards the enrollee's TrOOP. In addition GSK urges CMS to seek the input of the Office of the Inspector General ("OIG") to provide manufacturers clear guidance on how PAPs may be allowed to assist enrollees with Part D prescription drug expenditures.

CMS proposes to allow assistance that enrollees receive from certain charitable organizations to count as "incurred costs"[98] for purposes of reaching catastrophic coverage. In doing so, CMS has defined "person" to include bona fide charities "unaffiliated with employers or insurers."[99] The Proposed Rule notes that to be permissible, such arrangements must comply with Federal fraud and abuse laws, including the anti-kickback statute, section 1128B(b) of the Act, as well as the civil monetary penalty provision at section 1128A(a)(5) of the Act. CMS further states that it is "considering whether assistance in paying enrollees' cost-sharing obligations provided through prescription drug patient assistance program sponsored by pharmaceutical manufacturers would be allowed"[100] under these laws.

GSK has a long history of assisting low-income patients. We would like to be able to continue to provide assistance to low-income Medicare enrollees in the doughnut hole who do not qualify for subsidies under Part D. In the first half of 2004, GSK provided more than $162 million worth of medicines to patients through our patient assistance programs. Approximately 35% of the patients enrolled in our programs are Medicare-eligible. Most of those patients have incomes below 135% of the federal poverty level and will receive a full subsidy under Part D, and thus will not be affected by the doughnut hole. However, approximately 10% of our enrollees are Medicare-eligibles with income above 135% of the federal poverty level. They may not be able to bear the burden of paying out-of-pocket for their drugs during the doughnut hole.

We are concerned, based on commentary in the Preamble to the Proposed Rule, that we may not be able to continue to provide assistance under the Proposed Rule and current law. One concern is that the provision of such assistance may result in an enrollee failing to reach a level where they would qualify for reduced cost sharing for all their drugs. In effect, if assistance provided through a PAP does not count toward TrOOP, the individual will still be responsible for paying the full amount of costs for other drugs up to the out-of-pocket threshold for other drugs.

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98 Proposed 42 C.F.R. § 423.100.

99 69 Fed.Reg. at 46650; *see also* Proposed 42 C.F.R. § 423.100.

100 69 Fed.Reg. at 46650.

Also, as CMS has noted in the Proposed Rule, it is not clear whether such assistance would be allowed under the aforementioned Federal fraud and abuse laws.

To continue to help low-income senior citizens who may not be able to afford the cost-sharing required under the Part D benefit, we will need assurances that assistance provided by manufacturers to enrollees is expressly allowed under the Federal fraud and abuse laws in a program where Medicare also is a payer. For manufacturers to be able to provide such assistance, CMS will need to obtain specific guidance on this issue from the HHS Office of Inspector General ("OIG").

We urge CMS to seek the OIG's input in providing manufacturers clear guidance on how PAPs may be allowed to assist enrollees with Part D prescription drug expenditures. We also urge CMS to clarify the types of assistance that manufacturers can provide, and clarify that the provision of such drugs would count toward an individual's out-of-pocket costs for purposes of qualifying for catastrophic coverage

Furthermore, CMS also needs to provide clear guidance on the valuation of the assistance provided by manufacturer PAPs for purposes of counting towards an enrollee's TrOOP.

VII. SPAPs and Part D

CMS should clarify that prices negotiated with a pharmaceutical manufacturer for Covered Part D drugs by a state pharmaceutical assistance program ("SPAP") as defined in Sections 423.4 and 423.464 of the Proposed Rule may be excluded from a pharmaceutical manufacturer's "best price" calculation for purposes of section 1927 of the Social Security Act (the "Medicaid Rebate Statute")

CMS should clarify that prices negotiated with a pharmaceutical manufacturer for Covered Part D drugs by a state pharmaceutical assistance program ("SPAP") as defined in Sections 423.4 and 423.464 of the Proposed Rule may be excluded from a pharmaceutical manufacturer's "best price" calculation for purposes of section 1927 of the Social Security Act (the "Medicaid Rebate Statute"). To do so, CMS must eliminate the confusion created by contradictory definitions of SPAPs in the Proposed Rule and recent guidance issued by CMS in the context of the Medicaid Rebate Statute.

Specifically, the Medicaid Rebate Statute, at § 1927(c)(1)(C)(i)(III) of the Social Security Act, excludes "prices used under a State pharmaceutical assistance program" from consideration in computing a pharmaceutical manufacturer's "best price" for the drug. However, guidance issued by CMS on June 23, 2003, through Medicaid Rebate Program Release No. 59 (restated in CMS State Medicaid Director Release # 124) ("Release 59"), put in place a set of criteria that have caused CMS to conclude that some SPAPs should not be excluded from best price computation, while other states' programs can be excluded from the best price computations. However, the Proposed Rule and Release 59 can be read as having conflicting definitions, as is explained more fully below.

This is problematic because the definition of an SPAP in the Medicare Modernization Act ("MMA") and the rules ultimately promulgated thereunder will not stand alone. Manufacturers will also have to consider the application of relevant CMS releases when considering the 'best price" implications of the prices negotiated with SPAPs for <u>all</u> the populations that may be served by the SPAP. The definition of SPAP for Medicare part D purposes will apply only to the subset of SPAPs that serve individuals who are also eligible for Medicare part D. Nevertheless, SPAPs also serve indigent, unemployed, and other individuals who are not eligible for Medicare, Medicaid, or other insurance programs. Indeed, some SPAPs serve -- and will likely continue to do so -- both Part D eligible and non-Part D eligible populations.

CMS should make it clear that prices offered by pharmaceutical manufacturers under both types of SPAPs should be excluded from a manufacturer's best price computation. Without clarification, it would be difficult, if not impossible, for a manufacturer to know if prices it has offered to an SPAP could be excluded from its best price calculation as a result of the contradictory definitions of SPAPs. SPAPs may not be able or willing to submit separate utilization data to manufacturers for its Part D eligible and non-Part D eligible enrollees. Such a

clarification would also encourage manufacturers to continue to offer discounts to SPAPs that provide pharmaceutical benefits to non-Part D eligible beneficiaries.

For example, CMS suggests in Release 59 that one defining feature of an SPAP is that the SPAP must be "specifically for disabled, indigent, low-income elderly or other financially vulnerable persons." There is no such "low-income" requirement in the MMA definition of an SPAP or under the Proposed Rule. Similarly, Release 59 suggests that to qualify as an SPAP, the program can not be funded with any Federal dollars. In contrast, the Proposed Rule excludes from the definition of an SPAP, among other things, any "program where the majority of the funding is from Federal grants, awards, contracts, entitlement programs or other Federal sources of funding" (§ 423.464(e)(iv) of the Proposed Rule (emphasis added)), thereby suggesting that some amount of Federal funding is acceptable for SPAPs in the context of the MMA.

It would not be in anyone's interest to permit confusion over definitions in a Medicaid rebate program guidance to undermine the coordination of part D benefits and SPAPs. To prevent this result, we propose that CMS define "State pharmacy assistance program" in the final regulations in a way that applies to SPAPs that serve either Part D eligible beneficiaries or non-Part D eligible beneficiaries, or both, and that will serve as an exemption from best price provision of the Medicaid Rebate Statute.

Furthermore, to make the criteria meaningful, we propose that the regulations provide an assurance that pharmaceutical manufacturers can rely in good faith upon an SPAP's representation that it meets the criteria to be excluded from the best price computation under the Medicaid Rebate Statute.

We propose that CMS clarify the provisions applicable to SPAPs by modifying § 423.464(e)(4) "Construction," by placing "(i)" after the title and adding new subparagraphs (ii) and (iii) at the end thereof, to read as follows:

(ii) Definition of an SPAP for purposes of Section 1927 of the Social Security Act. Notwithstanding § 423.464(e)(1), an SPAP operated by or under contract with a State shall be considered a "State pharmaceutical assistance program" for purposes of Section 1927 of the Social Security Act if it:

(A) is a program designed by or on behalf of a State specifically for disabled, indigent, elderly or other financially vulnerable persons;

(B) is not a State Medicaid program, a section 1115 demonstration program, or any other program where the majority of funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding; and

(C) either

(I) directly dispenses pharmaceutical products to its qualified beneficiaries or directly reimburses providers, Medicare-endorsed discount cards, a Medicare prescription drug plan, or a Medicare Advantage prescription drug plan; or

(II) provides assistance with the cost-sharing requirements of a private health plan, a Medicare part D plan or a Medicare Advantage prescription drug plan, or provides a pharmaceutical benefit or discount, either alone or in conjunction with other medical benefits or services.

(iii) *Pharmaceutical Manufacturer's Good Faith Reliance. For purposes of filing price reports under § 1927 of the Social Security Act, a pharmaceutical manufacturer can rely in good faith upon an SPAP's assurance that the SPAP meets the criteria of this part.*

VI. Subpart C.1.a. and Subpart J.6.c. – Coordination of Benefits Under Part B and Part D

To minimize confusion by enrollees and physicians and to ensure that patients obtain appropriate access to medically necessary therapies, GSK encourages CMS to provide seamless coordination of the Part B and Part D benefits

We urge CMS to clarify that the statement in the preamble that "*any drug covered under A or B could not be covered under D, whether it was covered for that individual or not*" applies only to individuals who have declined to enroll in Part B, with respect to drugs for which Part B coverage would have been available for that individual under Part B.

GSK supports CMS's recognition of Part D as a benefit intended to fill gaps in existing Medicare coverage of prescription drugs[101] and to implement Part D in a manner that "'wraps around' existing Part B drug benefits to the greatest extent possible."[102] Medicare Part B provides only limited coverage for drugs provided incident to a physician's service. Part D will provide Medicare enrollees with greater access to the therapies they need.

To minimize confusion by enrollees and physicians and to ensure that patients obtain appropriate access to medically necessary therapies, GSK encourages CMS to provide seamless coordination of the Part B and Part D benefits.

The coordination process should allow physicians to submit claims under Part B for consideration if the product was administered by the physician and arrange for any portion of the claim rejected under Part B to be automatically submitted to the patient's plan. The Part D plan would then reimburse the physician as an out-of-network provider. This process would reduce delays in needed care for these enrollees. Additionally, GSK urges CMS to consider the needs of special populations, including cancer patients among others, whose continuity of care should not deteriorate due to the interaction between Part B and Part D. We specifically address our recommendations with respect to special populations elsewhere in this document.

Additionally, we are concerned that the preamble language to Subpart J.6.c. creates some confusion. CMS states that "any drug covered under A or B could not be covered under D, whether it was covered for that individual or not."[103] This appears to be inconsistent with the provisions of the MMA and the Proposed Rule.

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101 69 Fed.Reg. at 46646.

102 69 Fed.Reg. at 46647.

103 69 Fed.Reg. at 46703.

We urge CMS to clarify that this statement applies only to individuals who have declined to enroll in Part B, with respect to drugs for which Part B coverage would have been available for that individual under Part B.[104]

To highlight some of the potential concerns facing enrollees who may have coverage under both Part B and Part D, we discuss specific examples were the interaction between Part B and D will be complicated. As background, under the MMA and the Proposed Rule, benefits will not be available under Part D for any drug for which payment is available under Part B for that individual.[105]

CMS has clarified that administration and dispensing will include "the setting, personnel, and method involved, and not simply the route of administration."[106] Enrollees will obtain benefits under Part B, where available, unless the Part B coverage criteria are not met. These criteria generally include that the drug is purchased and administered by the physician and that the therapy usually is not self-administered by the patient. If any of these criteria are not met, then the drug will be covered under Part D, as long as the drug is on the formulary or the enrollee has received an exception to the formulary. Thus, Part D coverage will be available in circumstances in which the individual is capable of self-administering a drug that typically is administered in a physician's office or outpatient setting. This interpretation is consistent with the intent of the MMA.

However, there are some products that may not be defined in such a straightforward fashion because they could be covered either under Part B or Part D, depending on the medical use for the product or the medical condition of the individual beneficiary. For example, Zofran® (ondansetron hydrochloride) is a treatment for chemotherapy induced nausea and vomiting (CINV) and for post operative nausea and vomiting (PONV). While the intravenous form of Zofran is clearly covered under Part B, the oral forms of the product can be covered under Part B if it is prescribed for use as an acute anti-emetic used as part of an anti-cancer chemotherapeutic regimen within 48 hours after the time of the administration of the anti-cancer chemotherapeutic agent as a full replacement for the anti-emetic therapy which would otherwise be administered intravenously or under Part D for other uses of the product, including product that is dispensed by the physician for PONV, or as adjunctive therapy to an intravenous anti-emetic. Therefore, if an oncologist uses IV Zofran prior to chemotherapy then the oral product would not be reimbursed for the 48 hour period post chemotherapy for the prevention of delayed nausea and vomiting under the DMERC provisions of the Part B benefit but could be reimbursed under Part D.

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104 We note that the MMA does not require that Part D benefits be unavailable in these circumstances to Medicare enrollees who have chosen not to enroll in Part B.

105 SSA § 1860D-2(e)(2)(B); Proposed 42 C.F.R. § 423.100.

106 69 Fed.Reg. at 46646.

A second example is hepatitis B vaccine. Part B currently covers hepatitis B vaccine furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations). Those regulations do provide definitions of high or intermediate risk, but also exclude patients who have chronic liver disease and others with a medical need for immunization against hepatitis B. Therefore, Part B would pay for hepatitis B vaccine for a patient who is defined as being at high or intermediate risk of hepatitis B but Part D would pay for hepatitis B vaccine for a patient with chronic liver disease.

Lastly, because immunization traditionally is covered as a medical benefit and not a pharmacy benefit, vaccine delivery even for those vaccines that fall entirely within the Part D benefit must be carefully coordinated to ensure that inclusion of vaccines on a plan formulary translates into a meaningful benefit for enrollees. This will require that vaccine administration be included in the definition of dispensing fee as well as clarification regarding how these claims should be processed, since vaccines tend to be purchased and administered by physicians.

VIII. Subpart C -- Dispensing Fees -- § 423.100

CMS should extend the definition of "dispensing fees" to include the administration costs associated with vaccines

CMS has proposed three possible interpretations of "dispensing fees" that would include alternative methods of accounting for costs associated with certain products. CMS is considering limiting an expanded definition of dispensing fees to home infusion therapies in that home infusion represents "the only circumstance we know of where the additional services associated with administering the drug would not already be covered under Medicare Part A or B and would be necessary to ensure effective delivery of the drug."[107] CMS requests comments on whether the administration of other drugs, specifically vaccines, may pose similar access problems for enrollees absent payment for administration supplies and services.[108] It will be important for CMS to ensure that the costs of vaccine administration are properly incorporated into the dispensing fee.

To best ensure Part D enrollees meaningful access to appropriate therapies, CMS should adopt the third option, which would include the costs of supplies, equipment and professional services necessary to administer home infusion drugs.[109] In proposing the third option, CMS recognizes that, absent payment for the supplies and services necessary for administration, certain pharmaceuticals or biologicals may, as a practical matter, be unavailable to many Part D enrollees, undermining the purpose of the Part D benefit.

CMS should, therefore, extend this definition to include the administration costs associated with vaccines. This policy would be consistent with existing Medicare Part B policy regarding vaccines. Part B covers only a limited number of vaccines, but for these vaccines Part B covers both the cost of the vaccine and the cost of administration. This ensures that enrollees for whom a vaccine is covered under Part B have meaningful access to this benefit. Congress clearly intended for the Part D benefit to include vaccines, specifically including vaccines in the statutory definition of covered Part D drugs. Thus, to provide meaningful coverage for vaccines, payment will need to include administration costs. Inadequate coverage of the administration costs will likely have a negative effect on vaccination rates among Medicare beneficiaries.

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107 69 Fed.Reg. at 46648.

108 69 Fed.Reg. at 46648.

109 69 Fed.Reg. at 46647.

IX. Subpart M -- Grievances, Coverage Determinations and Appeals

The exceptions, appeals and grievance processes CMS proposes will not adequately protect Medicare enrollees enrolled in Part D plans and will make it difficult for them to navigate the appeals process to obtain therapies. We urge CMS to redesign its proposed framework to provide Part D enrollees with a clear and reasonable way to obtain the prescription drugs they need. Our specific suggestions are as follows:

1. Reduce the Timeframe for the Appeals Process

CMS must reduce the timeframe in which plans must respond to enrollee appeals or requests for exceptions to provide enrollees with adequate access to the prescription drug benefit.

GSK is concerned that enrollees will experience significant delays in accessing prescription drugs that their treating physician(s) feel are most appropriate because a Part D plan has determined that an appeal must be initiated. The MMA requires that Part D plans follow an appeals process that is consistent with the existing process for appeals of Part C benefits under Medicare Advantage plans.[110] In fact, CMS proposes a process that largely mirrors the Part C appeals process. The MMA does not require, however, that the process for appeals under the Part D benefit incorporate the same timeframes as are set forth for Part C benefits. CMS may shorten the timeframes and still meet the statutory requirement that the appeals process for Part D is consistent with the Part C appeals process.

Reducing the timeframe for appeals would appropriately reflect the difference between prescription medications and other services as well as the manner in which prescription drugs generally are paid. Under Part C, appeals typically relate to payment for physician and hospital benefits after the beneficiary already has received the services. Under Part D, however, an enrollee may be denied a necessary drug at the pharmacy. Thus, under Part D, the enrollee must either go without the drug or pay for the drug out-of-pocket until the appeal is resolved. If an enrollee cannot afford to pay for the drug, the enrollee will need to take a formulary drug that may be less effective or has greater side effects and may not represent the best therapeutic option in the opinion of the treating physician. The enrollee may be forced to go without the therapy altogether while the appeal is resolved. In either case, the enrollee will forgo the therapy that his or her physician deemed most effective.

[110] SSA § 1860D-4(g).

In addition to the therapeutic and financial burdens the length of this process may impose on an enrollee, this process also may require the enrollee to make multiple visits to his or her physician(s) and the pharmacy, thus increasing the burden on frail or elderly patients.[111]

GSK urges CMS to reduce the timeframe of the appeals process to lessen the burden on enrollees and to ensure adequate access to medically necessary drugs. Clearly, the most expedient and beneficial process for the enrollee would be for online, point-of-sale adjudication. Most health plans, or their PBMs, have the ability for online contact with a clinical pharmacist who can make contact with the treating physician to obtain any information necessary to resolve the appeal while the patient is in the pharmacy. Only if a contemporaneous resolution cannot be reached would further appeals processes be implemented.

GSK also recommends that CMS reduce the timeframe for the exceptions process. Given the importance of continuity in how many medications are taken, the timeliness in responding to an exception request is particularly important to the implementation of a meaningful prescription drug benefit. Indeed, Congress recognized the unique challenges that an appeals process may pose for a prescription drug benefit by specifically requiring plans to institute a separate exceptions process. It is not useful to have a separate exceptions process if the timeframe for that process may be as long as for the regular appeals process. *We request that CMS modify the exceptions timeframe to require Part D plans to respond to an exceptions request within 72 hours or at the point-of-sale, if possible. This is consistent with the practice typical in private plans, and will allow enrollees to better access the therapies they need.*

2. Provide Access to an Emergency Supply of Medication

Plans should be required to provide enrollees with an emergency supply of medication while resolving any appeals or exceptions requests.

CMS proposes that a plan be required to provide an emergency supply of medication only for continued coverage of a drug being removed from the plan's formulary, where the plan has failed to act on an exceptions request within a certain timeframe.[112] CMS makes no provision for an emergency supply during the normal course of the exceptions process or during the appeals process.

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111 The financial burden on enrollees here is increased by the fact that enrollees may not have access to negotiated prices for drugs not on the formulary. Under the Proposed Rule, negotiated prices must be available to enrollees if no benefits are payable due to the application of a deductible or 100% coinsurance requirement. 42 C.F.R. § 423.104(h).

112 Proposed 42 C.F.R. § 423.578(c)(2).

GSK recommends that CMS require plans to make an emergency supply of a drug available anytime an enrollee is already taking the drug and an exceptions request or appeal is underway, not simply when a plan has failed to act in a timely manner.

It is not medically appropriate for a patient to simply discontinue an ongoing therapy or switch therapies during an appeals process. This is particularly true for vulnerable populations, including individuals that have multiple medical conditions or need drugs that require very individualized dosing, such as antidepressants or antipsychotics.

Furthermore, proper drug therapy is a function not only of prescribing the correct drug, but also of titrating to the correct dose, especially with agents that have a very narrow therapeutic window. Failure to maintain the patient at adequate dosing could put the enrollee at an increased medical risk. This requirement will provide the enrollee with continued access to an ongoing necessary therapy, as well as provide plans with an appropriate incentive to respond to exceptions requests and appeals in a timely fashion.

3. Clarify that Denial of a Claim is a Coverage Determination

The denial of a claim at the pharmacy should be considered a coverage determination for purposes of enabling an enrollee to begin the appeals or exceptions process.

Under the Medicare program, a denial of benefits generally is considered an adverse coverage determination that triggers a requirement that a notice and an explanation of appeal rights be sent to the beneficiary. Under the Proposed Rule, however, a Part D enrollee – or his or her authorized representative – would need to initiate and seek a "coverage determination" or "exception" from his or her Part D plan; denial of a claim at the pharmacy would not be sufficient.

GSK is concerned that this is inconsistent with the Medicare program and will impede an enrollee's ability to appeal. Failure to maintain proper drug therapy throughout the appeal process could subject the enrollee to untoward medical outcomes.

We request that CMS clarify in the final rule that the denial of the claim at the pharmacy is a coverage determination. This will allow an enrollee to receive information about the appeals process at the point of the denial. This also will eliminate an extra, unnecessary step by allowing an enrollee whose claim has been denied to seek an appeal without first having to request a coverage determination.

4. Allow Appeals When the Enrollee Has No Payment Liability

Eliminate the prohibition on appeals where an enrollee has no financial liability.

Under the Proposed Rule, an appeal right would not exist when the enrollee bears no payment liability.[113] This provision is inconsistent with the goals of Part D, and *we strongly urge CMS to eliminate this provision in the final rule.*

Under the Proposed Rule, an enrollee's authorized representative or prescribing physician may request a coverage determination[114] or an exception.[115] Yet CMS proposes to disallow an appeal where another party – such as a family member, other health insurance, or a State Pharmaceutical Assistance Program ("SPAP") – has paid for the prescription. The MMA specifically contemplates that at least some enrollees will have access to assistance with their prescription drug costs from sources other than Part D. [116] The MMA also expressly requires Part D plans to coordinate with SPAPs.

Prohibiting appeals where a third party has provided payment for a drug is likely to discourage these third parties from providing such payment until a Part D appeal has been exhausted. This will be particularly detrimental to those low-income enrollees who rely on SPAPs to access prescription drugs. Ultimately, the burden of the appeals process will shift to the enrollees least able to manage such a complex process.

In the meantime, such expenditures for non-formulary drugs will not count as "incurred costs" for purposes of reaching the out-of-pocket limit. This will result in enrollees taking longer to reach their catastrophic coverage, which, in turn, will increase the liability of SPAPs and other charitable organizations that assist low-income enrollees with their prescription drug costs. This prohibition also has the effect of relieving Part D plans from their obligations to enrollees. Part D plans will have a strong incentive to shift costs to an enrollee's other health coverage, because the Part D plan will be protected from appeals.

GSK strongly urges CMS to eliminate this provision and clarify that Part D plans are required to pay for drugs consistent with their agreement with CMS and their obligations under the MMA and implementing regulations, regardless of whether an enrollee has secondary coverage.

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[113] Proposed C.F.R. § 423.562(c)(1).

[114] Proposed 42 C.F.R. § 423.566.

[115] Proposed 42 C.F.R. § 423.578(a)(3).

[116] *See, e.g.*, Proposed 42 C.F.R. § 423.452 – 42 C.F.R. § 423.464.

5. Provide Access to Therapies After Mid-Year Formulary Changes

Enrollees taking a drug should be granted continued access to that drug at the same cost-sharing level for the duration of the plan year; alternately, an automatic exceptions process should be instituted for these enrollees upon a formulary change as well as for dual eligibles as they switch from Medicaid to Part D.

CMS proposes that Part D plans be required to establish an exceptions process for situations in which an enrollee is using a drug and the formulary or cost-sharing status changes mid-year or at the beginning of a plan year.[117] *GSK urges CMS to prohibit plans from making changes mid-year that result in removal of a drug from a formulary or increases the cost-sharing required of an enrollee. Otherwise, plans can engage in "bait-and-switch" tactics to the detriment of the enrollee.*

If CMS declines to require plans to limit such changes to the beginning of a plan year, we request that CMS provide a mechanism for automatic exceptions request for enrollees already taking a drug for which the formulary or tiered status is changed. For these enrollees, a plan would need to respond to an automatically generated exceptions request. Otherwise, these enrollees will receive notice of the drug's change in status, have to seek a coverage determination, and then have to initiate an exceptions request. This will result in delays in receiving treatment. For many drug therapies, it is not clinically acceptable for an enrollee to stop and then re-start a prescription while the exceptions or appeals process is resolved. As noted above, such changes may require laboratory tests and physician visits.

We also urge CMS to institute such an automatic exceptions process for dual eligibles when they first switch to Part D. Again, this would enable these enrollees to maintain their current therapies while the exceptions process is underway.

6. Standards for Reviewing Exceptions Requests

The final rule should allow plans to require a prescribing physician to certify that a therapy <u>would not be</u> as effective for an individual.

The MMA requires plans to pay for a nonpreferred drug under the same terms applicable to a preferred drug where the prescribing physician has determined that the preferred drug would not be as effective for the individual for treatment of the same condition, would have adverse effects for the individual, or both.[118] In the Proposed Rule, CMS has established several criteria in addition to the physician's certification required by the MMA that plans must consider during

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117 Proposed 42 C.F.R. § 423.578(a)(1)(i)-(ii); § 423.578(b)(1)(ii).

118 SSA § 1860D-4(g)(2).

review of an exceptions request for a preferred formulary placement. *We urge CMS to remove these additional requirements and revise this regulatory provision to appropriately reflect the intent of the MMA.*

CMS should require a plan to grant an exceptions request where the prescribing physician makes the MMA-required certifications. This would appropriately defer to the prescribing physician as the best determinate of what drug is the safest, most effective, and medically necessary for an individual patient.

GSK also is concerned that CMS has not properly implemented the MMA in implementing the physician certification provision. The MMA permits a Part D plan to require a physician's certification that a preferred drug "*would not be* as effective for the individual or *would have* adverse effects for the individual or both."[119] In the Proposed Rule, CMS allows a plan to require a physician's written certification that a preferred drug "*is* not as effective for the enrollee" as the requested drug.[120] These proposed regulations could be viewed as permitting plans to institute step therapy or "fail first" requirements prior to granting an exceptions request.

We urge CMS to finalize this provision by allowing plans to require the prescribing physician to certify that a therapy would not be as effective for an individual.

7. Therapeutic Equivalence

CMS should not establish a different definition of therapeutic equivalence for the exceptions process than it does for the rest of the Part D benefit, and therapeutic equivalence should be defined in reference to the Orange Book.

The Proposed Rule states that a plan's exceptions criteria should include "[c]onsideration of whether the requested prescription drug that is the subject of the exceptions request is the therapeutic equivalent of any other drug on the sponsor's formulary."[121] Not only has CMS imposed extra criteria on the exceptions process, but in doing so CMS has also inappropriately included a special definition of "therapeutically equivalent" applicable only to this subsection.

For purposes of the exceptions process, the Proposed Rule defines "therapeutically equivalent" as a preferred drug that has "equal effect and no difference when substituted for the requested drug."[122] Yet the definitions section of the Proposed Rule -- § 423.100 -- defines "therapeutically equivalent" as referring to "drugs that are rated as therapeutic equivalent under

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119 Id. at § 1860D-4(g)(2) (*emphasis added*).

120 Proposed 42 C.F.R. § 423.578(a)(4).

121 Proposed 42 C.F.R. § 423.578(a)(2)(iii).

122 Proposed 42 C.F.R. § 423.578(a)(2)(iii).

the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations.'"[123]

GSK supports the definition proposed in § 423.100 as the commonly accepted definition of "therapeutically equivalent." *We urge CMS to avoid establishing a separate definition for exceptions requests.*

X. Subparts C, F, G, K, Q, and R -- Disclosure of Negotiated Price Information

GSK urges CMS to

(1) extend the confidentiality protection of the Medicaid Rebate statute to information obtained by CMS to carry out Medicare payments to Part D plans, data regarding specific drug claims, and other information that CMS deems necessary under various sections of the Proposed Rules, and all negotiated price information submitted to or reviewed by CMS under part D;

(2) make explicit that the Trade Secrets Act[124] applies to pricing or other confidential information that CMS obtains or reviews from plans as it implements Part D;

(3) adopt a regulation mirroring the section of the Federal Acquisition Regulation relating to the protection of confidential and proprietary information; and

(4) provide notice to pharmaceutical manufacturers prior to releasing confidential information under the Freedom of Information Act

1. GSK urges CMS to extend the confidentiality provisions of the Medicaid rebate statute to all of the information that CMS may obtain from plans in the course of administering the Part D benefit.

In the Proposed Rule, CMS specifies the types of information it may require plan sponsors and MA organizations to report. This information includes data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers and passed through to

[123] Proposed 42 C.F.R. § 423.100

[124] 18 U.S.C. § 1905.

Part D enrollees,[125] information necessary to carry out Medicare payments to plan sponsors and MA organizations,[126] data regarding drug claims at an individual level,[127] and other information the agency deems necessary.[128] In addition to these types of information, CMS expects to request detailed pricing information from Part D plans so that it may review the appropriateness of bids, compare bids, and determine allowable costs associated with reinsurance payments, risk corridors and subsidies.[129]

The information that CMS will require from Part D plan sponsors and MA organizations necessarily will include commercially sensitive information that Part D plans obtain from pharmaceutical manufacturers. GSK is concerned that the Proposed Rule does not adequately protect this confidential and proprietary information.

The information that Part D plans will need to submit to CMS is only partially protected under the Proposed Rule. Under Proposed 42 C.F.R. § 423.104(h), the confidentiality protections of the Medicaid rebate statute[130] extend only to the data that plans submit to CMS regarding aggregate negotiated price concessions. The MMA and the Proposed Rule also provide limited protection for the information CMS obtains from plans for the purpose of carrying out payments to plan sponsors and MA organizations.[131] Proposed § 423.322(b) limits the use of this information to purposes consistent with carrying out provisions related to such payments. While this provision does provide some protection against misuse of the information, we are concerned that there is no protection against disclosure of the information. *Extending the confidentiality protections of the Medicaid rebate statute to this information would provide manufacturers with assurances that their confidential and proprietary information will not be inappropriately disclosed.*

CMS also may require plans to submit specific data on drug claims[132] and other detailed data that CMS may deem necessary under § 423.265, § 423.505, §423.863, and § 423.888. The Proposed Rule does not provide any confidentiality protections for any of this information. We are concerned that this lack of protection could result in the inappropriate release of commercially sensitive information that plans obtain from pharmaceutical manufacturers.

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[125] Proposed 42 C.F.R. § 423.104(h).

[126] Proposed 42 C.F.R.§ 423.322(a).

[127] Proposed 42 C.F.R. § 423.329(b)(3).

[128] *Id.*

[129] *See, e.g.*, Proposed 42 C.F.R. § 423.265; § 423.505; §423.863; § 423.888.

[130] SSA §1927(b)(3)(D).

[131] Proposed 42 C.F.R. § 423.322(b). CMS suggests in the preamble that this information may include "the quantity, type, and costs of pharmaceutical prescriptions filled by enrollees." 69 Fed.Reg. at 46686.

[132] Proposed § 423.329(b)(3).

We urge CMS to extend the confidentiality protections of the Medicaid rebate statute to all negotiated pricing information submitted to or reviewed by CMS under Part D, including information obtained under Subparts F, G, K, Q, and R of the Proposed Rule.

We are concerned that the Proposed Rule construes the confidentiality provisions of the MMA too narrowly in extending the Medicaid rebate protections only to aggregate pricing information. While Congress left it to CMS to determine exactly what types of information it would need to properly implement Part D, it seems likely that Congress intended to provide the Medicaid rebate statute protections more broadly to pricing data reported to CMS, and not solely to aggregated pricing information. In fact, the Medicaid rebate statute applies more generally to "information disclosed by manufacturers or wholesalers,"[133] and in effect prohibits the disclosure of pricing information regarding specific drugs. It is this type of specified, disaggregated information that is the most commercially sensitive.

Extending the Medicaid Rebate statute protections will assure manufacturers that their proprietary information will be protected when it is held by CMS. This is particularly important, because, as discussed below, Part D plans may not have sufficient motivation to protect the commercially sensitive information that they obtain from manufacturers.

2. *We urge CMS to clarify in the final rule that the Trade Secrets Act[134] applies to pricing or other confidential information that CMS obtains or reviews from plans as it implements Part D.*

The Trade Secrets Act precludes agency officials or employees from disclosing commercially sensitive information, including certain pricing information. The disclosure of this type of proprietary information would cause substantial competitive harm to manufacturers, as well as to Part D plans. Such disclosure also would impede negotiations between manufacturers and plans. Making clear that this type of specific pricing information constitutes a trade secret would help to protect against the disclosure of such information that CMS obtains from Part D plans and would facilitate the negotiation between these parties.

3. GSK urges CMS to adopt a regulation mirroring the section of the Federal Acquisition Regulation relating to the protection of confidential and proprietary information.[135]

This regulation would apply to all bids submitted by either a risk-bearing plan or a fallback plan and would help to clearly identify confidential and proprietary information.

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[133] § 1927(b)(3)(D).

[134] 18 U.S.C. § 1905.

[135] *See* 48 C.F.R. § 52.215-1(e).

4. *Finally, we urge CMS to provide notice to pharmaceutical manufacturers prior to releasing confidential information under the Freedom of Information Act ("FOIA").*

Federal agencies are required to use "good faith efforts to advise submitters of confidential commercial information" regarding requests for the release of confidential information under FOIA.[136] To that end, the Department of Health and Human Services ("HHS") has adopted a "balanced approach in administering FOIA."[137] Specifically, HHS "recognize[s] the legitimate interests of organizations or persons who have submitted records to the Department or *who would otherwise be affected by release of records*."[138]

Given the unique nature of the reporting requirements under Part D, in which plans report the confidential price information of pharmaceutical manufacturers, it is clear that pharmaceutical manufacturers would be affected by the release of the sensitive price information contained in Part D plan's proposals. Thus, GSK respectfully requests that in addition to notifying Part D plans of a FOIA request, that CMS also provide notice to pharmaceutical manufacturers. This additional notice would allow the entity that would be truly affected by the release of the confidential commercial information the opportunity to review the request and provide the appropriate objection, if necessary.

HHS FOIA regulations currently contemplate the provision of notice to a large number of submitters. Specifically, if CMS "must notify a large number of submitters, [it] may do this by posting or publishing a notice in a place where the submitters are reasonably likely to become aware of it."[139] By posting relevant FOIA requests on a central website, with the ability for submitters to receive e-mail notices of new requests, CMS would provide both Part D plans and pharmaceutical manufacturers sufficient notice to meet CMS FOIA response deadlines or request a time extension. We appreciate CMS's consideration of these specific requests designed to ensure the adequate protection of manufacturers' confidential information.

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136 Executive Order 12,600, 52 Fed. Reg. 23781.

137 42 C.F.R. § 5.2.

138 *Id.* (emphasis added).

139 42 C.F.R. 5.65(d)(1).

XI. Subpart Q -- Non-Interference with Respect to Fallback Plans

GSK recommends that CMS clearly indicate in the final rule that it will not set price benchmarks, create incentive payments, or otherwise interfere with the price structure for Part D drugs, whether provided through fallback plans or not.

Congress explicitly prohibits the Secretary from interfering in Part D negotiations between pharmaceutical manufacturers and plan sponsors and more generally from instituting a particular "price structure for the reimbursement of covered Part D drugs."[140] The Proposed Rule should be clarified to ensure that this prohibition will be observed in the context of fallback plans. While we appreciate CMS's recognition of the risk of running afoul of this non-interference provision, particularly with respect to fallback plans,[141] *we request that CMS clearly indicate in the final rule that it will not set price benchmarks, create incentive payments, or otherwise interfere with the price structure for Part D drugs, whether or not provided through fallback plans.*

It is possible that there will be regions in which one Part D plan or MA-PD is operating alongside a fallback plan. In these situations, it will be especially important that CMS not interfere with the negotiations between a pharmaceutical manufacturer and the Part D plan, MA-PD, or the fallback plan. The Proposed Rule could be interpreted as CMS suggesting that it may seek to influence a fallback plan's negotiations with pharmaceutical manufacturers by scrutinizing the negotiated prices for drugs available through the fallback plan or otherwise instituting a price structure for these plans.[142] *We urge CMS to carefully observe the requirements of the non-interference provisions with respect to fallback plans and to be particularly aware of the non-interference requirements in situations in which a fallback plan is offered alongside an at-risk plan in the same region.*

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[140] SSA § 1860D-11(i).

[141] 69 Fed.Reg. at 46734-5.

[142] *See* 69 Fed.Reg. at 46734-5.

XII. Section 423.159 -- Electronic prescription program

In developing standards for electronic prescribing, CMS must keep as their primary objective the preservation of the physician-patient relationship to facilitate medical choices most appropriate for each patient. Electronic prescribing should support all aspects of the prescribing decision, from choosing the most appropriate drug to resolving all appeals or grievances about that choice. CMS must ensure that the final standards are applicable in the real world with a variety of practice sizes and settings and, therefore, should err on the side of requiring a full demonstration project before the final standards are implemented.

GSK supports the policy of the Medicare Modernization Act to encourage the adoption of electronic prescribing. Widespread adoption of electronic prescribing with the appropriate standards has the potential to (i) enhance patient safety and (ii) improve quality of care, while at the same time realizing significant efficiencies in the delivery of care and reducing overall health care costs.

There are literally hundreds of highly technical issues surrounding the development of electronic standards, interoperability, terminology, privacy, etc. If the critical goal of improving quality of care is to be preserved, CMS must not lose sight of the overarching consideration in implementing this new technology: the importance of the physician-patient relationship and the ability of the physician and patient to make the most appropriate medical choices. Those choices relate both to the decision on which drug will most effectively treat the patient's disease and to the patient's options for filling that prescription.

Within the health care system, in addition to appropriate treatment considerations, there are also financial incentives for payors, pharmacies, drug manufacturers, and other participants to encourage or select the use of certain drugs. While the electronic prescribing system must operate within the context of a specific drug benefit plan in which costs are a relevant consideration, its primary focus should be ensuring safety and improving patient quality; it should not be used merely as a cost-savings tool. *The standards must ensure that the ultimate decision on what drug to prescribe – if any – and how to get drugs dispensed remains in the hands of the patient and the physician or other practitioner.*

There are many examples of how electronic prescribing can help save costs while at the same time ensuring quality of care through preservation of physician and patient treatment choice. For example, the electronic prescribing initiative has the potential to greatly simplify the process of satisfying health plan prior authorization, physician "dispense as written" orders, physician attestation regarding appropriate use, drug interaction alerts, step therapy, co-payment appeals, and denial of coverage appeals. These processes are typically performed manually at great cost to the plan and physician and great inconvenience to the patient. In the current system, these well-intentioned efforts actually dissuade patients from filling their prescriptions, thus contributing to poor outcomes and increased health care costs. *The inclusion of electronic*

"Point of Care" fulfillment processes for each of the above mentioned interventions, therefore, should be an essential feature of an electronic prescribing system.

It is easy to get carried away with the prospect of a "perfect" electronic prescribing environment in which physicians will ideally have all of the information they need to prescribe the medicine that is the most clinically effective and cost effective for the patient and in which the prescription will be transmitted quickly and without error to the chosen dispenser, whether that be a physical pharmacy or a mail-order facility. However, CMS must not lose sight of the reality that underlying this electronic communications system are real patients with less–than-perfect memories, who often face obstacles to filling and complying with their prescriptions.

For example, one of the stated advantages of electronic prescribing is doing away with the paper prescription that the patient must deliver to a pharmacy. Paper prescriptions are often the cause of errors, non-compliance, and inefficiencies due to handwriting errors and obstacles to the ability of patients to have their prescriptions filled. The resulting underutilization and non-compliance are major sources of inefficiencies and costs in the system.

However, in many cases it is the prescription – the piece of paper -- that helps patients remember to get their prescriptions filled. In implementing an electronic prescribing system that eventually could obviate the need for paper prescriptions, we must keep in mind the human elements in play and ensure that there are still adequate incentives and tools available to help patients follow through in getting prescriptions filled, either for themselves or those for whom they are responsible.

We encourage CMS to also consider the other real-world factors that will influence the use of electronic prescribing technology. That is, standards for electronic prescribing must be flexible and scalable to be applicable in the wide variety of clinical settings and specialties, from small to large health care organizations, and low to high volume prescribing practices. *The system must be flexible to support varying physician and patient needs.*

For example, a physician may write a prescription for a long-term medication that the patient chooses to receive by mail order. If the mail order medication will take several days to a week to be delivered, the physician may want to split the prescription and write a prescription for one week's worth of medicine so it can be filled locally. The standards must be sufficiently flexible to support situations like this that vary from most common practices.

The standards must be written with the understanding that electronic prescribing is not just a stand-alone application but must become a collective part of a full electronic health record. *Ultimately, it must have interoperability so that each physician can have the full patient medical history and other information he or she needs in a reliable and user-friendly form.*

Finally, the law requires the Secretary to conduct a pilot project once the initial standards have been adopted; the law allows the Secretary to by-pass the pilot project if there is already

adequate industry experience with the standards the Secretary is planning to adopt. We encourage CMS to exercise caution in this regard.

With the introduction of a new technology that is complex and uncertain, yet so critical to patient safety and the delivery of quality care, we encourage the Secretary to exercise the power to forego a pilot project only if there is extremely high confidence level in the industry experience with the proposed standards. The Secretary should err on the side of requiring further demonstrations to ensure the effectiveness and quality of all aspects of the new standards in a variety of real-world settings.

Conclusion

As CMS prepares the final rule and other regulations to implement the MMA, we ask the agency to remain focused on the statute's greater purpose: to provide Medicare enrollees with important drug therapies in clinically appropriate and cost-effective settings. Patients' access to advanced therapies depends upon Medicare's appropriate reimbursement to providers for those therapies. GSK appreciates the opportunity to comment on the issues we have identified in this comment letter, and we look forward to working with CMS to create a Part D prescription drug benefit that ensures Medicare enrollees meaningful access to vital drug therapies. Please feel free to contact me at (215) 751-4557 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Dean Hakanson. MD
Vice President
GlaxoSmithKline

Attachment

September 17, 2004

BY EMAIL AND OVERNIGHT DELIVERY

Lynn Lang
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Comments of GlaxoSmithKline on the Draft Model Guidelines

Dear Ms. Lang:

GlaxoSmithKline ("GSK") appreciates this opportunity to comment on the draft document entitled "Medicare Prescription Drug Benefit Model Guidelines" (the "Draft Guidelines") that the United States Pharmacopeia ("USP") recently released. GSK is a world leading research-based pharmaceutical company with a mission to improve the quality of human life by enabling people to do more, feel better, and live longer.

GSK supports the implementation of the new Medicare prescription drug benefit ("Medicare Part D") and the delivery of that benefit through competing private-sector prescription plans. GSK applauds USP for acting quickly to produce the Draft Guidelines and appreciates the substantial effort invested by the USP Panel in undertaking this complicated task. We believe the final USP model guidelines ("Model Guidelines"), if developed consistent with USP's mission envisioned by Congress in the Medicare Modernization Act ("Statute"), can be an important component in the successful implementation of Medicare Part D.

EXECUTIVE SUMMARY

Medicare Part D prescription drug plans ("PDPs") with formulary structures (categories and pharmacologic classes) consistent with the Model Guidelines are subjected to <u>less review and scrutiny</u> by the Centers for Medicare & Medicaid Services ("CMS"). In our view, this requires USP to be especially vigilant in its development of the Model Guidelines to ensure that the categories and classes in the Guidelines are sufficient to protect vulnerable Medicare beneficiaries from discrimination by PDPs and to ensure access to a meaningful range of safe and effective medicines for all beneficiaries -- a large, diverse population with a wide spectrum of health conditions, comorbidities and treatment needs. Upon a thorough

review of the Draft Guidelines, GSK believes that the Draft Model Guidelines fall far short of this critical role envisioned by Congress.

For example, the USP proposed "Respiratory Tract Medications" Therapeutic Class contradicts the nationally accepted NIH/NHLBI/NAEPP practice guideline. The practice guideline specifically lists three different medication classes patients must have. However the proposed Model Guidelines places all three into a single pharmacologic class, which would have the effect of discriminating against Medicare beneficiaries with asthma, particularly the sicker beneficiaries.

Another example is the model Blood Glucose Regulating Agents therapeutic category where all oral hypoglycemic agents are placed in one class. Practice guidelines, published research and standard of practice recognize the natural progression of Type 2 Diabetes over time, resulting in a decrease in pancreatic beta cell function and reduced secretion of insulin. There may also be an increase in insulin resistance. The result is loss of glycemic control over time regardless of the treatment used (diet, sulfonylureas, metformin or insulin). During the course of diabetes treatment, physicians typically add therapies without dropping current therapies to meet escalating patient needs (from monotherapy to increasing use of oral polytherapy to oral polytherapy plus insulin). Because the proposed Model Guidelines do not assure coverage for polytherapy for diabetes, the sickest diabetic beneficiaries would be discouraged from enrolling in plans that adhere to the Model Guidelines.

Accordingly, in finalizing the Guidelines, we urge USP to ensure that the Model Guidelines accomplish the purpose that Congress intended - to prevent PDPs from discouraging sicker and more costly beneficiaries from enrolling due to the plan's formulary design and to ensure beneficiaries access to the drugs they need. To achieve that result, GSK recommends (i) that the "recommended subdivisions" in the Draft Guidelines be moved into pharmacologic classes and (ii) that various categories, classes and the currently proposed "recommended subdivisions" be modified so that, when final, the Model Guidelines are more closely aligned with currently accepted clinical practice as discussed below. Moreover, based on our assessment of the literature and accepted medical practice, we have identified a need for additional categories or classes for products that USP appears to have overlooked. [1] In addition, we believe that USP should identify how it will react to newly approved drugs and changes in indications for already approved drugs, and how it will review existing categories and classes to ensure that they remain consistent with current clinical practice.

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1 While we include a discussion below about a number of products that were seemingly overlooked, it would be helpful to see the list of drugs by category or class that USP is supposed to prepare for CMS as soon as possible to further our understanding of how USP believes the categories or classes are populated.

ASSESSMENT OF THE MODEL FORMULARY GUIDELINES

I. Ensuring that the Model Guidelines Serve Their Intended Purpose

The new Medicare prescription drug program holds the potential to greatly increase Medicare beneficiaries' access to prescription drugs not currently covered by Medicare. GSK is concerned, however, that the substantial benefits of Medicare Part D will be jeopardized by how some prescription drug plans ("PDPs") implement the program, particularly with respect to the design of their formularies. Congress shared this concern and included in the statute several significant and independent beneficiary protections regarding formulary structure and development. CMS may approve a PDP only if the PDP satisfies these important requirements. [2]

One such key patient protection provision developed by Congress (and placed among the provisions labeled "Beneficiary Protections for Qualified Prescription Drug Coverage") is the requirement that patients have access to multiple "drugs" (at least two drugs) within each "therapeutic category and class" of the formulary. Given this requirement, the formulary categories and classes that a PDP uses to structure its formulary are critical in determining what types of drugs are available to beneficiaries covered by the formulary. The Statute also requires that upon review of the plan, CMS "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan." [3] In other words, CMS must determine that the PDP and its benefit ensures access to a meaningful range of drugs necessary for treatment of beneficiaries and that the PDP's therapeutic category and class structure does not discriminates against the sickest and costliest beneficiaries by failing to assure them this access to the types of drugs that they need.

Under the Statute, approval of individual PDPs is generally left to CMS following its careful review of the PDP's application. However, Congress directed CMS to seek the assistance of the USP in the development of a list of categories and classes that may be adopted and used by PDPs (*i.e.*, the Model Guidelines) in structuring their formularies. If a PDP's formulary structure is consistent with the categories and classes in the Model Guidelines, CMS may not find that the design of

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2 Social Security Act ("SSA") § 1860D-11(e)(2).

3 SSA § 1860D-11(e)(2)(D)(i).

the plan's formulary categories and classes violate the requirement not to "to substantially discourage enrollment" by eligible beneficiaries through its plan design and benefits. This insulates a PDP from some scrutiny of its formulary. On the other hand, the Statute does not require plans to follow the Model Guidelines. PDPs with formularies using categories and classes different from the Model Guidelines may obtain approval from CMS only upon the agency's review of its categories and classes, in addition to all formulary and other requirements required by the Statute and CMS regulations.

This Congressional mandate and role for guidelines from USP has led some to refer to the Model Guidelines as a "safe harbor" for PDPs. While this characterization may be an overstatement in that consistency with the Model Guidelines does not insulate the plan entirely from review of its formulary by CMS, the fact that the Model Guidelines provide even a partial "safe harbor" from CMS' ability to police the effect on patient access of category and class designs in PDP formularies, in our view, bestows a significant responsibility on USP. That is, USP has the responsibility to ensure that the categories and classes in the Model Guidelines ensure access and are not transformed into a means for PDPs to effectively deny access to medications to select groups of Medicare beneficiaries.

Unfortunately, there is evidence that the Draft Guidelines have been shaped by a desire on the part of USP to balance the number of categories and classes against the position of many prospective PDPs that fewer categories or classes are needed to give them flexibility to, among other things, design their plans to ensure "cost effectiveness." [4] The decision to create numerous "recommended subdivisions" rather than having such groupings included as categories or classes likewise illustrates USP's departure from its charge from Congress and its misplaced focus on balancing the protection of beneficiaries with the desires of plans. The result of this focus is a less granular set of categories and classes that would, in effect, allow a PDP to evade review by CMS whether the categories and classes in its formulary would discourage sicker and more costly beneficiaries from enrolling in its plan. At the same time, as illustrated with numerous examples in our analysis below, it is evident that the categories and classes in the Draft Guidelines are structured in a manner that would allow plans not to provide numerous, critically needed drugs to treat the Medicare patient population consistent with accepted medical standards and nationally recognized treatment guidelines.

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4 *E.g.* Draft Guidelines at 7 (discussing the "challenge of balancing access to needed drugs with the need for the Model Guidelines to be practical for" drug plans).

GSK is also concerned that USP has given insufficient consideration to the unique and distinct drug needs of the elderly and disabled patient population that will enroll in Medicare Part D. The "environmental scan" performed for USP in support of its efforts to develop the Draft Guidelines and on which the USP heavily relied, focused almost exclusively on the employer group health plan population, not the Medicare population. However the Medicare patient population is a very different population from enrollees in employer group health plans with respect to the use of drug therapies. The Medicare population typically has multiple chronic conditions and requires a wider variety of medications. Indeed, elderly Medicare beneficiaries often require drug treatments for chronic conditions such as osteoporosis, hypertension, diabetes, cardiovascular disease or depression – conditions that require simultaneous administration of multiple medications that must be taken for extended periods of time.[5] Elderly patients with chronic diseases are more susceptible to medication adverse events than the general population. Therefore, access to adverse-event reducing drugs is essential for these beneficiaries. Physicians must have access to the wide range of medicines needed to treat appropriately this population's often complex medical conditions, especially in light of the elderly patient's greater sensitivity to drug interactions and side effects.

GSK urges USP to provide a matrix of categories and classes that, if followed by a PDP, would ensure that the plan makes available to enrolled Medicare beneficiaries and their treating physicians all of the drugs that they would need.[6] This matrix must be developed by carefully reviewing the clinical and scientific evidence regarding the set of drugs needed by the Medicare patient population, not by balancing that evidence with the cost concerns of PDPs. Any such balancing will be the job of CMS in implementing the new prescription drug program. Because the Model Guidelines will provide a means for plans to avoid some level review by CMS, it is imperative that there be no room within the Model Guidelines to allow plans to discourage beneficiary enrollment. While this might appear to create a higher burden for plans, they have the option of adopting different categories and classes and having them reviewed by CMS.

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5 See Report to the President, "Prescription Drug Coverage, Spending, Utilization, and Prices," From Department of Health & Human Services, April 2000, available at http://aspe.hhs.gov/health/reports/drugstudy/.

6 We also request that USP identify how it will perform the congressionally mandated function of updating the Model Guidelines to reflect changes in the uses of drugs and the addition of new drugs. There needs to be a predictable mechanism for doing so in a timely fashion. For newly approved drugs, in particular, GSK believes that there needs to be a prompt mechanism for determining whether a new category or class must be added.

II. Assessment of Current Categories, Classes and Subdivisions

Based on our review of the Draft Model Guidelines, considerable changes need to be made to the list of categories and classes to ensure that plans following the Model Guidelines will not be able to discourage enrollment by certain types of Medicare beneficiaries and that the enrollees have access to the range of medicines needed to appropriately treat their medical conditions. Avoiding adverse events should be a specific consideration in establishing pharmacologic classes. Even drugs in the same therapeutic category and pharmacologic class will have different side-effect and adverse event profiles. This is particularly necessary for patients with chronic conditions because they are more susceptible to medication adverse events than the general population. This means that pharmacologic classifications should include classes that allow avoidance of adverse events and not just traditional chemical class or mechanisms of action. A starting point would be to include all of the currently "recommended subdivisions" in the Draft Guidelines as pharmacologic classes in the final Model Guidelines. However, that alone would not be sufficient, as there would need to be changes to the categories, classes and subdivisions that appear in the Draft Guidelines We address these changes below.

A. Analgesics Therapeutic Category

By offering Opioid Analgesics and Non-opioid Analgesics as the only options in the Analgesics Pharmacological Classification, the proposed Model Guideline conflicts with leading peer-reviewed arthritis treatment guideline recommendations and associated pharmacologic classifications and potentially limits patient access to safe and effective alternatives for pain relief. For this reason, GSK recommends that COX-2 selective inhibitors be added as a Pharmacologic Class in this category.

Key goals of the American College of Rheumatology Osteoarthritis Guideline include control of pain and avoidance of toxic effects from therapy.

> *"The goals of the contemporary management of the patient with OA continue to include control of pain and improvement in function and health-related quality of life, with avoidance, if possible, of toxic effects of therapy."*[1]

When describing the pharmacologic options, the intent of these guidelines clearly is to separate the COX-2 selective inhibitors from the non-selective NSAIDs. As described, COX-2 selective inhibitors are first line therapy for patients who fail to manage their pain with adequate doses of acetaminophen.

> *"Toxicity is the major reason for not recommending the use of NSAIDs as first-line therapy for patients with OA of the hip. Data from epidemiologic studies demonstrate that among persons ages 65 and older, 20-30% of all hospitalizations and deaths due to peptic ulcer disease were attributable to NSAID therapy."*[2]

The importance of this recommendation is highlighted by the incidence of major complications and death from gastrointestinal bleeds due to non-selective COX inhibitors (NSAIDs). This represents a public health problem for patients requiring the management of chronic pain. Hospital admissions arise in 0.25 - 1.58% of users per year and deaths occur in 7,000 US patients annually. [1] In many cases of major GI bleed due to NSAIDs there is no prior warning.

Table 3. Pharmacologic therapy for patients with osteoarthritis*
(Taken from ACR OA Hip & Knee Guideline)

Oral
Acetaminophen
COX-2-specific inhibitor
*Non-selective NSAID plus misoprostol or a proton pump inhibitor***
Nonacetylated salicylate
Other pure analgesics Tramadol

Opioids Intraarticular
Glucocorticoids
Hyaluronan
Topical
Capsaicin
Methylsalicylate

- *The choice of agent(s) should be individualized for each patient as noted in the text. COX-2 = cyclooxygenase 2; NSAID = nonsteroidal anti-inflammatory drug.*

***Misoprostol and proton pump inhibitors are recommended in patients who are at increased risk for upper gastrointestinal adverse events.* [1]

Subsequent to the writing of the guidelines noted above, several large outcome studies have been published confirming that COX-2 selective inhibitors can reduce GI morbidity 50% to 80% vs. non-selective NSAIDs. The VIGOR study [3] showed a 50% reduction in GI risk for patients taking rofecoxib versus an NSAID. The TARGET study shows an even greater reduction of approximately 80% for lumaricoxib. [i] Short-term endoscopy studies for all available COX-2 drugs show substantial risk reductions for endoscopic ulcers. [4]

The American Pain Society (APS) recently released a clinical guideline on the treatment of acute and chronic pain associated with arthritis. This multidisciplinary, evidence-based guideline was developed by a panel of experts in arthritis pain management confirms the use of COX-2 specific inhibitors prior to the use of the non-selective NSAIDs.

> *"For persons with moderate to severe pain from osteoarthritis and rheumatoid arthritis, COX-2 nonsteroidal anti-inflammatory drugs (NSAIDs) are the best choice for their pain-relieving potency and lower incidence of gastrointestinal (GI) side effects. Use of non-selective NSAIDs should be considered only if the patient does not respond to acetaminophen and COX-2 drugs, and is not at risk for NSAID-induced GI side effects. Because of the high cost of COX-2 agents, some patients may benefit from non-selective NSAID therapy combined with a medication to moderate GI distress."* [4]

Early concerns that rofecoxib-specific increases in cardiovascular risk may represent a class effect have been negated by the benign CV profile shown in the TARGET study. [5]

The American College of Rheumatology guidelines for the management of rheumatoid arthritis points out that patients with RA are twice as likely as OA patient to have a

serious complication from non-selective NSAID therapy. Strategies to avoid the GI toxic effects of non-selective NSAIDs, include the use of a highly selective COX-2 inhibitor.[6]

These data, taken together, shows that the COX-2 drugs are sufficiently different in their safety profile from ns-NSAIDS as to represent a distinct class of medications, offering patients a distinct benefit over ns-NSAIDs. These drugs should be considered as separate therapeutic options for patients at risk of serious GI bleeding (advanced age, chronic use and other risk factors).

For these reasons, GSK recommends that the Analgesics Therapeutic Category be revised as follows.

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	*Recommended Subdivisions*
Analgesics	Opioid Analgesics	
	Non-opioid Analgesics	
	COX-2 Inhibitors	

1. Altman RD, Hochberg MC, Moskowitz RW, Schnitzer TJ. Recommendations for the Medical Management of Osteoarthritis of the Hip and Knee. American College of Rheumatology Subcommittee on Osteoarthritis Guidelines. *Arthritis & Rheumatism*. 2000; 43;1905-1915.

2. Hochberg MC, Altman RD, Brandt KD, Kenneth D, Clark BM, Dieppe P, Griffin MR, Roland W, TJ Schnitzer. Guidelines for the Medical Management of Osteoarthritis, Part I. Osteoarthritis of the Hip. Arthritis & Rheumatism. *Official Journal of the American College of Rheumatology*. 1995;38;1535-1540.

3. Bombardier C, et al. Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis. *New England Journal of Medicine*. 2000; 1520 – 1528.

4. Schnitzer TJ, Burmester GR, Mysler E, Hochberg MC, Doherty M, Ehrsam E, Gitton X, et al. Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), reduction in ulcer complications: randomised controlled trial *Lancet*. 2004; 364: 665–74.

5. US package inserts: BEXTRA, CELECOIB, VIOXX.

6. Farkouh ME, Kirshner H, Harrington RA, Ruland S, Freek WA, et al. Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), cardiovascular outcomes: randomized controlled trial. *Lancet* 2004; 364: 675–84

B. **Antibacterials Therapeutic Category, All Pharmacologic Classes (Nos. 5 – 13)**

The proposed antibacterials pharmacologic classes are not aligned with accepted medical practice and treatment guidelines. According to the CDC, drug-resistant infections require accurate detection and appropriate treatment as they pose a significant threat to public health[1].

Community-acquired infections and the number of medications to which they are resistant is increasing[2]. Organisms that are resistant to multiple anti-bacterial medications are increasing, therefore access to the most specific and potent antibacterial medications is essential.

The currently defined subdivisions are actually antibacterial classes and should be listed as such. Each formulation and derivation is unique and specific to their antibacterial actions, effectiveness and benefits. These drugs are not interchangeable because they combat different types of bacterial infections (gram negative vs. gram positive, broad spectrum vs. specific). In addition, an individual patient might need more than one agent at a time.

Therefore, GSK proposes that the following classification be used for the Antibacterials Therapeutic Category.

Therapeutic Category	Pharmacologic Class	Recommended Subdivisions
Antibacterials	Beta Lactam, Penicillins	
	• Penicillin G-related Penicillins	
	• Penicillins, Amino Derivative	
	• Penicillinase-resistant Penicillins	
	• Extended Spectrum Penicillins	
	Beta-Lactam, Cephalosporins	
	• Cephalosporins, 1st Generation	
	• Cephalosporins, 2nd Generation	
	• Cephalosporins, 3rd Generation	

	• Cephalosporins, 4th Generation	
	Beta-Lactam, Other	
	• Carbacephems	
	• Carbapenems	
	• Cephamycins	
	• Monobactams	
	Quinolones	
	• Quinolones, Fluorinated	
	• Quinolones, Non-fluorinated	
	Sulfonamide/Related Antibacterials	
	Aminoglycosides	
	Macrolides	
	• Erythromycins	
	• Macrolides, Other	
	Tetracyclines	
	Antibacterials, Other	
	• Antifolates	
	• Glycopeptides	
	• Lincomycins	
	• Nitrofurans	
	• Oxazolidinones	
	• Polymyxins	
	• Streptogramins	
	• Other	

References
1. Centers for Disease Control (CDC) Second Annual Progress Report: Implementation of *A Public Health Action Plan to Combat Antimicrobial Resistance. Part 1: Domestic Issues*. June 2004. Executive Summary. http://www.cdc.gov/drugresistance/actionplan/2003report/executivesummary.pdf. Accessed September 16, 2004.

2. Goossens, H. Sprenger, MJW. Community acquired infections and bacterial resistance. *BMJ*, 1998;317:654-657.

C. Anticonvulsants Therapeutic Category (No. 14)

GSK recommends adding four (4) pharmacologic class listings titled "sodium channel blocker", "calcium channel blocker", "GABA systems" and "glutamate receptors" to the therapeutic category titled "anticonvulsants".

Various types of seizures respond differently to anticonvulsant agents with response rate often based on a drug's mechanism of action. Furthermore, selection of an antiepileptic drug depends on if the treatment is for new onset or refractory epilepsy. In accordance with the American Academy of Neurology (AAN)/American Epilepsy Society (AES) treatment guidelines, broad access to anticonvulsant agents is required to treat the multiple forms of epilepsy, to accommodate disease response variability and to account for the vast differences in drug side effects, toxicity, and adverse event profiles among the many agents. [1,1] Access to anticonvulsants with different mechanisms of action is particularly important for patients with refractory epilepsy. According to the AAN/AES treatment guidelines, the average number of failed anticonvulsants in studies involving refractory patients was often eight or more.

The Model Guidelines present potentially serious problems for Medicare part D patients including:

- Placing patients at undue risk by failing to ensure access to newer agents which often have fewer safety concerns, better side effect profiles and a broader therapeutic concentration range
- Not ensuring coverage of medications to treat each type of seizure including partial (focal or local) seizures, generalized seizures and unclassified epileptic seizures
- Reducing the likelihood that patients with refractory disease will find one anticonvulsant or a combination of anticonvulsants that will control their seizures.

The Model Guidelines make it possible for a PDP to cover only older agents, those that can have higher toxicity profiles, those with a high likelihood for a side effect or to cover agents that address just one or two mechanisms of seizure activity. In addition, even if limiting coverage of anticonvulsant medications addressed the goal for seizure control for all types of seizures, even in refractory patients, it would not recognize the additional, but equally important, goals of therapy that impact a patient's quality of life including optimal cognitive, physical and psychological functioning.[2]

Drug therapy selection is based on the seizure type, disease duration, mechanism of drug action and the side effect or adverse event profile. The elderly beneficiaries covered by Medicare part D may be especially vulnerable to drug side effects as are most patients with increasing age. Therefore, limiting drug coverage by narrowly

defining the anticonvulsant therapeutic category could result in excessive adverse event and toxicity burden in this already high risk population.

For these reasons GSK proposes the following change to the Model Guidelines.

Reference Line	Therapeutic Category	Pharmacologic Class	Recommended Subdivisions
14	Anticonvulsants	Sodium Channel Blocker	
15		Calcium Channel Blocker	
16		GABA Systems	
17		Glutamate Receptors	

References:

[1] French JA, Kanner AM, Bautista J, et al. Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new onset epilepsy. Report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. 2004;62:1252-1260.
NOTE: the guideline reference is available online at http://www.neurology.org/cgi/reprint/62/8/1252.pdf

[2] French JA, Kanner AM, Bautista J, et al. Efficacy and tolerability of the new antiepileptic drugs II: Treatment of refractory epilepsy. Report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. 2004;62:1261-1273.
NOTE: the guideline reference is available online at http://www.neurology.org/cgi/reprint/62/8/1261.pdf

D. Anti-depressants Therapeutic Category, Reuptake Inhibitors and Other, Pharmacologic Classes_ (Nos. 15, 16, 17)

GSK recommends that subdivisions for anti-depressants be made pharmacologic classes, which is consistent with APA Practice Guideline for the Treatment of Patients with Major Depressive Disorder.

Of the nearly 35 million Americans age 65 and older, an estimated 2 million have a depressive illness (major depressive disorder, dysthymic disorder or bipolar disorder.)[1] Chronic medical illness afflicts eighty eight percent of people aged 65 or older, and those with chronic illnesses have a high prevalence of major depressive illness[2]. Depression associated with chronic medical illness may also lead not only to increased health care utilization and morbidity but also to increased mortality[3]. The National Institute of Mental Health considers depression in people age 65 and older to be a major public health problem[1].

The American Psychiatric Association guideline for treatment of patients with major depressive disorder emphasizes the necessity of continuation of medication through acute and maintenance phases. The goal is to treat the symptoms acutely (1-2 months) to achieve response. To reduce the likelihood of relapse, this response should be maintained for an additional 2-6 months[4]. Thus, depressed patients should be treated with an antidepressant for at least 4-9 months. More than 40% of these patients, however, discontinue therapy within the first three months of treatment due to poor tolerability[5].

In order to assure continuous treatment, a range of anti-depressant medication options are needed for initial therapy as well as for replacement medication. CMS will realize medical cost savings as medication adherence improves because total cost of care decreases significantly. Additional drug cost is more than offset by medical cost savings. Patients who stay on therapy for more than 90 days not only have an improved chance of recovery, but their annual medical costs can be reduced by more than $2,000.[6,7]

The proposed pharmacologic classifications under the antidepressant therapeutic category inappropriately link different mechanisms of action under a single heading. It also links medications that have considerable differences in safety as well as side-effect profile.

We recognize that USP will be looking at which specific drugs would fit into each classification/subdivision, but we would like to clarify that buproprion does not fit into the specific categories and would be considered antidepressant, other, or a new pharmacologic classification would need to be added.

Therefore, GSK proposes that the following classification be used for the Antidepressant Therapeutic Category.

Therapeutic Category	Pharmacologic Class	Recommended Subdivisions
Antidepressants	Monoamine Oxidase Inhibitors	
	SNRI	
	SSRI	
	Tricyclics	
	Antidepressants, other	

References:

1. Older adults: Depression and suicide facts. National Institute of Mental Health. http://www.nimh.nih.gov/HealthInformation/elderlydepsuicide.cfm. Accessed September 15, 2004.
2. Katon, WJ. Clinical and health services relationships between major depression, depressive symptoms, and general medical illness. Biol Psychiatry. 2003; 54:216-226.
3. Katon, W. Sullivan, MD. Depression and chronic medical illness. J Clin Psychiatry. 1990 Jun; 51 Suppl:3-11.
4. American Psychiatric Association practice guideline for the treatment of patients with major depressive disorder. Am J Psychiatry 2000 Apr;157(4 Suppl):1-45.
5. Bull SA, Hunkeler, EM, Lee, JY, et al. Discontinuing or switching selective serotonin-reuptake inhibitors. Ann Pharmacother, 2002;36:578-584.
6. Thompson D, Buesching D, Gregor KJ, et al. Patterns of antidepressant use and their relation to costs of care. *Am J Managed Care.* 1996;2(9):1239-1246.
7. Tseng, CW, Brook, RH, Keeler, E, et al. Cost lowering strategies used by Medicare beneficiaries who exceed drug benefit caps and have a gap in drug coverage. JAMA 2004;8:952-960.

E. Antidotes, Deterrents and Poison Control Therapeutic Category, Antidotes Pharmacologic Classes (No. 18)

The term "opioid antagonist" in the current subdivision of antidotes has become outdated and should be changed to specify "centrally acting opioid antagonists." A new opioid antagonist pharmacologic classification "peripherally acting opioid agonist" should be added to the Gastrointestinal Medications section for differentiation.

The new class of agent is peri registration for the treatment of Post Operative Ileus and under development for other gastrointestinal conditions. The two distinct mechanisms of action and clearly different potential indications should be differentiated in the USP model guidelines.

GSK recommends the following change to the Draft Model Guidelines

Therapeutic Category	Pharmacologic Classification	Recommended Subdivisions
Antidotes, Deterrents, and Poison Control	Antidotes Centrally Acting Opioid Antagonist	
	Antidotes: Antivenins	
	Antidotes: Ion Exchange Resins	
	Antidotes, Other	
	Antidotes:Heavy Metal Antagonists	

F. Antiemetics Therapeutic Class, New Pharmacologic Class for NK1

The National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemetics (v.1.2004) guidelines now identify NK1 inhibitors for use as prophylaxis with highly emetogenic chemotherapy regiments in combination with a 5HT3 antagonist.[1] They are also recommended for use as an option for moderately emetogenic chemotherapy in combination with dexamethasone for the prevention of delayed nausea and vomiting.

Therefore, GSK requests that this new class be added to the proposed formulary listing.

Therapeutic Category	Pharmacologic Classification	Recommended Subdivisions
Antiemetics	NK1 inhibitors	
	5-HT3 Antagonists	
	Antiemetics, other	

Reference:

1. Practice Guidelines in Oncology – v.1.2004. National Comprehensive Cancer Network, Inc. Available at http://www.nccn.org/professionals/physician_gls/PDF/antiemesis.pdf

G. Antihistamines Therapeutic Category, H1 Blockers and H2 Blockers Pharmacologic Classes (Nos. 28, 29)

The antihistamine therapeutic category and classes are too narrowly defined and do not incorporate recognized practice guidelines for the treatment and management of allergies, which include a broader range of conditions and recommended treatments.

Of all allergy-related conditions and symptoms, allergic rhinitis is of major concern. Allergic rhinitis affects up to 40 million Americans and is the sixth most prevalent chronic disease in the United States[1]. In 1995, it was estimated that the direct and indirect costs for the management of this condition was 2.7 billion dollars, excluding costs for accompanying asthma and sinusitis. In 1996, Ray et al, estimated that the direct medical costs for allergic rhinitis, as a primary or secondary diagnosis, at 5.9 billion dollars accounting for airway related diseases[2].

Allergic rhinitis is defined as inflammation of the nasal mucosa precipitated by exposure to inhaled allergens producing a specific immunologic response[3]. "Untreated allergic rhinitis develops into a chronic state of inflammation and nasal obstruction that frequently leads to much more serious diseases in both the upper and lower airways. Allergic rhinitis is closely associated with, and may be a causative factor in, asthma, sinusitis, otitis media with effusion (OME), and polyps."[4,5]

Antihistamines work by blocking the H_1-receptor site and inhibiting the effects of histamine. Antihistamines relieve rhinorrhea, sneezing, itching and ocular symptoms; however in general, they do not effectively relieve nasal obstruction[6].

Decongestants constrict blood vessels in the nose and reduce mucosal edema to relieve nasal obstruction. They are less effective for rhinorrhea, sneezing and itching. Decongestants are available in topical and oral formulations. Decongestants are often combined with antihistamines to provide relief of all nasal symptoms[7].

Intranasal corticosteroid preparations relieve all major nasal symptoms of allergic rhinitis, including nasal obstruction, rhinorrhea, sneezing and itching. These preparations are applied directly to the site of inflammation and inhibit the activity of inflammatory cells and their mediators: histamine, leukotrienes and prostaglandins. The Joint Task Force states "…nasally inhaled corticosteroids are the most effective medication class in controlling symptoms of allergic rhinitis."[6]

Leukotriene modifiers are a class of drugs used to treat asthma. Of the three leukotriene modifier agents available, only montelukast is indicated for the relief of symptoms of seasonal allergic rhinitis. It inhibits one of the many classes of

inflammatory mediators, leukotrienes, by binding to leukotriene C_4, D_4, and E_4 receptors[7].

Mast cell stabilizers treat allergies by blocking the release of histamine and preventing mast cells from degranulating. Intranasal cromlyn sodium is used for the prevention and treatment of the nasal symptoms of allergic rhinitis. Although its mechanism is thought to involve degranulation of mast cells, it has not been fully elucidated[8].

Anticholinergic agents such as intranasal ipratropium bromide is indicated for the symptomatic relief of rhinorrhea associated with allergic and non-allergic perennial rhinitis in adults and children 12 years of age and older. It does not relieve nasal congestion, sneezing or post-nasal drip.

GSK recommends that the Therapeutic Category "Antihistamines" be updated and renamed "Anti-allergy." The proposed H1 and H2 blocker pharmacologic classes should be replaced with the new classes, which reflect Joint Task Force guidelines for appropriate treatment of allergy symptoms, including allergic rhinitis:

- antihistamines,
- decongestants
- intranasal corticosteroids
- leukotriene modifiers
- mast cell stabilizers
- anticholinergics

For these reasons GSK recommends the following changes to the Model Guidelines.

<table>
<tr><th>THERAPEUTIC CATEGORY</th><th>PHARMACOLOGIC CLASS</th><th>Recommended Subdivisions</th></tr>
<tr><td rowspan="2">Anti-allergy</td><td rowspan="2">antihistamines,
decongestants
intranasal corticosteroids
leukotriene modifiers
mast cell stabilizers
anticholinergics</td><td></td></tr>
<tr><td></td></tr>
</table>

References:

1. Dykewicz MS, Fineman S, Skoner, et al. Diagnosis and Management of Rhinitis: Complete Guidelines of the Joint Task Force on Practice Parameters in Allergy, Asthma, and Immunology. Ann Allergy Asthma Immunol 1998; 81: 478-518/ Naclerio RM. Allergic rhinitis. N Engl J Med 1991;325:860-869.

2. Ray NF, Baraniuk JN, Thamer M, et al. Direct Expenditures for the Treatment of Allergic Rhinoconjuctivitis in 1999, Including the Contribution of Related Airway Illness. J Allergy Clin Immunol 1999;103:401-407.

3. Dykewicz MS, Fineman S, Skoner, et al. Diagnosis and Management of Rhinitis: Complete Guidelines of the Joint Task Force on Practice Parameters in Allergy, Asthma, and Immunology. Ann Allergy Asthma Immunol 1998; 81: 478-518/ Naclerio RM. Allergic rhinitis. N Engl J Med 1991;325:860-869.

4. Dykewicz MS, Fineman S, Skoner, et al. Diagnosis and Management of Rhinitis: Complete Guidelines of the Joint Task Force on Practice Parameters in Allergy, Asthma, and Immunology. Ann Allergy Asthma Immunol 1998; 81: 478-518.

5. Rachelefsky GS. National guidelines needed to manage rhinitis and prevent complications. Annals of Allergy, Asthma, & Immunology. 1999;82(3):296-305.

6. Naclerio RM. Allergic rhinitis. N Engl J Med 1991;325:860-869.

7. Naclerio RM. Allergic rhinitis. N Engl J Med 1991;325:860-869.

8. Dykewicz MS, Fineman S, Skoner, et al. Diagnosis and Management of Rhinitis: Complete Guidelines of the Joint Task Force on Practice Parameters in Allergy, Asthma, and Immunology. Ann Allergy Asthma Immunol 1998; 81: 478-518.

9. HON Dossier – Allergy Glossary-Leukotreine. Available at: http://www.hon.ch/Library/Theme/Allergy/Glossary/leukotriene.html. Accessed on September 16, 2004.

10. Naclerio RM. Allergic rhinitis. N Engl J Med 1991;325:860-869.

11. HON Dossier – Allergy Glossary–Anti-cholinergic. Available at: http://www.hon.ch/Library/Theme/Allergy/Glossary/anti-cholinergic.html. Accessed on September 16, 2004.

H. Anti-Inflammatory Therapeutic Category

By combining COX-2 Inhibitors, Salicylates and Other Nonsteroidals as subdivisions of the Nonsteroidal class in the Anti-inflammatories Therapeutic Category, the proposed Model Guildeline conflicts with leading peer-reviewed arthritis treatment guideline recommendations and associated pharmacologic classifications and potentially limits patient access to safe and effective options for pain relief. For this reason, GSK recommends that COX-2 Inhibitors, Salicylates and Other Nonsteroidals be listed as separate Pharmacologic Classes.

Key goals of the American College of Rheumatology Osteoarthritis Guideline include control of pain and avoidance of toxic effects from therapy.

> *"The goals of the contemporary management of the patient with OA continue to include control of pain and improvement in function and health-related quality of life, with avoidance, if possible, of toxic effects of therapy."*[1]

When describing the pharmacologic options, the intent of these guidelines clearly is to separate the COX-2 selective inhibitors from the non-selective NSAIDs. As described, COX-2 selective inhibitors are first line therapy for patients who fail to manage their pain with adequate doses of acetaminophen.

> *"Toxicity is the major reason for not recommending the use of NSAIDs as first-line therapy for patients with OA of the hip. Data from epidemiologic studies demonstrate that among persons ages 65 and older, 20-30% of all hospitalizations and deaths due to peptic ulcer disease were attributable to NSAID therapy."*[2]

The importance of this recommendation is highlighted by the incidence of major complications and death from gastrointestinal bleeds due to non-selective COX inhibitors (NSAIDs). This represents a public health problem for patients requiring the management of chronic pain. Hospital admissions arise in 0.25 - 1.58% of users per year and deaths occur in 7,000 US patients annually. [1] In many cases of major GI bleed due to NSAIDs there is no prior warning.

Table 3. Pharmacologic therapy for patients with osteoarthritis*
(Taken from ACR OA Hip & Knee Guideline)

Oral
Acetaminophen
COX-2-specific inhibitor
*Nonselective NSAID plus misoprostol or a proton pump inhibitor***
Nonacetylated salicylate
Other pure analgesics Tramadol

Opioids Intraarticular
Glucocorticoids
Hyaluronan
Topical
Capsaicin
Methylsalicylate

- *The choice of agent(s) should be individualized for each patient as noted in the text. COX-2 = cyclooxygenase 2; NSAID = nonsteroidal antiinflammatory drug.*

***Misoprostol and proton pump inhibitors are recommended in patients who are at increased risk for upper gastrointestinal adverse events.* [1]

Subsequent to the writing of the guidelines noted above, several large outcome studies have been published confirming that COX-2 selective inhibitors can reduce GI morbidity 50% to 80% vs. non-selective NSAIDs. The VIGOR study [5] showed a 50% reduction in GI risk for patients taking rofecoxib versus an NSAID. The TARGET study shows an even greater reduction of approximately 80% for lumaricoxib. [6] Short-term endoscopy studies for all available COX-2 drugs show substantial risk reductions for endoscopic ulcers. [7]

The American Pain Society (APS) recently released a clinical guideline on the treatment of acute and chronic pain associated with arthritis. This multidisciplinary, evidence-based guideline was developed by a panel of experts in arthritis pain management confirms the use of COX-2 specific inhibitors prior to the use of the non-specific NSAIDs.

> *"For persons with moderate to severe pain from osteoarthritis and rheumatoid arthritis, COX-2 nonsteroidal anti-inflammatory drugs (NSAIDs) are the best choice for their pain-relieving potency and lower incidence of gastrointestinal (GI) side effects. Use of nonselective NSAIDs should be considered only if the patient does not respond to acetaminophen and COX-2 drugs, and is not at risk for NSAID-induced GI side effects. Because of the high cost of COX-2 agents, some patients may benefit from nonspecific NSAID therapy combined with a medication to moderate GI distress."* [6]

Early concerns that rofecoxib-specific increases in cardiovascular risk may represent a class effect have been negated by the benign CV profile shown in the TARGET study. [9]

The American College of Rheumatology guidelines for the management of rheumatoid arthritis points out that patients with RA are twice as likely as OA patient to have a serious complication from non-specific NSAID therapy. Strategies to avoid the GI toxic effects of nonspecific NSAIDs, include the use of a highly selective COX-2 inhibitor.[10]

These data, taken together, shows that the COX-2 drugs are sufficiently different in their safety profile from ns-NSAIDS as to represent a distinct class of medications, offering patients a distinct benefit over ns-NSAIDs. These drugs should be considered as separate therapeutic

options for patients at risk of serious GI bleeding (advanced age, chronic use and other risk factors).

For these reasons, GSK recommends that the Anti-inflammatory Therapeutic Category be revised as follows.

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	*Recommended Subdivisions*
Anti-inflammatory	Corticosteroids (see Hormones)	
	COX-2 Inhibitors	
	Salicylates	
	Nonsteroidals, Other	

References:

1. Altman RD, Hochberg MC, Moskowitz RW, Schnitzer TJ. Recommendations for the Medical Management of Osteoarthrits of the Hip and Knee. American College of Rheumatology Subcommittee on Osteoarthritis Guidelines. *Arthritis & Rheumatism*. 2000; 43;1905-1915.

2. Hocberg MC, Altman RD, Brandt KD, Clark BM, Dieppe PA, et al. Special Article Guidelines for the Medical Management of Osteoarthritis Part I. Osteoarthritis of the Hip. *Arthritis & Rheumatism*. 1995;38; 1535-1540.

3. Ombardier CB, et al. COMPARISON OF UPPER GASTROINTESTINAL TOXICITY OF ROFECOXIB AND NAPROXEN IN PATIENTS WITH RHEUMATOID ARTHRITIS CLAIRE B OMBARDIER. *New England Journal of Medicine*. 2000;1520 – 1528.

4. Schnitzer TJ, Bumester GR, Mysler E, Hochber MC, Doherty M, et al. Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), reduction in ulcer complications: randomised controlled trial. *Lancet.* 2004; 364; 665–74.

5. US package inserts, BEXTRA, CELECOXIB, VIOXX

6. Schnitzer TJ, Burmester GR, Mysler E, Hocberg MC, Doherty M, et al. Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), reduction in ulcer complications: randomised controlled trial. Lancet 2004; 364: 665–74

7. Farkouh ME, Kirshner H, Harrington RA, Ruland S, Freek WA, et al. Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), cardiovascular outcomes: randomized controlled trial. *Lancet* 2004; 364: 675–84

8. Newsome G. American College of Rheumatology. Guidelines for the Management of Rheumatoid Arthritis. 2002 Update. American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Arthritis and Rheumatism. 2002; 46; 328-346.

I. Antineoplastics Therapeutic Category, All Pharmacologic Classes

Current cancer treatment practice creates a unique situation that clearly does not fit well within the proposed draft USP formulary categories and the potential minimum requirement of two drugs per category.

Cancer is not one disease but rather a wide range of diseases, with products from multiple pharmacological classes used based on tumor type, stage of disease, available biomarkers, proven combination regimens and patient tolerability. Included in the pharmacological classes used in the treatment of cancer are antineoplastics, hormone suppressants, immune suppressants and other immunological agents. Current treatment guidelines, such as the NCCN Guidelines in Oncology, often offer a range of options for management based not purely on labeled indications but also on available scientific evidence for all of the product categories outlined above.[1] Therefore, many cancer treatments are used by physicians off label.

As written, many of the proposed categories in the draft USP formulary guide do not contain any self-administered products. As an example, many future self-administered products are likely to fall within the proposed "Targeted Molecular Therapies" section. This section could therefore potentially cover several very distinct classes of targeted molecular therapies, which have very discreet targets, indications, lines of therapy, tumor types, potential combination uses and biomarker requirements for use.

Cancer products that have similar mechanisms of action frequently have very different indications not only by tumor type but also by stage of disease and recommended combination regimens. Unlike many other therapy areas, Oncology is often characterized by initial approvals often being gained as accelerated indications for niche or highly refractory patient groups. Subsequent development then often leads to an expansion to earlier lines of therapy, alternative combination protocols and different tumor types. There are often significant time gaps between this evidence being published and its incorporation into product labeling, compendia and practice and treatment guidelines.

Based on the points above, GSK has significant concerns that, with the currently proposed formulary and the proposed requirement that only two drugs of any one category need be covered by the PDPs, many Medicare beneficiaries who may benefit from cancer therapies will be discriminated against by being denied appropriate treatment options for the management of their Cancer.

GSK therefore recommends that the USP grant an exception for anti-cancer therapies including antineoplastics, hormones suppressants, immune suppressants and other immunological agents and permit an open formulary for all Cancer treatment options.

Reference:

1. NCCN/ACS Treatment Guidelines for Patients. National Comprehensive Cancer Network. 2004. http://www.nccn.org/professionals/physician_gls/f_guidelines.asp#site

J. Antiparkinson Agents – Therapeutic Category (No. 47)

GSK recommends expanding the Therapeutic Category defined as "Antiparkinson Agents" to "Antiparkinson and Movement Disorder Agents."

Movement disorders are neurological motor disturbances characterized by either abnormally increased motor activity or by abnormally decreased motor function or mobility. It is believed that Movement Disorders develop from an abnormally functioning basal ganglia, the portion of the brain deep in the cerebral hemispheres most responsible for the body's motor control.[1]

In the current USP draft guidelines, treatments for Parkinson's disease do not fully address Movement Disorders. Movement Disorders include but are not limited to Parkinson's Disease, Dystonia, Restless Legs Syndrome, Essential Tremor, Multiple System Atrophy (MSA), Progressive Supranuclear Palsy (PSP), Huntington's Disease, Tourette Syndrome, Ataxia, Tics, Rett Syndrome, Spasticity and Wilson Disease. This is consistent with Parkinson's Disease & Movement Disorders, Fourth Edition, Editors, Joseph J. Jankovich, M.D., and Eduardo Tolosa, M.D., Lippincott Williams & Wilkins, New York, 2002.

Clinicians who care for those afflicted with Parkinson's disease and other movement disorders need a broad array of pharmacologic agents to address the complexities of these conditions. If this category is not expanded to address movement disorders, Medicare beneficiaries will be disadvantaged from receiving the appropriate medications to treat these conditions.

Therefore, we recommend that USP expand the Antiparkinson Agents Therapeutic Category to "Antiparkinson and Movement Disorder Agents."

<u>Reference</u>:

1. Department of Neurology, Baylor College of Medicine, www.bcm.edu/neurol/struct/park/park/.html.

K. <u>Therapeutic Category: Antivirals, Pharmacologic Classes (Nos. 58-69):</u>

The proposed HIV pharmacologic classes should be removed from the antivirals therapeutic category. Limiting coverage and restricting access to HIV treatments jeopardizes the lives of HIV patients. This special population should be treated as such under Medicare Part D.

The standard of care in HIV is a minimum of three HIV drugs at any one time. Those three drugs are usually from only one or two pharmacologic classes at a given time[1]. Two drugs each from the proposed pharmacologic classes is contrary to the DHHS guidelines for HIV. In fact, specifying any limited number of agents in these classes is contrary to national treatment guidelines. For example, the vast majority of people on treatment for HIV are taking a "backbone" of two drugs from the nucleoside/nucleotide reverse transcriptase inhibitor category. Even though the drugs are in the same pharmaceutical class and have the same general mechanism of action, a specific mutation in the HIV virus may render some drugs in this class unusable, while others are highly effective. There are several of these specific mutations (or patterns of mutations) so it is not possible to single out two drugs that would be effective in all patients.[2]

Research and practice have shown that adherence to medication regimens is essential in HIV treatment [3]. In order to enable patient adherence to medication, HIV therapy must be individualized for the patient based on a number of issues, including:

- pill burden
- dosing frequency
- toxicities
- drug-drug interactions
- pregnancy
- co-morbid conditions
- level of HIV in the blood[4]

Creating HIV pharmacologic classifications in an effort to reduce costs will have the opposite effect, increasing adverse events for patients and costs for CMS. Reducing the number of classifications further increases CMS cost and put HIV beneficiaries' lives in danger.

Therefore, based on these reasons, GSK proposes that the proposed HIV pharmacologic classes should be removed from the antivirals therapeutic category.

References

1. US .Department of Health and Human Services Guidelines for HIV. 2004. http://www.dhhs.gov/diseases/index.shtml. Accessed on September 16, 2004 Page 13.

2. US .Department of Health and Human Services Guidelines for HIV. 2004. Page 13 http://www.dhhs.gov/diseases/index.shtml. Accessed on September 16, 2004. page 19.

3. Mylonakis, E, Paliou, M, Rich, JD. Plasma viral load testing in the management of HIV infection. American Family Physician , February 1, 2001. Available at http://www. aafp.org.afp/20010201/483.html. Accessed on September 16, 2004.

4. US .Department of Health and Human Services Guidelines for HIV. 2004. Page 13 http://www.dhhs.gov/diseases/index.shtml. Accessed on September 16, 2004. page 53 .

L. Bipolar Agents Therapeutic Category (No. 76)

GSK recommends adding two (2) pharmacologic class listings titled "Mania or Mixed Episodes" and "Bipolar Depression" to the therapeutic category titled "Bipolar Agents". Although not pharmacologic classes per se, the pharmacologic class listings recommended mirror the treatment categories used in the American Psychiatric Association (APA) Practice Guideline for the Treatment of Patients with Bipolar Disorder (April 2002 Revision).[1]

The current Draft Model Guidelines fail to recognize the distinct episodes of bipolar disorder, which include mania, depression and mixed episodes, as well as distinctions between acute and maintenance treatment. As written, the two agents that could be selected by a PDP may or may not provide adequate treatment for all types of bipolar episodes. For instance, the two selected agents may only treat acute mania and not adequately prevent recurrence of bipolar depression. This is recognized in the APA Practice Guideline which makes separate treatment recommendation for the different episodes of bipolar disorder. Accordingly, practitioners require access to a minimum of four therapeutic categories: antipsychotics, anticonvulsants, antidepressants and mood stabilizers (e.g., lithium) to adequately manage both the acute and long-term treatment of bipolar disorder, as well as the types of episodes.

The goal of short term treatment for bipolar disorder is to control acute symptoms and help a patient return to normal function. However, the goal of long term treatment is help prevent future relapse, reduce symptoms, including risk of suicide and improve a patient's general functioning. [2] Furthermore, as bipolar disorder is usually a long term illness, maintenance treatment presents a unique challenge. Agents used in the short term treatment of bipolar disorder are often used long term, despite limited evidence to support their use. Therefore, agents that have demonstrated safety and efficacy in long term treatment are of importance in the overall therapy of a patient with bipolar disorder.

The devastating consequences of bipolar disorder and the failure of a single agent to effectively treat all bipolar episodes require broad access to multiple medications. The current Model Guideline places Medicare part D patients at enormous risk for inadequate access to critical bipolar disorder medications. Furthermore, inappropriate drug selection can contribute to rapid cycling, a difficult to treat condition where patients experience four or more mood disturbances within a single year. In particular, there are suggestions that use of antidepressants in patients with bipolar disorder may contribute to rapid cycling.[1] Therefore, a clear distinction between bipolar depression and unipolar depression, for the purposes of treatment, is required.
[1]

In addition, a recent survey revealed that 69% of patients with bipolar disorder were misdiagnosed with major depression (60%), anxiety disorder (26%), schizophrenia (18%) and borderline personality disorder (17%). [3] The high rate of misdiagnoses, in addition to the reasons noted above, underscores the need to have bipolar agents as a therapeutic category.

Proposed Classification – Bipolar Agents

Reference Line	Therapeutic Category	Pharmacologic Class	Recommended Subdivisions
76	**Bipolar Agents**	**Mania or Mixed Episodes**	
77		**Bipolar Depression**	

Bipolar References
1.American Psychiatric Association. Practice guideline for the treatment of patients with bipolar disorder (revision). *Am J Psychiatry*. 2002;159(4 suppl):1-50.

2. American Psychiatric Association. Practice guideline for the treatment of patients with bipolar disorder (revision). *Am J Psychiatry*. 2002;159(4 suppl):30.

3. Hirshfeld RMA, Lewis L, Vornik LA. Perceptions and impact of bipolar disorder: how far have we really come? Results of the National Depressive and Manic-Depressive Association 2000 survey of individuals with bipolar disorder. *J Clin Psychiatry*. 2003;64:161-174.

M. Blood Glucose Regulating Agents Therapeutic Category:, Insulins Pharmacologic Class (No. 77) and Hypoglycemic Agents, Oral Pharmacologic Class (No.78)

The proposed pharmacologic classification "Hypoglycemic Agents, Oral" is inconsistent with appropriate treatment of diabetes recognized in peer-reviewed scientific literature and standard medical practice. Further, compliant formularies would allow discrimination against sicker Medicare beneficiaries. To resolve these problems with the proposed classifications, we strongly support redefining "recommended subdivisions" as "pharmacologic classes", thereby requiring formulary coverage for each class and assuring coverage for appropriate multiple medication use.

Type 2 Diabetes (T2D) is a progressive disease where glycemic control is lost over time regardless of the treatment used (e.g. diet, sulfonylureas, metformin or insulin). Recent studies have shown that approximately 64% of patients with Type 2 Diabetes are not at the American Diabetes Association (ADA) A1C goal of 7% or lower, therefore demonstrating the need for more intensive treatment strategies and broad access to available treatment options.[1] During the course of T2D treatment, physicians typically add therapies without dropping current therapies to meet escalating patient needs (from monotherapy to increasing use of oral polytherapy to oral polytherapy plus insulin).

This standard of practice is supported in the literature as demonstrated in the classic Turner paper from the landmark UK Prospective Diabetes Study (UKPDS), which observed outcomes for more than 4000 patients randomized to 'conventional' versus 'intensive' therapy over a ten year period. The study demonstrated that there is a progressive need for multiple therapies to control hyperglycemia (by 3 years approximately 50% of patients will need more than one agent, and by 9 years 75% of patients will need multiple agents to achieve A1C goals).[2] The amassing of compelling evidence such as this is increasingly challenging the previous slow addition of further hypoglycemic agents in favor of a more intensive stepwise treatment approach involving combination therapy.[3,4] The pathophysiology of T2D reveals complex metabolic defects that cause the disease which may explain the need for multiple medications. The importance of using multiple medications that target these defects (insulin resistance, defective pancreatic insulin secretion, hepatic glucose production etc) is also described by Inzucchi in JAMA.[5] The right combination must be driven by patient-specific criteria such as tolerability, contraindications etc. However, physicians have relatively few treatment options to treat type 2 diabetes, particularly since several therapies are poorly tolerated.[6,7]

Therefore, the proposed oral hypoglycemic classification, within the Draft Model Guidelines does not assure that the necessary variety of medications needed to target the multiple defects would be covered. Participating PDPs limiting the number of

therapies to two could thus discriminate against beneficiaries requiring polytherapy (particularly those unable to tolerate one or more of the covered agents).

This creates significant concerns, not only regarding access to quality care for those who need it most but also regarding potential escalation of costs. Diabetes cost the US an estimated $132 billion in medical expenditures and lost productivity.[8] The significant direct medical costs are driven by the costs of complications of the disease.[9] As demonstrated in two papers from Diabetes Care and JAMA, improved glycemic control is associated with significant cost savings.[10,11] Because the use of appropriate medications can reduce direct costs, limiting medication coverage for diabetes is likely to have a negative impact on total CMS expenditures. The ADA recognizes the staggering costs of direct medical care for diabetes (e.g., hospitalizations for complications) versus the much lower costs of medications (broken out by outpatient meds, insulins/injectables, oral antidiabetics) which could reduce those complications.[8]

Therefore, GSK recommends the following changes to the Model Guidelines.

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	*Recommended Subdivisions*
Blood Glucose Regulating Agents	Insulin: Rapid	
	Insulin: Short	
	Insulin: Intermediate	
	Insulin: Long	
	Alpha Glucosidase Inhibitors	
	Meglitinides	
	Biguanides	
	Sulphonylureas	
	Thiazolidinediones	

We will also be proposing to CMS that diabetes be considered a special population under Medicare Part D regulations.

References:

1. Koro, CE, Bowlin, SJ, Bourgeois, N, et al. Glycemic control from 1988-2000 among U.S. adults diagnosed with type 2 diabetes. *Diabetes Care*. 2004; 27:17-20.
2. Turner, RC, Cull, CA, Frighi, V, et al. Glycemic control with diet, sulfonylurea, metformin, or insulin in patients with type 2 diabetes mellitus. *JAMA*. 1999; 1:2005-2012.
3. Gerich, EJ. Redefining the clinical management of type 2 diabetes: matching therapy to pathophysiology. *Eur J Clin Invest*. 2002 Jun; 32 Suppl 3:46-53.
4. Nathan, DM. Clinical practice. Initial management of glycemia in type 2 diabetes mellitus. *N Engl J Med*. 2002 Oct 24; 347(17):1342-9.
5. Inzzucchi, SE. Oral antihyperglycemic therapy for type 2 diabetes. *JAMA*.2002; 287; 360-372.
6. Harrower, AD. Comparative tolerability of sulphonylureas in diabetes mellitus. *Drug Safety*. 2000, 22; 313-320.
7. Kirpichnikov D, McFarlane, SI, Soweres, JR. Metformin: an update. *Annals of Internal Medicine*.2002; 137; 25-33.
8. HoganP, Dall T, Nikolov P et al. Economic Costs of Diabetes in the US in 2002. *Diabetes Care*. 2003;26: 917-932.
9. Gilmer, TP, O'Connor, PJ, Manning, WG, Rush, WA. The cost to health plans of poor glycemic control. *Diabetes Care*. 1997; 20; 1847-1853.
10. Wagner, EH, Sandhu, N, Newton, KM, et al. Effect of improved glycemic control on health care costs and utilization. *JAMA*. 2001; 285;182-189.
11. Menzen, J, Langley-Hawthorne, C, Friedman, M, et al. Potential short-term economic benefits of improved glycemic control. *Diabetes Care*. 2001; 24; 51-55.

N. Therapeutic Category: Blood Products/Modifiers/Volume Expanders

Pharmacologic Classes: Blood formation and Anitcoagulants (80-84)

GSK recommends adding three (3) pharmacologic class listings titled "Agent for Anemia", "Agent for Neutropenia", "Agent for Thrombocytopenia and Other" to the Therapeutic Category titled "Blood Products/Modifiers/ Volume Expanders". The current category of Colony Stimulating Factors is too broad and excludes several current products by definition.

In addition, GSK recommends the pharmacologic class of Anticoagulants should be updated to be consistent with The Seventh 2003 ACCP (American College of Chest Physicians) Guidelines on Antithrombotic Therapy and Thrombolytic Therapy scheduled for release on September 24, 2004. At least one covered drug from the six subdivisions of anticoagulants must be included as they cover distinct mechanisms of action.

Proposed Classification

Reference Line	**Therapeutic Category**	**Pharmacologic Class**	**Recommended Subdivisions**
81	Blood Products/Modifiers/ Volume Expanders	Agent for Anemia	
		Agent for Neutropenia	
		Agent for Thrombocytopenia and Other	
Reference Line	**Therapeutic Category**	**Pharmacologic Class**	**Recommended Subdivisions**
82	Blood Products/Modifiers/ Volume Expanders	Anticoagulants	Heparin, Unfractionated
			Heparin, Low Molecular Weight
			Direct Thrombin Inhibitors
			Factor Xa Inhibitors
			Vitamin K Antagonists

			Thrombolytic Agents

O. Cardiovascular Medicines Therapeutic Category, Beta-Blockers/Related Pharmacologic Class with Recommended Subdivisions of Nonselective, Cardioselective, and Alpha-beta Blockers.

Because of the unique properties and clinical benefits of the classes listed in the Beta-blocker "recommended subdivisions," we recommend that the USP Model Guidelines Pharmacologic Classification for Beta-Blockers/Related be changed to list Nonselective, Cardioselective, and Alpha-beta Blockers as unique pharmacologic classifications.

Beta-blockers are currently used for a broad spectrum of cardiovascular diseases (i.e. hypertension, angina pectoris, antiarrhythmics, hypertropic subaortic stenosis, left ventricular dysfunction following myocardial infarction, and mild to severe heart failure of ischemic or cardiomypatic origin, plus other non-cardiovascular applications). The current proposed classification suggests there is no significant difference among the three subdivisions and that there is, in essence, a class effect for all agents for all applications. The UCLA Heart Failure Clinical Practice Guidelines, however, recognize the differences among these classes, as evidenced in the following quote:

> "The ACC/AHA guidelines recommend using only those beta-blockers and those doses that have been proven to reduce mortality (i.e., mortality reduction is not a class effect)." [1]

Not all beta-blockers have been proven to reduce mortality in patients with Class I-IV heart failure, and not all of those have been proven to work across the entire spectrum of disease.

Similar arguments can also be made for use of beta blockers in diabetics. In diabetics, heart disease is a frequent complication with significant mortality and morbidity. Because of the impact on glycemic control, those beta-blockers that have a neutral effect on glycemic control should be explicitly covered. Older beta generation beta blockers, i.e., the non-selective, may have an adverse detrimental effect on glycemic control. The American Diabetes Association (ADA) 2004 Clinical Practice Recommendations reinforces the differences in beta blockers as exemplified in the following :

> "Utilization of β-blockade, ACE inhibitors, or possibly angiotensin receptor blockers is essential in preventing remodeling with its associated decline in ventricular function. Beta-Blockers not only prevent, but may also reverse, cardiac remodeling. Glycemic control may also play an important role in the

> therapy of diabetic HF. The adverse metabolic side effects that have been associated with β-adrenergic inhibitors in the diabetic patient may be circumvented by use of a third-generation β-Blocker. Prophylactic utilization of ACE inhibitors and β-Blockers to avoid rather than await, the need to treat high-risk diabetic patients."[2]

The alpha-beta-blocker subdivision is recognized as a third-generation beta blocker.

Because of the unique properties that alpha-beta-blockers have beyond just beta blocker effect, alpha-beta blockers do not belong in the beta blocker class as a subdivision. The addition of alpha-blockade to beta-blockade creates more complete adrenergic effects and additional ancillary pharmacologic properties which may include antioxidant, antiapoptotic, antiproliferative, electrophysiologic and metabolic effects. These unique effects differentiates alpha-beta-blockers from traditional beta blocker, warranting a separate pharmacologic classification. Although an argument could be made to simply put the alpha-beta blockers in a distinct class without placing the beta blockers in separate classes, we recommend that all three be listed as separate due their uniqueness and the lack of class effect

Therapeutic Category	**Pharmacologic Class**	**Recommended Subdivisions**
Cardiovascular	Nonselective Beta Blocker	
	Cardioselective Beta Blocker	
	Alpha-beta Blockers	

References:

1. UCLA Heart Failure Clinical Practice Guidelines-2003

2. Reference in support of the ADA 2004 Clinical Practice Recommendations: Diabetes Care 26:2433-2441, 2003; "Heart Failure – The frequent, forgotten, and often fatal complication of diabetes"; ADA

P. Gastrointestinal Medications Therapeutic Category, New Pharmacologic Class

The term "opioid antagonist" in the current subdivision of antidotes has become outdated and should be changed to specify "centrally acting opioid antagonists." A new opioid antagonist pharmacologic classification "peripherally acting opioid agonist" should be added to the Gastrointestinal Medications section for differentiation.

The new class of agent is peri registration for the treatment of Post Operative Ileus and under development for other Gastrointestinal conditions. The two distinct mechanisms of action and clearly different potential indications should be differentiated in the USP model guidelines.

Therefore, GSK recommends the following addition to the Draft Model Guidelines.

Therapeutic Category	Pharmacologic Classification	Recommended Subdivisions
Gastrointestinal Medications	Peripherally Acting Opioid Antagonist	

Q. Genitourinary Medicines Therapeutic Category; Benign Prostatic Hyperplasia (BPH) Agents Pharmacologic Class (No. 114)

The proposed BPH Pharmacologic Class is inconsistent with nationally recognized BPH treatment guidelines. The AUA guidelines specify two types of medications with distinct mechanisms of action and recommend using both types of agents for some patients. The proposed classifications do not assure access to appropriate medications for men with BPH because plans could choose any two medications and not at least one from each class.

To be consistent with recognized practice guidelines, GSK recommends changes to the BPH pharmacologic class which include a subdivision for alpha-blockers and a subdivision for 5ARIs. Because the recommended treatment for BPH includes both treatment of the underlying disease along with reduction in urinary retention and BPH related surgery, both of these subdivisions should have at least one covered drug.

Benign prostatic hyperplasia (BPH) is a progressive disease where the prostate continues to enlarge over time. The prevalence is age dependent, beginning usually after age 40; by age 60, prevalence is greater than 50%, and by age 85, as high as 90%[1]. Treatment is based on severity of symptoms and is directed to reduce prostate size through specific drug therapy or surgery (TURP or prostatectomy). The current pharmacological treatment options for lower urinary tract symptoms (LUTS) secondary to BPH include α-blockers and 5α-reductase inhibitors or 5ARIs. Alpha-blockers are recognized as appropriate therapy for prostatic enlargement and are used for relief of symptoms as well as prevention of disease progression. 5ARIs are effective for symptoms associated with prostatic enlargement, prevent disease progression and reduce the risk of acute urinary retention and the need for BPH-related surgery. Combination therapy, utilizing both 5ARIs with an alpha-blocker, appears to be more effective than alpha-blocker monotherapy in reducing the likelihood of acute urinary retention and surgery.[1,2,3,4] The European Urological Association (EUA) 2004 guidelines are consistent with the AUA guidelines[2].

With a higher prevalence of BPH in men over 65, it is especially important to assure access to appropriate medications. Left untreated, 1 in 6 patients with an enlarged prostate and symptoms may experience acute urinary retention or BPH related surgery over a 4-year time period[5].

For these reasons GSK recommends the following changes to the Model Guidelines.

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	Recommended Subdivisions
Genitourinary Medications	BPH Agents	*Alpha-blockers*
		5α-Reductase Inhibitors

References:

1. American Urological Association (AUA) Guideline on management of benign prostatic hyperplasia. 2003. Chapter 1: Diagnosis and treatment recommendations. The Journal of Urology, 170; 530-547.

2. European Urological Association (EUA) Guidelines on benign prostatic hyperplasia (Update 2004). Available at http://www.uroweb.nl/files/uploaded_files/guidelines/BPH_August_2004.pdf. Accessed September 15, 2004.

3. Barkin, J, Guimaraes, B, Jacobi, G, et al. 2003. Alpha-blocker therapy can be withdrawn in the majority of men following initial combination therapy with the dual 5ά-reductase inhibitor dutasteride. European Urology, 44; 461-466.

4. McConnell, JD, Roehrborn, CG, Bautista, OM. 2003. The long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. N Engl J Med, 2003;349; 2387-2398.

5. Debruyne, F Barkin, J, van Erps, P, et al. 2004. Efficacy and safety of long-term treatment with the dual 5ά-reductase inhibitor dutasteride in men with symptomatic benign prostatic hyperplasia. European Urology, 46:488-495.

R. Immunological Agents Therapeutic Category (No. 125)

The proposed Model Guidelines consider vaccines to be a recommended subdivision of the Immune Stimulants Pharmacologic Class, Immunological Agents Therapeutic Category.

While a plan may choose not to provide immunization to Medicare beneficiaries, it is in the interest of public health and the health of individuals to facilitate the ability of PDPs and MA-PDs to choose to provide immunizations. This would be consistent not only with the health of individuals but also consistent with overall public health objectives.

For this reason, GSK recommends that the USP establish Vaccines as a Therapeutic Category (stating that this category may not need to be populated as part of the Part D "safe harbor" standard) and establish a number of Pharmacological Classes, each with a disease that can be prevented by vaccines. Each disease has a specific vaccine, and these vaccines are not interchangeable in the same way as may be the case with other products with similar mechanisms of action.

Some adult immunizations are already provided under Medicare Part B (e.g., influenza, pneumococcal, hepatitis B to select populations). However, senior adults may need immunizations that are not currently covered by Part B. For example, Healthy People 2010 includes an objective of reducing levels of hepatitis A from the 1997 baseline of 11.3 new cases per 100,000 people to 4.5 new cases per 100,000 by 2010.[1] One of the strategies is to target high risk adults over age 40. The availability of hepatitis A vaccine from a plan offering a Part D benefit would make it easier to meet that objective. In addition, Healthy People 2010 contains an objective to reduce cases of Hepatitis B from the 1997 baseline of 15.0 cases per 100,000 to 3.8 cases per 100,000 by 2010.[1] Universal immunization of children will go a long way to reaching that objective, but there are many seniors outside of the traditional high risk groups currently eligible for Medicare covered hepatitis B immunization who have never been immunized. This additional population may still be at risk because hepatitis B is a blood-borne pathogen that may be contracted in a variety of circumstances. In fact, hepatitis B is easier to contract than HIV. Another category of beneficiaries who should be vaccinated, according to the CDC, are travelers to selected countries.

For these reasons, GSK requests that the following Pharmacologic Classes be considered for inclusion in the Immunological Agents Therapeutic Category:

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	*Recommended Subdivisions*
Immunological Agents	Tetanus-Diphtheria Vaccine	
	Influenza (Flu) Vaccine	
	Pneumococcal Vaccine	
	Hepatitis B Vaccine	
	Hepatitis A Vaccine	
	Hepatitis A and B Vaccine	
	Measles-Mumps-Rubella (MMR) Vaccine	
	Varicella (chickenpox) Vaccine	
	Polio Vaccine	
	Yellow Fever Vaccine	
	Typhoid Vaccine	

Reference:

1. Healthy People 2010. 14 Immunization and Infectious Diseases. Available at www.healthypeople.gov/Document/HTML/Volume1/14Immunization.htm

S. Hormones, Stimulant/Replacement – Therapeutic Category (No. 117)

GSK recommends adding one (1) new therapeutic category entitled "Bone Affecting Agents, Bone Resorption Inhibitors/Bone Formation Agents. Such a therapeutic category is consistent with how bisphosphonates are categorized in two of the official pharmaceutical compendia, the USPDI and the American Hospital Formulary Service (AHFS).

In the current draft guidelines, treatments for osteoporosis are lumped into an overly broad category of "Hormones, Stimulants/Replacements" that includes treatments for thyroid disorders, sexual dysfunction, menopausal symptoms, pituitary and other disorders. This therapeutic category is inappropriate for bisphosphonates used for the treatment and prevention of osteoporosis, as bisphosphonates are neither hormone stimulants nor hormone replacements.

Osteoporosis, which means "porous bones," is a condition of excessive skeletal fragility resulting in bones that break easily. According to the National Osteoporosis Foundation (NOF), osteoporosis and osteopenia (low bone mass) affect an estimated 44 million American women and men age 50 and over. This number is expected to rise to more than 52 million by 2010.

Osteoporosis is the primary cause of hip fracture, which can lead to permanent disability, loss of independence and sometimes even death. Collapsing spinal vertebrae can produce stooped posture and a "dowager's hump," resulting in loss of height and severe back pain. Osteoporosis leads to 1.5 million fractures per year, mostly in the hip, spine and wrist. According to the National Institutes of Health (NIH), one in two women and one in four men older than 50 will suffer a vertebral fracture, and the annual cost of treatment is estimated at $17 billion and rising. These numbers are only expected to rise as the U.S. population ages.

Osteoporosis, if not prevented or appropriately treated, is costly to the Medicare program. According to one estimate, Medicare pays for about 75% of hospital costs associated with osteoporosis-related admissions among adults age 45 and older. [1]

Although some bone loss is expected as people age, osteoporosis is no longer viewed as inevitable. Diagnosis and treatment may begin before bones break, delaying the disease's onset and diminishing its severity. Most important, early intervention can prevent devastating fractures.

Given the importance of this disease to the Medicare population, and the need for flexibility in addressing the needs of both the healthy and frail elderly in terms of co-morbidities, drug-drug interactions and other parameters of patient care, we recommend that USP create a separate therapeutic category for these agents

designated as "Bone Affecting Agents, Bone Resorption Inhibitors/Bone Formation Agents."

Such a therapeutic category is consistent with how bisphosphonates are categorized in two of the official pharmaceutical compendia, the USPDI and the American Hospital Formulary Service (AHFS). The USPDI lists bisphosphonates (and raloxifene) as "category: bone resorption inhibitors." Additionally, the AHFS includes bisphosphonates under section 92:00, Unclassified Therapeutic Agents, recognizing that an appropriate pharmacologic-therapeutic category does not exist in their classification system. AHFS *does* have a category for hormones (68:00 Hormones and Synthetic Substitutes, which, like the USP draft guidelines, includes the subcategories of adrenals, pituitary, thyroid, estrogens, and others), but does not include bisphosphonates in the same category.

We further recommend that the pharmacologic classes within the new therapeutic category be designated as follows: Bone Resorption Inhibitors - Bisphosphonates, Bone Resorption Inhibitors – Hormone/Hormone-like, Bone Resorption Agents – Other, Bone Formation Agents – Parathyroid Hormones.

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	Recommended Subdivisions
Bone Affecting Agents, Bone Resorption Inhibitors/Bone Formation Agents	Bone Resorption Inhibitors - Bisphosphonates	
	Bone Resorption Inhibitors – Hormone/Hormone-like	
	Bone Resorption Agents – Other	
	Bone Formation Agents – Parathyroid Hormones	

If USP does not wish to place osteoporosis drugs in their own category, we recommend at a minimum that the category 118 be expanded and renamed "Hormone/Hormone Antagonist/Hormone Substitutes/ Bone Affecting Agents/Bone Resorption Inhibitors/Bone Formation Agents" to account for the broad range of treatments covered in this category and to appropriately characterize the osteoporosis agents as pharmacologic classes within the category. (We note that as a general matter, the term "Hormone, Hormone Antagonist and Hormone Substitutes" is more consistent

with the standard nomenclature used in Medical Subject Headings.) We further recommend that the pharmacologic classes named above be included in such category.

Reference:

1. Testimony before the USP of the National Osteoporosis Foundation, the American Society for Bone and Mineral Research and the International Society for clinical Densitometry, August 27, 2004, citing Max W, Sinnot P, Kao C, Sung HY, Ride DP. The burden of osteoporosis in California, 1998. Osteoporos Int. 2002; 13(6): 493-500.

T. Respiratory Tract Medications Therapeutic Category Pharmacologic Classes: Antiasthma/Antileucotrienes (No. 136) Antiasthma/Bronchodilators (No. 137), Antiasthma Agents, other (No. 138), Mast Cell Stabilizers (No. 139), Mucolytics (No. 140) and Respiratory Tract Medications, Other (No. 141)

As currently constructed, the pharmacologic classes and subdivisions of the Respiratory Tract Medications Category proposed by USP present the available pharmacologic agents in a manner that is inconsistent with their mechanism of action, inconsistent with recommendations of evidence-based, nationally accepted practice guidelines [1,2,3] and inconsistent with accepted clinical practice for treating asthma and COPD.

GSK recommends that the proposed Respiratory Tract Medications Category pharmacologic classifications and subdivisions be replaced with the following classes (no subdivisions; alphabetic order):

- **Anticholinergics**
- **Beta-agonists – long acting**
- **Beta-agonists – short acting**
- **Inhaled Corticosteroids**
- **Leukotriene Modifiers**
- **Mucolytics**
- **Respiratory Tract Medication – other**

The proposed USP classification for Respiratory Tract Medications compresses three different classes of medications, the short acting beta-agonist (SABA), inhaled corticosteroids (ICS) and long-acting beta-agonists (LABA) into a single artificial grouping that doesn't reflect their differing mechanisms of action, guideline recommendations or standard clinical practice. Accordingly, the proposed structure creates potential for therapy for Medicare patients that is both inconsistent with national guidelines and inadequate to control disease.

Note: Because Mast Cell Stabilizers are rarely used in practice, USP should consider dropping them as pharmacologic classifications or consider them part of the "other" classification.

GSK is also concerned that the proposed Respiratory Tract Category and associated pharmacologic classes emphasize "anti-asthma" therapies and do not adequately address the different treatment options necessary for Medicare beneficiaries with COPD.

Revising the Respiratory Tract pharmacologic classes as outlined above creates a close alignment with long-standing treatment guidelines and clinical practice standards and should thus help ensure access to appropriate treatment options for Medicare patients with asthma and COPD.

Regarding asthma, the NIH/NHLBI guidelines indicate that patients with persistent asthma require at least two types of medication. Specifically, the guidelines state:

> "All patients need to have a short acting-inhaled beta2-agonist (SABA) to take as needed for symptoms. Patients with mild, moderate or severe persistent asthma require daily long-term-control medication to control their asthma (page 9)." Further, patients with moderate persistent asthma may need and patients with severe persistent asthma should have a long acting inhaled beta2-agonist in addition to the short acting beta2-agonist and a controller medication (page 11). [4]

Current clinical practice for asthma reflects the guidelines in that most treated asthma patients are managed with multiple medications. Market databases show that while a small portion of asthma patients (~20%) are managed with SABA alone, the vast majority of patients with asthma (~80%) require multiple medications to control their disease. [5]

COPD is a distinct, complex, multi-component disease characterized by airflow limitation that is not fully reversible. There are specific ICD-9 codes, nationally and internationally recognized guidelines [2,3] and treatment recommendations specifically for COPD.

The guidelines indicate that appropriate treatment for COPD often includes simultaneous use of multiple medications. Specifically, Celli B, MacNee W, et al. in *Standards for the Diagnosis and Treatment of Patients with COPD: a Summary of the ATS/ERS Position Paper* [3] state that:

- Combining different therapeutic agents produces a greater change in lung function and symptoms than single agents alone.
- Data from trials combining long-acting inhaled beta-agonists and inhaled corticosteroids show a significant additional effect on pulmonary function and a reduction in symptoms in those receiving combination therapy compared with its components.
- The largest effects in terms of exacerbations and health status are seen in patients with an FEV1<50% predicted, where combining treatment is clearly better than either component alone.

Again, as with asthma, the norm for treatment of COPD in clinical practice includes the use of multiple medications. Market databases show that nearly 90% of patients currently being treated for COPD receive more than one class of medication.

GSK proposes the following changes to the Model Guidelines:

THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	*Recommended Subdivisions*
Respiratory Tract Medications	Anticholinergics	none
	Beta-agonists – long acting	
	Beta-agonists – short acting	
	Inhaled Corticosteroids	
	Leukotriene Modifiers	
	Mucolytics	
	Respiratory Tract Medication – other	

References:

1. National Institutes of Health National Heart Lung and Blood Institute. National Asthma Education and Prevention Program. Executive summary of the NAEPP expert panel report. Guidelines for the diagnosis and management of asthma- update on selected topics 2002. NIH Publication No. 02-5075. June 2002.

2. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: Executive Summary—Updated 2003. Bethesda, Md: NIH, NHLBI; 2003.

3. Celli B, MacNee W, et al. Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. Eur Respir J 2004;23:932-946

4. National Institutes of Health National Heart Lung and Blood Institute. National Asthma Education and Prevention Program. Executive summary of the NAEPP expert panel report. Guidelines for the diagnosis and management of asthma- update on selected topics 2002. NIH Publication No. 02-5075. June 2002.

5. Surveillance Data, Incorporated (SDI), June 2004.

III. Need for New Categories or Classes

In addition to the above revisions to the groupings in the Draft Guidelines, we believe that a number of products were missed in USP's creation of these groupings. Below we identify these omissions and provide suggested categories or classes for each.

A. Obesity Therapeutic Category

Obesity is associated with diabetes, coronary heart disease and hypertension. Because of the impact of these diseases for the elderly population especially, obesity treatments should be included as a therapeutic class in the Model Guidelines.

Obesity has been shown to increase the risk of developing diabetes, and conversely, interventional data has shown that weight management medications can effectively prevent diabetes.[1] Also, the American Heart Association (AHA) has classified obesity as a modifiable risk factor for coronary heart disease. Risk estimates from population studies suggest that >=75% of hypertension can be directly attributed to obesity. Obesity has a strong effect on lipoprotein metabolism, regardless of ethnic group. Increased weight is a determinant of higher levels of triglycerides, elevated LDL-C and low HDL-C. Conversely, weight loss is associated with a healthier lipoprotein profile in both men and women: triglycerides decrease, HDL-C increases and LDL-C decreases. [2,3,4,5,6]

Therefore, GSK requests that the following changes be made to the Model Guidelines:

THERAPEUTIC CATEGORY	**PHARMACOLOGIC CLASS**	***Recommended Subdivisions***
Obesity	**Centrally Acting**	*Sympathomametic*
		Non –sympathomametic
	Peripherally Acting	*Digestive Inhibitors*
	Hormonal Manipulation	

These proposed classes are drawn from the categories identified for the pharmacotherapy treatment of obesity by the National Institutes of Health (The Practical Guide. Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. Available at http://www.nhlbi.nih.gov/guidelines/obesity/prctgd_b.pdf . Accessed September 15, 2004.) and the American Academy of Family Physicians (Drug Therapy for Obesity. http://www.aafp.org/afp/20000401/2131.html. Accessed September 15, 2004.)

References:

1. The XENDOS trial (Diabetes Care 27:155-161, 2004).

2. American Heart Association conference entitled "Obesity: Impact on Cardiovascular Disease" was held May 22-24, 1998, http://www.americanheart.org/presenter.jhtml?identifier=1818

3. Risk Stratification of Obesity as a Coronary Risk Factor. American Journal of Cardiology 2002;90:697-701

4. Risk Stratification of Obesity as a Coronary Risk Factor. American Journal of Cardiology 2002;90:697-701

5. Obesity Is Independently Associated With Coronary Endothelial Dysfunction in Patients with Normal or Mildly Diseased Coronary Arteries. J Amer Coll Cardiol 2001;37:1523-8

6. The Relationship of Obesity and the Development of Coronary Heart Disease to Longitudinal Changes in Systolic Blood Pressure. Coll. Antropol 1998;22(2):333-344.

A. **Addition of Future New Therapeutic Categories and Pharmacologic Classes**

Critical to these processes is that the USP remain aware of newly approved drugs, new indications and other clinical developments that would warrant prompt revision to categories and classes in the Model Guidelines, and that all pertinent information is obtained by USP. The Statute assigns USP the function of adding new categories and classes to the Model Guidelines. The preamble to the Part D rules states that "the USP will revise its classification system periodically to reflect changes in therapeutic uses of covered Part D drugs and any additions of new covered Part D drugs." 69 Fed Reg 46660. According to the USP Web site, the Cooperative Agreement provides that the Guidelines will need to be revised over time, based on new information (such as therapeutic uses) about existing drugs and FDA approval of new drugs. In addition to establishing a mechanism for its own review of the Model Guidelines, we also recommend that USP establish a mechanism by which any interested member of the public (*e.g.*, patient groups, physicians, and manufacturers) can submit information to USP to identify a potential need for revision to the Model Guidelines. This mechanism should ensure that information related to newly approved drugs is easily identified so that the expedited process for such requests discussed above can commence immediately. Moreover, consistent with the USP's commitment to an open and public process, we believe that as issues are raised for consideration, the USP should use its Web site to publicize the consideration of such issues so that the public can submit information that it believes relevant to any such issues. In GSK's view, these processes and the involvement of the public will help ensure that the Model Guidelines remain current and thus continue to ensure that beneficiaries have access to a meaningful range of therapies.

CONCLUSION

GSK appreciates the opportunity to comment on the Draft Guidelines, and we recognize the extensive efforts of the USP in the development of the Model Guidelines. Yet, we believe considerable work remains in finalizing the guidelines so that they serve their intended purpose – the identification of categories and classes that, if followed by a PDP plan, will ensure that beneficiaries can enroll in the plan and have access to the drugs they need. While making all of the subdivisions in the Draft Guidelines categories or classes would be a positive step towards reaching this goal, as described above, certain changes also must be made to the categories, classes and subdivisions. Moreover, additional categories or classes must be developed to address products that seemingly were overlooked in the development of the Draft Guidelines. Please feel free to contact Debbie Fritz, PhD., at (919) 483-2191 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Dean Hakanson, MD
Vice-President
GlaxoSmithKline

CMS-4068-P-1219

Submitter : Miss. Binita Patel **Date & Time:** 10/04/2004 08:10:44

Organization : UNC- Chapel Hill

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I am currently a 3rd year PharmD student at the University of North Carolina at Chapel Hill. I am concerned about the proposed regulation that allows plans to establish preferred and non-preferred pharmacies. If this occurs, my role as a pharmacist will not be what I have spent the past three years working towards. I joined this profession because its core value of being able to help patients. If patients are forced to go to other places to receive their medications, I will not be about to fulfill my duties as a pharmacist. At UNC, our academic focus has been on the patient. If you decide to implement this law, then we will not be able to practice.

Also, patients with two more chronic diseases and two or more drugs should qualify for medication therapy management services. A pharmacist can offer so much knowledge to patients in regards to medication management. Everyday, patients use their medications incorrectly causing harm to them. If pharmacists were there to intervene, we could eliminate such problems. Certain disease states can be very well managed if there was adequate knowledge by the patient.

Thank you for considering my view.

Binita Patel

CMS-4068-P-1220

Submitter : Dr. Clifford Wong **Date & Time:** 10/04/2004 08:10:00

Organization : MedImpact Healthcare Systems, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Part III: Collection of Information Requirements
Recommendations in the area are:
* Where ever possible, use the standards developed and adopted by HIPAA or other regulating entities. Examples are: NCPDP 5.1 transmission, X12 standards (270/271, 834, 835, etc.).
* If the standard record formats do not meet Part D requirements, then the recommendation is to interface with the appropriate sub-groups to begin modifications once data requirements are known.
* Utilize the current Drug Discount Card standards if possible, since many systems have been programmed for these record formats. This includes enrollment application information, Request/Response records to CMS for eligibility verificiation, disenrollment, etc.

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

See attachment for comments

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

See attachment for comments

Issues 11-20

FALLBACK PLANS

See attachment for comments

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

See attachment for comments.

CMS-4068-P-1220-Attach-4.doc

CMS-4068-P-1220-Attach-3.doc

CMS-4068-P-1220-Attach-2.doc

CMS-4068-P-1220-Attach-1.doc

CMS-4068-P-1220-Attach-1.doc

CMS-4068-P-1220-Attach-2.doc

CMS-4068-P-1220-Attach-4.doc

CMS-4068-P-1220-Attach-3.doc

CMS-4068-P-1220-Attach-4.doc

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CMS-4068-P-1220-Attach-2.doc

CMS-4068-P-1220-Attach-1.doc

CMS-4068-P-1220-Attach-3.doc

MedImpact Healthcare Systems Inc, Comments for
Medicare Prescription Drug Benefit Proposed Rules Review: File Code CMS-4068 P

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

Summary: We are required to implement population based drug utilization management and quality assurance programs as well as targeted medication therapy management programs for individual patients. We may already have some of these programs in place, but will need to develop new programs and processes to meet this requirement. We will be required to submit data to an independent Quality Improvement Organization for the purpose of monitoring. Sponsors are encouraged to use electronic prescribing and physician incentives are included. We are required to be accredited as a PDP sponsor.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans		
FR Page #	***Excerpt***	***Comment/Question***
46667 D.2.	*"Cost & Utilization Management, QA, MTM, Programs to control fraud, abuse, and waste.* "…drug utilization management and quality assurance systems are generally considered to be population based while medication therapy management involves targeted, direct patient care.	

MedImpact Healthcare Systems Inc, Comments for
Medicare Prescription Drug Benefit Proposed Rules Review: File Code CMS-4068 P

46667	*P&T Committee oversight of cost-effective drug utilization management programs* "We believe that a cost-effective drug utilization management program could also employ the use of prior authorization, step therapy, tiered cost-sharing, and other tools to manage utilization" "Although we have not included proposed regulations, we are considering in the final rule a requirement that these tools should be under the direction and oversight of a Pharmacy and Therapeutics Committee to ensure an appropriate balance between clinical efficacy and cost effectiveness."	1. MedImpact's comment speaks to optimizing the use of the noted tools provided by PBMs to supporting MA PD or PDPs in their efforts to provide a quality, affordable, and accessible drug benefit. CMS rules must allow PBMs to exercise and use all available tools at their disposal to help manage the quality and cost of providing drug benefits to large populations. Benefit design strategies allowing actuarially equivalent products need to be considered and modeled with a creative intent based upon a societal mission to serve our elderly population. P & T committees provide quality oversight in the arena of drug therapeutics and selection based upon scientific evidence. It is our belief that P & T selects the best available clinical products and then supports the efforts of the PBM team to effectively design the benefit structures to administer affordability and accessibility. The fundamental guiding principle in the regulation is to provide actuarial equivalence to assure equivalent financial value to the beneficiary. The primary role of P & T remains to assure QUALITY while the AFFORDABILITY and ACCESSIBILITY of the drug benefit is achieved by a team consisting of pharmacists, actuaries, benefits experts, I.T. designers, and many others. We do not believe that there is a need for language requiring P & T oversight over the broad operations of a PBM. The Chief Medical Officer exercises that critical oversight role in assuring that corporate philosophy balances clinical quality with fiscal responsibility. 2. We would further note that "quality" includes the principles of safety and efficacy. Thus P & T has an expansive role and responsibility in this stead whereas benefits design and systems management to administer a benefits design is clearly in a different arena requiring support from actuaries, I.T. analysts, finance experts, actuaries, and of course pharmacists. We do not see where the limited time resources of a physician led team needs to provide direct oversight in the operations and technology arena.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans		
FR Page #	***Excerpt***	***Comment/Question***
	P&T Committee oversight of cost-effective drug utilization management programs *(Continued)*	I would recommend that we emphasis that the P&T Committee focus not only on Quality, but the evaluation of the Safety and Efficacy of the drug products available under a defined program. The benefit strategies are uniquely different from P&T activities of product review and recommendations and your point carries this message out. If this is helpful, attached are some excerpts from the current P&T charter: Committee description: A committee shall exist at MedImpact Healthcare Systems that will be the policy recommending body to MedImpact administration and the Health Services staff and the administration, pharmacy and related benefit administration departments of client health care organizations and plans on matters related to the therapeutic use of drugs. This committee shall be called the Pharmacy & Therapeutics Committee ("Committee"). To serve in an advisory capacity to MedImpact administration and to the medical, health care and related benefit professionals of MedImpact clients on matters pertaining to the use of drugs, including recommendations on the coverage for specific drug therapies.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans		
FR Page #	***Excerpt***	***Comment/Question***
	P&T Committee oversight of cost-effective drug utilization management programs *(Continued)*	Committee scope: • To recommend therapeutic designations and appropriate prescribing guidelines to assist with the placement of products on Drug Formulary(ies) acceptable for use in the ambulatory care setting and provide for ongoing constant revision. • To initiate or direct recommended Drug Use Review (DUR) and Drug Use Evaluation (DUE) programs. • To advise MedImpact Healthcare Systems on suitable educational programs and make recommendations in the implementation of effective drug control procedures. • To document such formulary or drug use functions that are used by MedImpact or delegated to it by clients.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans		
FR Page #	***Excerpt***	***Comment/Question***
46667	*Notice to members about cost-effective drug utilization management programs* "In addition, appropriate drug utilization management programs would have policies and systems in place to assist in preventing overutilization and underutilization of prescribed medications. PDP sponsors and MA Organizations offering MA-PD plans must inform enrollees of program requirements and procedures in order to prevent unintended interruptions in drug therapy. For example, enrollees would be made aware of how to proceed if special circumstances require their prescriptions be refilled before the targeted refill date."	1. PBM systems can detect and prevent early refills based upon protocols established by MCO, MA plans. We are not clear as to what special circumstance would require prescriptions to be filled BEFORE the targeted refill date. Patients have access to a vast network of over 50,000 pharmacies and can have refills completed on virtually any given day. Our sophisticated systems in combination with that of the chain retail pharmacies provide virtual access. Patients on specialty or unique prescription items definitely have to plan their prescription needs more carefully. We believe that enrollees and their care givers have accountability to manage their care and to plan accordingly .
46667 D.2.b	*Quality assurance requirements and the Omnibus Reconciliation Act of 1990* "We are proposing the quality assurance programs include requirements for drug utilization review, patient counseling, and patient information record keeping. We believe that these requirements would generally need to comply with section 4401 of the Omnibus Reconciliation Act of 1990 as codified in 42 CFR 456.705 and section 1927(g)(2)(A) of the At, and we are considering such specific requirements for the final rule…….We solicit comments on whether the Medicaid standards are in fact industry standards, whether they are appropriate standards for part D, and if they are, how they should be adapted for use in part D."	1. DUR review and patient information record keeping are done in compliance with OBRA 90 at the MCO, MA and contracted provider levels. Patient counseling at the pharmacy point of service is mandated by State law and is a cornerstone of retail pharmacy practice. Pharmacy consultation is provided to all patients, not just Medicaid. Quality Assurance in an integrated health care delivery system has advantages which are not as readily achieved in a network provider model. Within integrated deliver systems, electronic medical records and electronic prescribing to staff type pharmacies is emerging. Access to powerful information systems such as this is not yet available to the network models utilizing contracted providers in medicine and pharmacy. Thus, record keeping and quality assurance program regulation evolution needs to be mindful of this reality. .

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans		
FR Page #	***Excerpt***	***Comment/Question***
46667	*Elements of a quality assurance program* "The elements that are currently viewed as desirable for quality assurance programs are – (1) electronic prescribing (which will become a requirement in the future as discussed later in this preamble); (2) clinical decision support systems; (3) educational interventions, which could be provided by QIO or could rely on other mechanisms; (4) bar codes; (5) adverse event reporting systems; and (6) provider and patient education. We do not expect PDPs and MA-PD plans to adopt all of these elements. However, we expect substantial innovation and rapid development of improved quality assurance systems in the new competitive and transparent market being created by the new Part D benefit.	1. Unclear about what type of policies and systems CMS refers to in this section. The implementation of HealthConnect over the next several years should enhance current quality assurance programs. 2. Electronic prescribing: MedImpact supports the evolution of this technology and will engage in furthering its development as required with MA, PDP clients. While this technology appears readily available, there are many challenges to be overcome to assure physician adoption and broad industry utilization. 3. Bar code technology for prescription dispensing is a standard of practice within the mail fulfillment industry and is just beginning to emerge in progressive retail pharmacy outlets using varying levels of automated dispensing technology. Retail stores with high prescription volume and pharmacist staffing shortages are beginning to invest in this technology. It will be many years before this technology will be implemented across all retail practice settings.
46667	*Definition of medication error* "…the Food and Drug Administration adopted the following definition of a medication error: > Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use (see 687 FR 12500 (March 14, 2003)). …We are citing this definition in this preamble as one that we would use initially in interpretive guidance."	1. This definition is broad and MA-PD plans may interpret reporting requirements differently, thus leading to different reporting rates. 2. "Medication error" reduction and management is a risk management process which is the accountability of the participating network pharmacy. PBMs are not engaged in the risk management process dealing with prescription dispensing errors at the retail pharmacy POS. The data within the PBM database is utilized for adjudication purposes and population management processes. The data within the participating network pharmacy system is utilized for direct patient care and prescription fulfillment. Any rules promulgated for QA involving medication error management needs to consider how separate and distinct information systems and organizations can work together to integrate and support broad QA mandates.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans		
FR Page #	***Excerpt***	***Comment/Question***
	Evaluation of quality assurance programs " Therefore, we particularly invite comments on how we could evaluate PDPs and MA-PDs based on the types of quality assurance measures and systems they have in place, how error rates can be used to compare and evaluate plans, and how this information could be best provided to beneficiaries to assist them in making their choices among plans"	1. CMS needs to be aware that integrated systems may effectively document and track errors or occurrences within a uniform overarching infrastructure. Network systems lacking such an overarching framework will be following separate guidelines and processes without a singular reporting point. It is reasonable to assume that data capture and reporting rates may be less within the network process and is not necessarily an accurate reflection of quality. A fair and scientific comparison would be based upon uniformly accepted standards. 2. MA PDs and PDPs are different organizational structures newly established to provide access to the new MMA with Medicare Part D. There are no current standards of comparison for this new entity. MAs may possibly be compared via current NCQA or HEDIS benchmarks for how they served their commercial populations. The contracted hospitals may be compared via their JCAHO ratings. State regulatory agencies will have incidents of complaints or citations. There are other not for profit organizations providing quality and service ratings which may be used, but none are focused specifically on the management of the pharmacy benefit. Comparison of pharmacy chains have been provided by various consumer based organizations. We would note that MMA is a broad modernization act which goes beyond just Part D. PBMs which may be PDPs or PDs for MA-PDs have been compared on service issues. This is a very complex issue and there are no simple and accurate ratings or processes which would serve consumers best. Consumers are focused on the cost of the premium and the value of the corresponding drug benefit which is provided via a network pharmacy. The fact that a chain pharmacy will probably serve MULTIPLE PDPs or MA-PDs will complicate targeted comparison even further. Are you comparing the retail POS outlet or the MA-PD or PDP plan? The benefit is defined by law and all variations are required to be actuarial equivalents. Comparison processes will need to wait until there is adequate experience and industry consensus as to what will be appropriate and fair quality benchmarks.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans		
FR Page #	***Excerpt***	***Comment/Question***
46668 - 69	*Medication therapy management services reimbursable* "Medication management services would be reimbursable when adopted by a plan only when provided to targeted beneficiaries as defined in §423.153(2) of our proposed rule and later in this preamble." "…services could include, but not be limited to, performing patient health status assessments, formulating prescription drug treatment plans, managing high cost "specialty" medications, evaluating and monitoring patient response to drug therapy, providing education and training , coordinating medication therapy with other care management services, and participating in State-approved collaborative drug therapy management." "We will ask a PDP sponsor or MA organization to disclose the fees it pays to pharmacists or others, including an explanation of those fees attributable to MTMP services."	1. We are not clear yet as to how MTMP services will be reimbursed and how that reimbursement will be provided to pharmacies at the POS. If such service is to be provided at the pharmacy POS, contractual negotiations will need to be undertaken to establish an appropriate fee schedule. Credentialing or evidence of competency in selected disease states will need to be provided. The shortage of pharmacists at the POS in the retail sector needs to be considered. Likewise, retail pharmacies in general do NOT have truly confidential areas for detailed consultations envisioned for MTMPs. Such services are most effectively provided in clinical environments such as integrated delivery systems, clinic offices, or by appointment in certain retail pharmacy facilities with adequate consultation facilities. 2. MA-PDs and PDPs will need to develop estimates of costs to submit with their solicitations under what we assume will be administrative costs incident to appropriate drug therapy. Enrollees will not pay for these services, thus the cost with appropriate margin must be built into the premiums for an adjusted or separate administrative costs line. There are no established models for this service and we will be evolving reasonable business assumptions and modeling to support a proposal. 3. Targeted enrollees who may benefit from this service are described as "taking multiple Part D covered drugs, and are likely to incur annual costs that exceed a certain level that we can determine." We believe that this may require forecasts to be done for 2006 but will require CMS to allow accrual of costs to be reconciled in the following year based on lack of present data. PDPs of MA PDs must develop forecasts by early 2005 to submit with their solicitation or to adjust their proposed cost structures to CMS at subsequent quarters. CMS must allow flexibility in this regard prior to formulation of firm and fast rules.

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46668 – 69	*Medication therapy management services targeted individuals* "Second, section 1860D4(c)(2)(A)(ii) of the Act requires that MTMP services be provided only for targeted individuals. In other words, not all members of a plan would be entitled to receive these services. As provided under §423.153(d)(2), "targeted beneficiaries" would be plan enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs that exceed a certain level that we determine. We would invite comments on how we should provide comments to drug plans in defining "multiple chronic diseases" and "multiple covered Part D drugs" for the purposes of determining which Part D enrollees would qualify for MTMP services, or whether such determinations are left to the plans as part of their benefit design." "In addition, we are concerned about the method that plans should use to determine that plans should use to determine the costs that enrollees are "likely to incur" to ascertain whether they qualify as targeted beneficiaries." "Active beneficiary participation and consistent delivery of quality MTMP services will require developing and maintaining on-going beneficiary-provider relationships."	1. Existing Disease Management programs manages patients with diabetes, asthma, CAD, CKD, CVD, CHF, hypertension, osteoporosis and depression. These would most likely be the type of disease states that CMS will be targeting. We will be dependent on ICD-9 coding and inferential data (e.g. prescription data, hospital discharge diagnosis, Encounter Coding System) to identify patients with these disease states. This methodology employed by the Disease Management programs results in a positive predictive value of 85-95% (=5%-15% false positives). We will need to determine how to identify patients with specific chronic diseases. 2. If eligibility for MTMP participation depends upon incurred costs, what are the criteria for ineligibility? Will patients transition in and out of MTMP? For example, suppose a member qualifies in year 1 based upon achieving a certain threshold for drug costs. Assume the program is successful and the member reduces their drug costs in year 2. Would the member still be eligible to enroll for year 3 or would they be disqualified? Such inconsistency may be confusing for members and may result in dissatisfaction with their health care.

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46669	*Pharmacists as MTMP providers* "Section 1860D-4(c)(2)(A)(i) of the Act specifically states that a pharmacist may furnish MTMP services. While we believe that pharmacists will be the primary providers of these services, MTMPs could also include other qualified health care professionals as providers of services."	1. How will we separate and bill non-pharmacists services in order to receive reimbursement? 2. Our comments above touch upon pharmacists in the retail network environment as providers of this service. We again reiterate the concern regarding the national shortage of pharmacists. Without a doubt, segments of the retail pharmacist industry lobbied successfully for this language. However, to effectively serve large populations, a supportive clinical, financial and operations infrastructure will be critical to the success of the program. We believe that the oversight for this process begins with the physician referring and guiding patients to MTMP based upon established protocols. MA-PDs, PDPs, PPOs will need to develop such protocols and guidelines with corresponding assumptions leading to cost forecast for premium adjustments. It would be difficult for self directed enrollment unless the patient is identified as a targeted individual enrollee. Some MA-PDs, PDPs may wish to contract with a subcontractor to provide such services. Pharmaceutical companies may wish to provide, support, or sponsor programs which could be of great value to enrollees utilizing their products. No doubt, the pharmacists will play a key role, but the scope and nature of intended MTMP is much more expansive and requires coordinated efforts which engage physicians, patient educators, laboratory data, medical records, and a long term care treatment plan for patients who have a variety of clinical conditions which broadly impact appropriate therapy beyond the prescription. While the notion of call centers seems impersonal, a pharmacist at a call center with the required medical data may be THE most effective facilitator and coordinator of the MTMP. 3. Cost effectiveness for such programs will require long term research involving all aspects of the continuum of care. We would suggest that models for implementation be provided research grant funding as well as operations funding to evolve the optimal models going forward. It would be a good investment to bring together an expert panel to envision various models and to solicit participants willing to commit to execution with a defined statistically significant population. In this way, we may evolve the best practice courses to optimize the use of Medicare and thus taxpayer dollars.

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46670 D.2.d.	*Additional fraud, abuse, and waste standards* "We would also like comments on the value added from requiring plans to develop comprehensive performance standards for use in evaluating internal processes that would appropriately and efficiency research, identify, monitor, and take immediate action to mitigate fraud, abuse, and waste" "For instance, PDPs and MA-PDs need to determine whether or not physicians are illegally prescribing narcotics. In addition to available appropriate data that might be supplied by us, the plans could develop and utilize methods such as data analysis , record audit of PBMSs, pharmacies, physicians, and other providers, DUR….."	1. Will CMS develop uniform standards for all MA-PD plans or will each MA-PD plan develop their own criteria? Will this data be used to compare against other MA-PD plans? How will CMS account for differences in internal processes? 2. CMS has demonstrated a strong interest in identifying physicians who are illegally prescribing narcotics. This was clear in the DDC rules as well. This type of reporting and tracking is not something PBMs have done as routine reporting to health plans or to law enforcement agencies. We would suggest that CMS keep this type of fraud and abuse detection separate from the clinical, financial, and business requirements needed to effectively administer the MMA Part D drug benefit. If such tracking is desirable to obtain prosecutorial evidence, CMS may wish to develop a proposal soliciting bids from PBMs or other claims processing firms to undertake this as a separate project in conjunction with appropriate state and federal law enforcement agencies. Compensation to the successful bidder would be provided to cover administrative as well as operations costs, materials, and start up investment. Successful identification of such illicit prescribing will require coordination with the dispensing pharmacies, federal and state law enforcement, and the appropriate medical and pharmacy licensing agencies. Generation of reports of possible illicit prescribing serves no value unless there is an action plan and infrastructure established to act upon the data. Data from the PBM will need to be reinforced with actual copies of prescriptions and identification of patients. Prosecutorial success requires significant investment in the data analysis at all levels of the fulfillment system. These are law enforcement processes which seem distinct from our clinical and drug benefit management core competencies. Should MA-PD and PDPs forecast costs for such endeavors in their solicitations? Who will pay for these services?

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46670	*Monitoring fraud, abuse, and waste* "One area of concern is inappropriate switching of prescriptions by a PDP or MA-PD plan without consulting a prescribing physician."	1. Pharmacists have been identified by national polls as one of the most trusted professionals in America. Also, the practice of pharmacy is highly regulated and pharmacists are trained and ingrained to practice within the scope of the law. Pharmacists will not put their licenses on the line to switch prescriptions illegally without consulting with and getting physician approval. Pharmacists licensed and registered in the state of practice should ALWAYS have responsibility and accountability for any switching programs instituted by that organization. CMS may wish to focus on developing rules that state as such. In no instance, should non-pharmacist managers supervise or over see such programs. Development of policies and procedures governing a switching program need to be reviewed and approved by the responsible pharmacy executive and manager who should assume accountability for compliance to governing federal and state laws. The practice of pharmacy by a pharmacist is regulated by the governing State Board of Pharmacy.

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46670	*Testing integrity analytical tools for effectiveness* "We also seek comments on the appropriateness, value and need for requiring the plans to test program integrity analytic tools for effectiveness, efficiency, and adaptability to the Medicare Benefit environment. For example, one approach could require the plans to provide any of the following in periodic reports; (1) Summary of data analysis activities, (2) resources, (3) tools, or (4) trend analysis. Alternatively, the plans could be required to develop their strategy and propose what each plan determines to be the best approach for detecting and deterring fraud and abuse. Furthermore, the plans could be asked to demonstrate that the agreed upon activities and outcomes that the plans achieve are in relation to the priorities established by us."	1. What would be the purpose of providing the noted periodic reports? PBMs consistently monitor drug trends to allow clients to make key decisions on how to manage their population of beneficiaries. In the competitive Medicare market place where margins are narrow and pricing is on a cost plus basis, what is the value of providing reports for which there is no defined actionable outcome? Rest assured that the MA-PD and PDP will be doing everything reasonable to manage drug spend as required by CMS and to achieve a reasonable profit within the allowable risk corridors. Development of additional reports requires IT investments and analyst support which adds to costs. We would rather invest all available dollars for appropriate drug spend. 2. The continuing note "Alternatively, the plans could be required to develop their strategy and propose what each plan determines to be the best approach for detecting and deterring fraud and abuse. Furthermore, the plans could be asked to demonstrate that the agreed upon activities …are in relation to priorities established by us." We believe that the drug benefit is one of the areas most easily monitored and analyzed due to the sophistication of the systems and establishment of NCPDP standard data formats. The pharmacy system is such that every transaction may be tracked back to a patient, a prescriber, a pharmacy and ultimately the prescription and the inventory of the dispensing pharmacy. If there is collusion between a local physician and a pharmacist, that may be detected most effectively at the local level and not by a population focused data base. Criminal fraud surely exists, but relative to prescription fraud and abuse in the Medicare population in particular with Controlled Substances, we are not knowing of the data which supports that assumption. We are confident that reports may be generated to identify prescribing outliers. We refer to our prior comments: Who wants this data and for what purpose? Who is willing to pay for such data gathering and analysis? And, should such costs be forecasted into any solicitation proposal to be a PDP or MA-PD?

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46670	*Consumer satisfaction surveys* Under §423.156 we would conduct consumer satisfaction surveys among enrollees of PDPs and MA Organizations offering MA-PD plans in order to provide comparative information about qualified prescription drug coverage to enrollees as part of our information dissemination efforts."	1. We would suggest that CMS and CAHPS provide straw man models of survey instruments to the MA-PDs and PDPs for input prior to final draft and distribution. 2. How will CAHPS/AHRQ differentiate satisfaction with the benefit versus the service provided by the network pharmacy? 3. If all plans are actuarially equivalent as approved by CMS, how will CMS differentiate consumer satisfaction?

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46670 D.4.	*Electronic prescribing program* "Section 1860D-4(e) of the Act contains provisions for electronic prescription programs. The statute contains specific provisions on when voluntary initial standards may be adopted (not later than September 1, 2005) and when final standards should be published (not later than April 1, 2008) and then effective (not later than 1 year after the date of promulgation of the final standards)."	1. 423.159(a) would require that PDP sponsors and MA PD PLANS must have the capacity to support e-prescribing programs. We would await the development of the final standards to ascertain how we could support such. 2. The statutory language is specific in that e-prescribing will also transmit data to the pharmacy such as: prescription, formulary information, medical history, possibility of any ADR, availability of lower priced alternative. Please note that "medical history" needs to be defined such that it may be transmitted in a NCPDP field. All the information to be provided to the pharmacy needs to fit a NCPDP approved field. This statute may require significant investment by all stakeholders in IT SYSTEMS. The discussion suggests that only the MA-PD and PDPs have the capability and capacity to undertake compliance to serve the pharmacies. We are supportive of e-Prescribing, but recognize that there will be significant investments required. Pharmacies will benefit by having a clean and almost pristine prescription readily adjudicated and easily entered into their internal pharmacy system. There may be costs associated with the provision of such data elements which will need to be shared across the entire provider continuum.

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	Electronic prescribing program (Continued)	3. There is NO REQUIREMENT THAT PHYSICIANS WRITE PRSCRIPTIOINS ELECTRONICALLY. This is the limiting adoption factor. The language allows differential payment to physicians who elect use e-Prescribing and comply with the forthcoming standards. MA PDs and MCOs will require time to revise their contracts with physicians within their network. Incentives will need to be designed and in place in the contract period prior to CMS implementation of the standard. Physicians will need to invest in the I.T. systems within their practice management systems to comply. Many physicians are appropriately concerned about the investment costs and the impact upon their office efficiency. There is not uniform agreement among physicians and other prescribers that the quality gains offset the lost efficiency and cost investments. The Medicare population is probably about 10-20% of any given physicians practice. Adoption of e-Prescribing will require a process that covers at least 66 to 75% of the physician's panel. The system will need to be able to serve almost his/her entire patient commercial panel as well. Physicians need ONE system that covers all. If the e-Prescribing is geared only for Medicare, adoption will be minimal as the investment ROI will be questioned.

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46671-72	*Physician incentives to use electronic prescribing* "We have added regulations at §423.159(b) of this proposed rule that would allow an MA-PD plan to provide a separate or differential payment to a participating physician who prescribed covered part D drugs in accordance with electronic prescription standards (Note that this provision only applies to MA-PD plans and not to PDPs). "Differential payments, at the MA organization's discretion, could take into consideration the cost to the physician in implementing the program and could be increased for participating physicians who use e-prescribing to significantly increase – (1) Formulary compliance where medically appropriate; (2) Use of lower cost, therapeutically equivalent alternatives; (3) Reductions in adverse drug interactions as evidenced by appropriate use of drug interaction checking functions in electronic prescribing; and (4) Efficiencies in filling and refilling prescriptions through reduced administrative costs." "We note that any payment must be in compliance with other Federal and State laws…"	1. Would we still be in compliance with California's Knox-Keene Health Care Service Plan Act? Would it apply in this situation since it involves Medicare patients only? **§ 1348.6. Contracts between health care service plans and licensed health care practitioners; prohibition on certain incentive plans** (a) No contract between a health care service plan and a physician, physician group, or other licensed health care practitioner shall contain any incentive plan that includes specific payment made directly, in any type or form, to a physician, physician group, or other licensed health care practitioner as an inducement to deny, reduce, limit, or delay specific, medically necessary, and appropriate services provided with respect to a specific enrollee or groups of enrollees with similar medical conditions. 2. Incentives for physician adoption need to take into account applicable state and other governing regulations. We would reiterate that adoption rate will be higher if the e-prescribing is applicable to at least 67-75% of the physicians entire panel. Unless the physician's office and treatment rooms are set up with the needed equipment (desk top or hand held) to assure optimal efficiency in serving patients, the actual e-prescribing may be done by a clerk or medical assistant on behalf of the physician. The pharmacy receives only what is inputted from the providers office whether it comes from the provider or his staff.

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46672	*Quality Improvement Organizations data requirements* "To fulfill this responsibility, QIOs would need access to data from the transactions between pharmacies and PDPs and MA-PD plans providing the Part D benefit" "The data would include payment related information (that is, plan identification, beneficiary HIC, date prescription filled, NDC, quantity dispensed, ingredient cost, dispensing fee, and pharmacy zip code) and additional items such as prescriber identifiers, dose, days supply, and other dispensing information. Potentially, the information gathered would be aggregated in our data warehouse, and then distributed to QIOs to fulfill their requirements for quality improvement as specified in their contracts and in response to requests."	1. Please provide data and examples as to the type of assistance that QIOs may provide to MA-PDs, PDPs. 2. QIOs are required to offer providers, practioners, MA organizations, and PDP sponsors QI assistance pertaining to health care services, including those related to prescriptions. Please provide list of some of the current QIO vendors approved by CMS. 3. Are the QIO costs to be included in the solicitation we submit, or are these costs already within the CMS forecast and resources are made available to the stakeholders? 4. How are QIOs assigned to stakeholders or do we solicit and hire our own?
46673 D.6	*Accreditation* "Section 1860D-4(j) of the Act requires that the provisions of section 1852(e)(4) of the Act relating to the treatment of accreditation will apply to PDP sponsors with respect to – (1) access to covered Part D drugs including the pharmacy access requirements and the use of standardized technology and formulary requirements; (2) quality assurance, drug utilization review, medication therapy management, and a program to control fraud, abuse, and waste; and (3) confidentiality and accuracy of enrollee records." "A PDP sponsor may be demed to meet the requirements that relate to access….quality assurance…DUR, MTM, and a program to control fraud, waste, and abuse……if it is accredited and periodically reaccredited by a private national accrediting organization under a process that we have determined meets a process and standards that are no less stringent than our applicable requirements. National accreditation organizations are those entities that offer accreditation services that are available in every State to every organization wishing to obtain accreditation status."	1. Please cite specific examples of accrediting organizations that would meet your standards. 2. PBMs are not usually accredited by JCAHO, NCQA-HEDIS. Would affiliation with a disease management organization who has met those accreditation standards for QA, DUR, suffice? 3. Would having disease state management programs within a PBM accredited by national accrediting agencies meet the CMS pending requirement?

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Part J: Coordination Under Part D Plans with Other Prescription Drug Coverage

Summary: CMS intends to implement section 1860D-11(J) OF THE Act at 423.464(a) of the proposed rule and require sponsors of Part D plans to coordinate with State Pharmaceutical Assistance Programs and other drug plans. In this section, CMS specifies the other plans with which Part D plans must coordinate benefits

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46696 J. 1.	"Whenever we mention or reference Part D Plans, we mean any or all of MA-PD plans, PDPs, and fallback prescription plans. Likewise th term Part D plan sponsor refers to MA organizations offering MA-PD plan, PDP sponsors, and eligble fall back entities offering fallback plans. "We propose to implement sections…of the act….of proposed rule and REQUIRE sponsors of Part D plans to coordinate with State pharmaceutical assistance programs and other prescription drug plans…..we specify the other plans with which Part D plans must coordinate benefits in accordance with section 1860D-24(b) of the Act and define SPAP in accordance with….	Coordination of Benefits will pose a unique challenge to PBMs functioning as contractors or subcontractors at risk or with MA-PDs. The scope of the proposed COB providers contributions to the TrOOP is daunting and will require significant IT investments by CMS or its contractor to support the process. We strongly recommend that CMS pursue Option 2 to provide a single point of contact option and requiring primary and secondary payers send required data to this source.
466697 J.2.	We will waive the pharmacy network access requirements described at 423.120(a)(3) of the proposed rule in the case of an MA-PD plan that provides access (other than through mail pharmacies) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization if we determine that the organization's pharmacy network is sufficient to provide comparable access for enrollees under the plan.	We have clients who own and operate their network of pharmacies who would qualify for the waiver. We encourage provision of such waivers where ever and whenever applicable to qualified MAs.
466698 J.4.a	**"** a. Employer Group Waivers**….**extends the waiver authority that is provided for MA organizations related to part C…of the Act and implemented at 422.106(c) to prescription drug plans related to Part D.	We will need to work closely with our MA plans as well as our direct employer group clients to assure that the appropriate waivers are captured and that the coordination of wrap around benefits are appropriately designed and reviewed for 2006. We will need to develop IT systems and reporting to provide needed data to allow employers to capture tax subsidies for enhanced and wrap around programs. We will need to examine every aspect of Part D to assure that employers optimize their retiree Part D investments.

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46699 J.5.	5. Medicare Secondary payer Procedures. ..provides that an MAS organization may charge or authorize a provider to seek reimbursement for services from a beneficiary or third parties to the extent that Medicare is made secondary payer under section… 6. Coordination of Benefits with Other Providers of Prescription Drug Coverage "c. Pharmacy dispensed drugs covered by Part B…are NOT reimbursed unless the pharmacy has a Medicare supplier number; thus a beneficiary could lose Part B coverage by filling a prescription at the wrong pharmacy. 1. Encourage Part D plans to enroll pharmacies with Medicare supplier numbers. 2. Encourage part D plans to inform beneficiaries whether their network pharmacies have Medicare supplier numbers… 3. Develop educational materials reminding pharmacies without Medicare supplier numbers that they must refund any payments collect from beneficiaries enrolled in Part B for part B drugs unless they first notify the beneficiary (through an advanced beneficiary notice (ABN) that Medicare will likely deny the claim."	Network pharmacies have no way of knowing whether beneficiaries are receiving Part B drugs incidental to an office visit unless advised as such by the patient. Education materials from Medicare should provide this information. Likewise, network pharmacy staff will need to inquire of their patients when DME drugs, immunosuppressive drugs, and oral anti cancer drugs are prescribed for Medicare beneficiaries. This is a major area of concern for coordination of benefits. PBMs planning to be Part D contractors or subcontractors will need to begin communicating with their participating pharmacies months in advance to urge filing for Medicare supplier numbers. Network contracts may need to be revised to require having such to be a participating pharmacy in the forthcoming Medicare Part D networks.

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46701 J.6	User fees for data transmission	Recommendation on User fees for the transmission of COB information: • Need to determine this for accurate Administration expenses. If the determination of the transmission fees is after the submission of Applications, then allowances should be considered once this is finalized. • For more accurate Administration expense calculation, a flat fee would be the best alternative. If transmission volume is used, it will be a variable expense, and adversely affect those entities that service large utilizing populations. It will also entail more accounting and administrative effort for verification and auditing. • Recommendation for fee billing is quarterly to reduce administrative overhead. • Payment method should be the discretion of the entity that performs this service (see Comment below for the recommendation on Option 2 for TROOP coordination).
46705 J.6.e.	Tracking True Out of Pocket (TrOOP) Costs	We support the notion of Option 2 where CMS would procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary or secondary. We believe that PBMs do not have the IT systems nor corresponding NCPDP standards in place to coordinate benefits from the wide range of entities offering some degree of prescription drug coverage which count as incurred costs to reach the annual limit. The law requires the system to be in effect January 1, 2006. We urge CMS to proceed in developing the business requirements and seeking bids from contractors to provide the single point of contact services essential to the success at the POS as well as for CMS financial process requirements. Advantages of Option 2 are: • TROOP information can be sent from all entities involved to a single point of contact using one standard record transmission format. The alternative is an administration impossibility. • Facilitator can manage all information to be available to all Part D entities (one single data repository). Facilitator can manage billing for transmission fees effectively. The alternative would be difficult to manage if information transmission fees were imposed.

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Part M: Grievances, Coverage Determinations, and Appeals

Summary: We are required to have grievance procedures in place. We are also required to have an exception process for non-formulary drugs and tiering of drugs. The non-formulary process appears to be consistent with our current non-formulary exception process, but the exception process for tiers may be more complicated. We are also required to have an appeals process.

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46718	*Appeals process for non-formulary drugs* "In addition, section 1860D-4(h)(2) of the Act specifies that appeals, involving coverage of a covered Part D drug that is not on a PDP's formulary, are permissible only if the prescribing physician determines that all covered Part D drugs, on any tier of the formulary for treatment of the same condition, would not be as effective for the individual as the nonformulary drug, would have adverse effects on the individual, or both"	1. PRIOR AUTHORIZATION processes currently in place would allow the review of denied claims. The PA process assures that the MCO MA will have final approval authority. Existing policies and procedures should suffice or have minor changes to adapt to the rules. Physicians may request PA at this time if only a non formulary drug meets the clinical requirements.
46720	*Exceptions to tiered-cost sharing structure* "…a PDP sponsor must establish an exceptions process that addresses each of the following sets of circumstances: (1) The enrollee is using a drug and the applicable tiered cost-sharing structure changes during the year; (2) the enrollee is using a drug and the applicable cost sharing structure changes at the beginning of the year; and (3) there is no preexisting use of this drug by the enrollee." "…Thus, in §423.578(a)(2) we have proposed a limited number of elements that must be included in any sponsor's exception criteria: (1) A description of the process used by the PDP to evaluate the physician's certification; (2) consideration of the cost of the requested drug compared to that of the preferred drug (3) consideration of whether the formulary includes a drug that is the therapeutic equivalent of the requested drug; and (4) consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested drug. We are also considering requiring a number of other exceptions criteria such as – (1) requiring PDP sponsors to establish a blanket rule permitting continued access to a drug at a given price when there is a mid-year change in the tiering structure;(2)	1. From a broad perspective, efforts to protect the beneficiary from tier changes may or may not be in the best interests of the patient or the program. If P & T makes a decision predicated on scientific evidence that an alternative drug is clinical equivalent and change is without risk, and there are significant cost savings, why would it not be permissible to change the patient through a well organized and managed process? If such a change is possible in the first quarter, the savings to the program achieved from a large volume of prescriptions are denied to the program for 9 months. Exceptions, of course, will be provided pursuant to physician data submittal. However, the tone of the proposed rules suggests that patients may be grandfathered or guaranteed a benefit irrespective of the clinical and scientific evidence supporting the change. We should likewise focus on assuring that the switch may be done legally and with sensitivity. 2. PDPs and MA-PD plans can adjust to the proposed CMS rules. It does not make good sense to negate the effectiveness of acquired discounts that were acquired after P & T approval. Any negotiated discounts will need to be adjusted for limited savings during any given year. For large populations, this could result in significant costs to the program. Cost forecasts submitted to CMS will need to be very conservative and adjusted for these restrictions. 3. The proposal to require patients to try a preferred drug and experience adverse effects before being permitted to resume use of an original drug will

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	requiring an enrollee who is using a drug that is subsequently removed from the sponsor's formulary or is no longer considered a preferred drug(s) to try a preferred drug(s), and experience adverse effects, before being permitted to resume using the original drug; (3) requiring a sponsor to establish exceptions criteria that are specific to particular classes of covered Part D drugs, such as cholesterol-lowering drugs; and (4) requiring sponsors to give enrollees an opportunity to request exceptions to a plan's tiered cost-sharing structure other than on a case-by-case basis. Additionally, we contemplated the possibility of establishing criteria for the review process used to evaluate plan formularies and tiering structures, and developing exceptions criteria are specific to classes of covered Part D drugs." "Like for tiering exceptions we are proposing that enrollees be required to request reconsideration by an independent review entity (IRE), as opposed to having these cases automatically forwarded to the IRE."	be very instrumental in helping our drug use management efforts. However, I have concerns that such a requirement diminishes physician judgment in determining the best medication for a given patient. In many cases, administratively requiring a patient who is taking a certain medication to try an alternative for the purposes of eliciting an adverse drug effect does not seem to be in the best interest of the patient. In addition to adverse effects, a particular drug may be ineffective for a given patient, which would be another appropriate reason to use an alternative drug 4. We can develop class specific exception rules. However, it seems to make more sense to have broad rules that are applicable across all drug classes. Please also consider that the Medicare book of business will be approximately 10-20% of our entire business as we still enjoy a large commercial segment of lives. We would like to keep singular policies and procedures to the degree possible. If we find that the CMS proposals make better sense across the board, we would certainly have no reluctance to propose them to our commercial clients. 5. The notion of an IRE is unique to PBMs who work closely with the Plan Sponsor to assure appropriate accessibility and reconsideration. We concur that it is not needed to automatically send all appeals to an IRE, BUT to have the enrollee request as such. However, we are likewise unfamiliar with the impact of an IRE process on the relationship between the enrollee, its health plan (MA) and the physician. Also, a work flow path would need to be developed such that the decision of the IRE is transmitted to the MA-PD, PDP, PBM in a timely manner. The appeal of tiers as well as drugs is an interesting notion that seems founded upon the assumption that all switches are predicated purely on cost without due consideration for quality. The draft of the CMS rules suggests that PBMS need to be able to utilize all its tools and technology to achieve best possible prices and cost management. Conversely, there are rules designed to offset those gains in an effort to protect the beneficiary. We suggest that CMS may safely assume that PBMs are focused on serving the needs of large populations and are sensitive to the potential negative impact of population based decisions on a very small percentage of individuals within that population. Please do not promulgate rules that compromise the value of the contribution to the vast majority of beneficiaries and to the overall program. 6. For the purposes of tiered cost sharing, we should clearly define the tier for single-source generic drugs (i.e. brand vs. generic copays?). Older generic

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		drugs may become single-source if all other manufacturers elect to discontinue production due to low use.

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Subpart Q: Guaranteeing Access to A Choice of Coverage (Qualifying Plans & Fallback Plans)

Summary: This section discusses the beneficiary's right to have access to a choice of at least two plans; the requirements and limitations on the bid submission; review and approval of fallback prescription drug plans; contract requirements specific to fallback plans; and the determination of enrollee premium and our payments for these plans.

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Subpart Q: Guaranteeing Access to A Choice of Coverage (Qualifying Plans & Fallback Plans)		
FR Page #	***Excerpt***	***Comment/Question***
46732 528	"…eligible fallback entity….meets all the requirements to be a PDP sponsor (except that it does not have to be capable of withstanding potential financial losses as a licensed risk bearing entity) and does not submit a bid under the risk bidding process for any PDP region for the first year of that contract period. An entity would be treated as submitting a bid under the competitive bidding process, and thus not be an EFE, if the entity was acting as a subcontractor for an integral part of the drug benefit management activities of a PDP sponsor that is submitting a bid for a prescription drug plan. An entity would NOT, however, be treated as a submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as a PDP sponsor with respect to a prescription drug plan, rather than offering an MA-PD plan. We anticipate that some eligible fallback entities may contrct with other entities for the performance of some required pharmacy benefit management functions…. As the result of this restriction, in bidding, eligible f allback entities would have decided not to submit either a full risk or limited risk bid in any region (either as a direct contractor, or as a subcontractor for a PDP sponsor) in order to be eligible to submit a fallback prescription drug bid in any region. …applies this restriction in the first year of a contract period.	Please validate and clarify the following: An organization may bid for Fall Back if: (1) No risk or limited risk bid submitted in any region as contractor or subcontractor to PDP. (2) PBM has no risk with MA partner to do MA-PD and NOT a PDP An organization is BARRED from bidding as Fall Back if: (1) Submitted bid to be PDP at risk in any region. (2) Submitted bid to be at risk with MA for MA-PD (3) Submitted bid as PDP subcontractor BARRED AS FALLBACK FOR: (1) 2^{ND} & 3^{RD} Year of contract cycle if bid for 1^{st} year. BARRED FROM RISK BID IF: (1) Wins Fall back in that region, barred for 4 years as risk bidder in that region. (2) Wins Fallback , barred everywhere for 3 year contract (3) Submitted a bid to be fallback plan in 2009, where 2009 is 1^{st} year of multi year fall back contract (4) Already approved as fallback in any PDP region for 2009. (5) Offers a fallback in 2008 for same region for which they would be submitting a 2009 risk bid. (6) Entity acts or will act as subcontractor for fallback plan of another entity. We would encourage CMS to have a most liberal interpretation of the law to encourage competition in the fallback bidding. Risk assumption is not something most PBMs would consider. However, PBMS have many MCO and MA clients who are considering entering the market as MA-PDs. Some MAs may request the PBM subcontracted to provide PD services to undertake some degree of risk. Thus, it would appear that this would preclude that PBM from being a fallback even in a different region. While the bidding process is geared to prevent the need for fallback, it may be wise to keep options open-especially since the number of Regions for Part D has not yet been determined.

CMS-4068-P-1221

Submitter : Mr. Johnny Bell **Date & Time:** 10/04/2004 08:10:31

Organization : Vital Care, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Pls see attached comments

CMS-4068-P-1221-Attach-1.doc

Dear Sir or Madam:

Vital Care Home Infusion Services is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Vital Care is a system of individually owned and operated infusion pharmacies specializing in providing high-tech services to rural and urban patients throughout the United States. With over 120 locations in 14 states, Vital Care can provide fast, efficient, and personalized to patients across the nation. Vital Care is based in Meridian, Mississippi and has been treating infusion patients since 1986. To date, Vital Care has treated approximately tens of thousands of patients. Vital Care was established for the purpose of providing a comprehensive scope of high-quality infusion therapies for stabilized patients in the home setting.

Vital Care appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home

administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B *has not resulted in additional access to home IVIG under Medicare*. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm.

CMS should establish **specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies** to ensure adequate enrollee access to home infusion therapy under Part D.

CMS should require **specific standards for home infusion pharmacies** under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

CMS should adopt the **X12N 837 P billing format** for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

CMS should **mandate that prescription drug plans maintain open formularies for infusion drugs** to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Johnny Bell
President/ Owner
Vital Care, Inc.

CMS-4068-P-1222

Submitter : Mrs. Jody Horak **Date & Time:** 10/04/2004 08:10:18

Organization : Toledo IV Care

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

please see attached comment.

CMS-4068-P-1222-Attach-1.doc

Toledo IV Care is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Toledo IV Care is an independent home infusion company based in Toledo, Ohio. We have been providing quality home infusion to patients for over a decade. Our patient/customer satisfaction scores for 2003 averaged 96.5%. Our services include a wide range of infusion medications that are acceptable to administer in the home care setting.

Toledo IV Care appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA")plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and

standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

* Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion perdiem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as itdoes in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at
http://www.nhianet.org/perdiemfinal.htm
http://www.nhianet.org/perdiemfinal.htm

* CMS should establish specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require specific standards for home infusion pharmacies under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the X12N 837 P billing format for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should mandate that prescription drug plans maintain open formularies for infusion drugs to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,
Jody Horak
Billing Manager
Toledo IV Care

Submitter : Edward Rivalsky **Date & Time:** 10/04/2004 08:10:03

Organization : Clinical Specialties Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

CLINICAL SPECIALTIES, INC (CSI) is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

CSI is in our 17th year of operation, with two locations in Ohio, Cleveland and Columbus, both of which are JCAHO accredited. We are a statewide independent provider of infusion therapy services, and a Medicare provider since 1988. We have access to payor contracts representing 7 million lives in Ohio. In addition to Medicare, Medicare Managed Plans, Ohio Medicaid, Pennsylvania Medicaid, Kentucky Medicaid, Michigan Medicaid, Indiana Medicaid, and the Ohio Bureaus of Workers Compensation representing over 90% of all lives in Ohio. We maintain an overall patient satisfaction of 99%, whereby written survey 99% of our patients say they would use our service again. CSI is currently providing over 4,000 courses of infusion therapy annually.

As President of CSI, and as a pharmacist practicing in infusion therapy field for the last 21 years I would like this opportunity to present my concerns regarding compensation for our services under the new Medicare Part D benefit. The dilemma is that while it is significantly more cost effective to treat infusion therapy patients in the home rather than in the hospital, what is the level of care needed to insure a safe and effective course of treatment, and how to compensate for it. Today an infusion therapy pharmacy bridges the care from the acute care setting to the home and there are many challenges that can be associated in the transition.

HISTORICAL PERSPECTIVE

During the 1980?s many of the commercial payors provided compensation for these services at a relatively high level, justifying the ?savings? as compared to a hospital stay. As providers became more experienced in providing these services, and as more providers entered this market, rates for services dropped dramatically, primarily due to competition. Accordingly, many providers exited from this market.

LEVEL OF CARE AND PATIENT OVERSIGHT NEEDED

In evaluating any compensation schedule, there is a need to look all components. In as such, home infusion unique because it does involve home nursing services (already compensated for under Medicare Part A, thus not necessary to be included), Home Medical Equipment, in the form of IV poles and infusion devices, generally covered as a Medicare Part B benefit, provided it is an `approved? therapy (and as such does not need to be compensated for under Medicare Part D. Also included in the services are various supplies, dispensing services, clinical monitoring services, care coordination services and numerous other pharmaceutical/patient `need? services to assure a safe and uneventful (adverse events can range from under or overdosing of therapy to re-hospitalization or treatment failure?it is rare for patients to report suffering extensively due to rather close monitoring that does occur in this field) course of treatment! In addition, there needs to be:

1) Tight coordination between all professionals to ensure a successful start of therapy,
2) On-call services, 24 hours, 7 days a week by all clinicians,
3) Patient initial instruction and on-going interviews to assure appropriate progress in the treatment regimen and in assuring patient involvement and compliance, once again to prevent treatment failure, identify adverse reactions early or to prevent re-hospitalization!

While simply stated above, these services are not easily performed at home, as you no longer have a controlled environment, such as a hospital or skilled nursing facility! As one would imagine, other administrative and support costs need to be considered.

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

OVERSIGHT OF PROVIDERS

? JCAHO, CHAPS, AAHCA or other accreditating body
? State Boards of Pharmacy. In our case, Ohio, Michigan, Indiana, Kentucky and Pennsylvania
? The Drug Enforcement Agency (DEA)
? OSHA
? CMS
? State Medicaid Programs
? USP 797 Standards, which may dramatically affect our ability to maintain our cost structure we currently operate under

CSI appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both MMA itself and CMS?s proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggest an interpretation of the Part D benefit to include not only the drugs that can be administered in patients? homes but the essential services, supplies and equipment that are integral to the provision of home infusion therapy (?dispensing fee option 3? as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage (?MA?) plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important ?demonstration project? of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

? Dispensing fee options 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS ?S? codes, already used by commercial and Medicate managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payor sector.
Thank you for your time and consideration!
Edward J Rivalsky
President & CEO
Clinical Specialties Inc

CMS-4068-P-1224

Submitter : Mr. Lawrence Lewis **Date & Time:** 10/04/2004 08:10:00

Organization : Mr. Lawrence Lewis

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Dear Review Committee,

This letter is from a concerned indivdiual living with HIV. I am fortunate to work full-time and have insurance that covers the medical care and needed prescriptions to manage living with HIV disease. However as a previous member of the St. Louis Ryan White Title I Planning Council, I was made aware of the potential changes to Medicare Prescription Drug Benefits and found myself extremely worried. Worried that individuals living with HIV/AIDS who qualify for Medicare or Medicaid are among the sickest and poorest of people living with HIV/AIDS, may no longer receive the quality of treatment previously afforded them. For many Medicare/Medicaid represented the last best option for their survival. Being among the sickest and poorest also means that they may be more susceptible to opportunistic infections and viral mutations. This puts them in a great need for various treatments. Not allowing such an indivdiual full access to avaialble treatments would be disappointing, especially in an error when many believe that more attention is being payed toward the Third World, than people in need treatment access right in the United States. Insuring that US citizens have access to needed treatment does not negate our responsibility to the world, but lets make sure we take care of our own. Please make whatever adjustments to this Prescription Drug Benefit Plan that are needed to insure that individuals currently receiving Medicare/Medicaid do not receive less benefits than they currently do and that new enrollees may have access to the best treatment option available for them. Shouldn't the treatment option best for the client be left to the client and the treating physician?

Respectfully,

Lawrence Lewis
4135 Potomac St.
St. Louis, MO 63116

CMS-4068-P-1225

Submitter : Patricia Wilson **Date & Time:** 10/04/2004 08:10:57

Organization : Associates

Category : Individual

Issue Areas/Comments

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Comments on proposed 42 C.F.R. parts 403, 411, 417 & 423, 69 Fed. Reg. 46632

ELIGIBILITY, ELECTION, AND ENROLLMENT

Comments on proposed 42 C.F.R. parts 403, 411, 417 & 423, 69 Fed. Reg. 46632

CMS-4068-P-1225-Attach-4.doc

CMS-4068-P-1225-Attach-2.doc

CMS-4068-P-1225-Attach-1.doc

CMS-4068-P-1225-Attach-3.doc

CMS-4068-P-1225-Attach-1.doc

CMS-4068-P-1225-Attach-3.doc

CMS-4068-P-1225-Attach-4.doc

CMS-4068-P-1225-Attach-2.doc

Associates & Wilson
1084 East Lancaster Avenue
Rosemont, PA 19010
AssocWilsn@AOL.com

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4068-P
Submitted to http://www.cms.hhs.gov/regulations/ecomments

Re: CMS-4068-P (Proposed 42 C.F.R. parts 403, 411, 417 & 423). 69 Fed. Reg. 46632, 8/3/2004.

Dear Sir or Madam:

This letter constitutes our comments on the Medicare Modernization Act and the proposed rules cited above. Also attached are three other papers which have been previously distributed that elaborate on some points addressed in this letter. This letter with attachments is being submitted electronically to www.cms.hhs.gov/regulations/ecomments as a Microsoft Word document. The submission was made before the deadline of 5pm on October 4, 2004.

1. **II.B. Eligibility and Enrollment, Paragraph 6 "Disenrollment by the PDP (§ 423.44)" 69 Fed. Reg. 46641-42**

Comment: Can you tell if the same individual is enrolled in more than one plan (either PDPs and/or MA-PDs). If you cannot make this determination, the potential for fraud or abuse arises.

The legal concept of 'residence" depends in large part on where the individual "intends" to reside. Perhaps other agencies, e.g., the IRS, already have a definition of "residence" that could be adopted by CMS.

2. **II. B. Eligiblility and Enrollment, Paragraphs 9 "Approval of Marketing Materials and Enrollment Forms (§ 423.50)" 69 Fed. Reg. 46643.-44**

Comment: The taxpayer is paying for drugs and drug management, not marketing of other services. Permitting PDP sponsors to mix prescription drug services and other business ventures targeted to enrollees could be asking for trouble. Additionally, it could confuse enrollees. The new drug benefit is confusing enough. The PDP sponsor should focus on one thing – drug management – and make that efficient and economical.

3. II.D.2.a & b. Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans. 69 Fed. Reg. 46666-67

Comment: Minimum Utilization Standards

You asked whether there were "industry standards" and whether CMS should adopt them for all utilization management programs. We think you are the responsible entity for setting minimum standards for all plans. It bears repeating that regardless of "industry standards" heath care costs, and particularly drug costs, continue to escalate to record highs. At the same time, the quality of American health care is lower than that enjoyed by Canadians or Europeans and at a cost much less than ours. The reality is that the government is going to pay billions of dollars for drugs. Relying on "transparency" and information on price discounts to motivate plans to "innovate and adopt the best techniques available" is uncertain at best. We suggest you can do better. On behalf of taxpayers, exercise responsible leadership and impose minimum standards that foster cost-effective utilization management programs.

Section 1860D-(c)(1)(A) provides that utilization programs must include incentives to reduce costs such as use of multiple source drugs, but does not preclude the Secretary from imposing other standard elements of utilization management. The regulation should mandate certain *minimum* utilization standards that must be implemented by all plans.

Specifically, we urge you to mandate one basic requirement for all utilization programs; namely, that the *prescription must include the diagnosis or diagnoses for which the drug is prescribed; the directions for use (i.e., the "sig" information), the quantity and strength dispensed and, in the case of certain drugs used in complex cases, require prior approval by an individual with special training or specialty certification.*[1]

It is assumed that this information will be electronically managed and available at the time of dispensing the drug.

Imposing this basic requirement is the corner stone for all other edits and reviews that support cost control, quality improvement, medication therapy management, and fraud and abuse detection. Among other things, it will:

- Allow smart drug utilization review (DUR) before the script is filled
- Allow screening for age appropriateness, etc.
- Create a drug record for each patient which can be used for therapeutic evaluation and to target disease management, wellness programs, etc.
- Create a drug record that can be screened for fraud and abuse. *Id.*

[1] See May 2002 *Statement on the National Action Plan to Assure the Appropriate Use of Therapeutic Agents in the Elderly Part 1* by Patricia L. Wilson and Loren G. Lipson, M.D.(submitted to DHHS/OS/OPHS/ODPHP) (copy attached).

Additionally, you could by regulation also impose a few other *minimum* requirements that should be included in all utilization programs[2]. These edits address both safety and fraud issues. Suggested edits include those that:

- Identify the prescribed dosage as more or less than the recommended dosage for a diagnosed condition.
- Correlate the daily or other frequency of dose for the specified period to a specific number of pills/agent, etc. to be covered. (e.g., four pills for a once a week use constitutes 30 day supply).
- Compare the above two (e.g., if one pill a day for 30 days is prescribed, but the recommended dose is two pills a day, the prescription must be checked). These edits will preclude stockpiling or other fraud.
- Identify prescriptions for initial dose versus maintenance doses (to assure that the correct dosage recommendation is followed).
- Identify off- label use such as edits that identify prescriptions for adjunctive agents,
- Identify prescriptions that preclude use of a generic.
- Identify whether the prescriber is licensed in the U.S.
- Are derived from evidence-based guidelines (e.g. "step therapy' or guidelines on clinically preferred drugs) that set either a dollar threshold and/or particular drugs for which prior approval must be obtained and/or utilization monitored.

The regulation should also mandate that utilization programs must identify the specific steps to be taken in the event that the edit is tripped, particularly steps for obtaining justification from the prescribing physician for the prescription. Under current practice for many PBMs, nothing more than a pharmacy override obtained by inputting several computer key strokes allows claims to process at two times the maximum recommended daily dose. This is not an adequate safeguard – nor is it an eligible claim.

The regulation should also require utilization programs to establish specific guidelines for:

- Determining if a drug requiring prior approval or specialist review is a Medicare Part B covered supply and medically appropriate in a particular case. This review should also establish the covered quantity for a specific period of time (i.e., weekly, 30 days, 90 days, etc.)
- Overriding any concurrent drug utilization review edit.

CMS should include in the regulation a provision that it will from time to time publish in the Federal Register a list of drugs susceptible to overutilization or abuse. You can rely on your own Office of the Actuary to identify drug candidates or take input from others who observe questionable utilization. Neurontin[3] is an example of a drug, FDA approved for adjunctive

[2] See October 2003 *Prescription Drug Benefit Management: Improving Quality, Promoting Better Access and Reducing Cost* by Patricia L. Wilson, prepared on behalf of the American Association of Health Plan's (AAHP) (copy attached).

[3] See November 2002 *Statement on the National Action Plan to Assure the Appropriate Use of Therapeutic Agents in the Elderly Part 2 – An Example - Neurontin* by Patricia L. Wilson and Loren G. Lipson, M.D.(submitted to DHHS/OS/OPHS/ODPHP) (copy attached).

therapy for epileptic seizures and postherpetic neuralgia, with excessive utilization. It was prescribed for almost a dozen unapproved off-label uses as a result of questionable non-peer reviewed "clinical" studies and financial incentives to hundreds of prescribing doctors, both paid for by the manufacturer.

Pharmacy and Therapeutics Committees have not been universally effective in setting up cost-effective coverage and utilization management programs. Often they view their job at the population management level. In this instance their guidance must be applied to individual enrollee circumstances. They should be involved, but the payer (you) should have the last word; that means, the authority to review the claims being paid, question any inaccurate or inappropriate payment, and impose specific remedies as appropriate. The regulation should thus specifically reserve CMS' authority to review, assess, and remedy utilization errors.

Comment: Quality Assurance 69 Fed. Reg. 46667

You asked for comments of what elements should be required for a quality improvement program. The proposed regulation fails to mandate minimum quality assurance standards. You should require at a minimum all of the desirable elements discussed at 46667 (electronic prescribing, clinical support, education interventions, bar codes, adverse event reporting, provider/patient education). To state that you do not expect the plans to adopt all of these elements is inexplicable.

Comment: Medication Therapy Management Programs 69 Fed. Reg. 4668-69

Targeted beneficiaries are those who:

- Have multiple chronic diseases
- Take multiple drugs, and
- Are likely to incur annual Part D costs that "exceed a level specified by the Secretary."

You propose not to set the amount of annual costs that qualify for receipt of MTMP services. You state that you do not have sufficient evidence, and assert that the plans would have better knowledge of the patients and therefore should set the amount.

We suggest that if it was intended that plans set varying amounts based on their unique populations, Congress would have said so. Given that this is an eligibility criterion in a national program, we submit that you, as the plan sponsor/financier, should establish the criterion on an even-handed basis that is not dependent on where an individual happens to live. We suggest it is doubtful that you have the authority to delegate the establishment of an eligibility criterion to private entities.

Upon consideration, should you agree with our observations, the question remains as to what you should do. You could review case management data from the Medicaid programs (or other sources) for guidance, and revise the amount as more data is reviewed. However, merely because the plans may have a more direct relationship with enrollees does not assure that they are in any better position to determine what the annual amount should be.

4. II.C.a. Covered Part D Drug, 69 Fed. Reg. 46646-47 (Proposed section 423.100 on Definitions at 69 Fed. Reg. 46815)

Comment: In defining covered drugs, the proposed regulatory definition first begins with the requirement that the supply is used by the enrollee for a medically accepted indication (proposed section 423.100 on Definitions at 69 Fed. Reg. 46815). The term "medically accepted indication" means "any use for a covered outpatient drug approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i)." What this all means is that the enrollee must have an illness or injury and that the use of the drug to treat that illness or injury must be an FDA approved use or a use supported by peer-reviewed, evidence-based literature and referenced as such by an authoritative group that can not be unduly influenced. Past references to sources not meeting these criteria have been removed.

A cornerstone therefore of efficient administration is to have the intended use (diagnosis or Dx) on the script (Rx). We refer to this as Dx on Rx.

An important corollary for efficient administration is to understand clearly what is not covered. For example, just because US Pharmacopoeia has a drug class or category for erectile dysfunction medication does not mean that they are covered. What we know from the exemplary work of the Institute of Medicine (IOM) on the quality of care in America, is that it is not where it needs to be. It urges improvements in systems of care that help physicians' help their patients. At its heart, the functioning of this Medicare Part D benefit can move us forward with a quantum leap or move us backward. Without guidance from those charged with regulatory authority on coverage criteria derived in part by defining what you don't cover (the exclusions), you run the risk of creating a monster that will do less than both seniors and tax payers deserve. Money will be wasted and care compromised. We urge CMS to be more definitive concerning coverage or more specifically exclusions. Let me use Periostat to explain the comments. The Medicare benefit is not a dental benefit. Periodontal treatments are not covered. And, Periostat is used for periodontal treatment. The largest PBMs who will function in this new marketplace (Medco, Caremark, Express Scripts) do not think as insurance companies or at-risk providers. As such, without guidance, a Periostat drug claim submitted will be a paid claim. Other functionaries such as Aetna and Prescription Solutions have background as both insurers and at-risk providers and as such are likely to do as inferred by failing to cover dental benefits under Part A and B and exclude Periostat under Part D. Beneficiaries in different parts of the country should receive the same treatment with respect to statuary exclusions. Without guidance from you, it will not happen.

The US taxpayer will pay much of the bill and guidance on coverage (meaning an eligible *and* ineligible claim) should be given by CMS as the plan sponsor/financier. It should not be left solely to a PDP or MA-PD.

Under a recent settlement involving Medicaid fraud between Pfizer and the US Attorney of Massachusetts, Neurontin claims for other than seizures (as adjunctive therapy) or for the pain associated with shingles were deemed fraudulent claims. In a Pharma Audioconference on June

23, 2004 (*Lessons of the Pfizer Settlement for Off Label Promotion – Compliance Issues and Practices*), referenced under comments with number 3 above, the Assistant United States Attorney for Massachusetts confirmed that the only legitimate Medicaid claims were for the 2 FDA approved uses - not the 80% of off-label use. While this case is an egregious one, it is not all that uncommon.

5. II.C.4.b Formulary Requirements, 69 Fed. Reg. 46659-60 (proposed section 423.120(b), 46 Fed. Reg. 46818-19) and Section 1860 D-4 (b)(3)(c)(ii) Beneficiary Protections for Qualified Prescription Drug Coverage

Comment: A formulary (a.k.a. preferred drug list) can serve several purposes:

1. It can address plan design in two ways:
    - To limit plan coverage to drugs on the list, unless a patient has gone through a review process to determine coverage eligibility,
    - To provide lower patient co-payments for formulary, and correspondingly, a higher patient share for non-formulary drugs.

    The first approach is what is commonly referred to as a "closed formulary" - limiting prescription coverage to only formulary medications – with the exception that if the listed drugs are not effective for the patient, a non-listed drug becomes preferred. The "preferred' approach (second alternative) differentiates the patient's share of prescription costs - with patients responsible for a higher share of covered, but non-formulary medications.

2. It can be a tool to help both physicians and patients select appropriate and cost-effective medications when there are multiple similar ("me too") medications available

As required by the statute, you have asked US Pharmacopoeia to develop categories and classes of prescription drugs that constitute a model guideline for formulary development. Their proposed guideline is now in the comment phase. However the charge and the model formulary guideline only addresses plan design (item 1 above). It does nothing to address item 2 above, the concept of which is implied under the "protection" title heading.

We encourage you to extend the concept of a model guideline for formularies to include, as a minimum, the following additional information:

- Notations about inappropriate use if a senior, a child or pregnant
- Notations when dose reductions should occur for seniors
- Notations where prior authorization is required to receive coverage since not all drugs on the formulary are covered for all individuals in all circumstances
- Notations about cost typically done currently by a relative ranking notation system.

A PDP or MA-PD could vary what notations apply to which drugs just as it changes which drugs are on or off the formulary. The PDP or MA-PD could also choose to use no notations, but would not be subject to the safeharbor treatment. What CMS does however is to encourage your intermediaries to give useful information to beneficiaries and physicians.

In addition, a truly useful formulary - one that helps both physicians and beneficiaries with care options - may also contain additional information including the best practice guidelines recommended by the body of experts for a specific condition such as hypertension, elevated cholesterol, mild, or moderate or severe asthma. For example, for hypertension, the 'preferred' drug list might show treatment recommendations from The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7). The explanations could be detailed including various degrees of hypertension (mild to severe), and with or without other conditions (diabetic, previous heart attack, etc.).

The rules as they are now proposed are strict for modification to a formulary. But the concept of formulary envisioned included the list of drugs covered under the formulary and not the expanded notion of appropriate use parameters that should be contained in the formulary. Therefore the proposed requirement that a formulary can only change once a year and then only with proper notice should be limited only to the drugs named on it. Changes about appropriate use can and should be made more frequently as evidence-based information presents itself. As an aside the requirements for an annual event change in the formulary must be modified to accommodate changes such as the removal of Vioxx from the marketplace because of increased health concerns. This could be either and FDA mandated withdraw, or a manufacturer-directed recall.

While time has not permitted us to fully review your proposed regulations, we hope these initial comments are both intelligible and useful. Should you have any questions, please call (610-519-0602).

Sincerely,

Patricia L. Wilson

Patricia L. Wilson
Consultant

Attachments:

- *Statement on the National Action Plan to Assure the Appropriate Use of Therapeutic Agents in the Elderly Part 1,* May 2002
- *Prescription Drug Benefit Management: Improving Quality, Promoting Better Access and Reducing Cost,* October 2003
- *Statement on the National Action Plan to Assure the Appropriate Use of Therapeutic Agents in the Elderly Part 2 – An Example – Neurontin,* November 2002

Prescription Drug Benefit Management: Improving Quality, Promoting Better Access and Reducing Cost

Excerpted from a Report Prepared by:

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October, 2003

Table of Contents

Executive Summary

As the Medicare conferees work towards a Medicare prescription drug benefit proposal for Medicare-eligible beneficiaries, it is important to reemphasize the tools that can improve the quality of care while protecting seniors from the high cost of prescription drugs. In this report, we focus on past and current programs to highlight pharmacy benefit management techniques that accomplish these important goals.

- ***Escalating prescription costs are particularly problematic in programs that do not utilize benefit management techniques. This is especially true for and in senior populations.*** It is important to understand the value of management of prescription drug benefit plans. This report uses data from the recently released Families USA study – *Out-of-Bounds: Rising Prescription Drug Prices for Seniors.* The study is based on the experience of the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE), a program that does not fully utilize prescription drug benefit management techniques. And specifically, we use PACE data to show how the use of a variety of management tools can reduce costs substantially while improving quality of care.

- ***Pharmacy management tools lower costs and improve access and improve quality of care.*** To illustrate the value of these management tools, prescription drug examples were chosen based on drug utilization data for the top 50 drugs under the PACE program and practices prevalent with marketplace innovators. Examples include:

  - *Step-therapy*. Step-therapy is used to ensure patient safety and reduce cost by placing the focus on drug value. This tool promotes use of proven therapies first before moving to newer, but not necessarily better and almost always more costly treatments. It aids doctors in focusing on what others recognize as appropriate, first-line care, rather than the drugs most recently advertised and promoted through pharmaceutical company sales efforts.

    Plavix, an anti-platelet agent, is an example. Common aspirin has been shown to be clinically equivalent to Plavix. Extensive marketing has made Plavix the fourth most utilized drug on PACE list, with annual charges of over $1,500 per user. If Plavix is made a non-formulary drug subject to prior authorization, patients are protected from the risk of potentially dangerous side effects and significant cost savings are achieved.

  - *Competitive pricing and care enhancements*. By negotiating dispensing rates and prices at retail pharmacies and limiting coverage to prescriptions filled at preferred network pharmacies, managed prescription drug benefit plans have generated significant savings. Consequently, any willing provider mandates will decrease the ability to develop a high-quality network at the lowest cost.

  - *Promotion of clinically preferred drugs*. New practice guidelines released by the National Institute of Health/National Heart Lung Blood Institute's Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC7) indicate diuretics (at less than $100 per year) as the preferred treatment for those

with uncomplicated hypertension – producing better outcomes than new medications. Yet diuretics are at the bottom of the PACE/Families list in terms of utilization. ACE inhibitors are not even on the list, and they are first-line therapy for those patients recovering from heart attacks. Using the PACE data, the use of these alternative drugs could produce potential savings ranging from $95 to $308 per person per year.

- ***Pharmacy management tools are critical to reducing medication errors.*** Pharmacy management tools and technology can and should be used to reduce errors and support health care practitioners.

- ***Pharmacy management tools are necessary to increase use of equally effective but lower cost products such as generics.*** With the advent of direct-to-consumer advertising of prescription drugs and more sophisticated pharmaceutical marketing to physicians, plan design and tools are necessary to provide incentives to use equally effective, but lower cost products.

- ***Pharmacy management tools include an integrated mail service pharmacy that reduce costs through greater efficiency.*** Mail service prescriptions are an integral part of the managed pharmacy system. The patient benefits from 90-day prescriptions for maintenance (long-term) medication delivered directly to their home. Beneficiaries appreciate the cost savings and the enhanced quality resulting from efficient delivery systems. Under PacifiCare's Prescription Solutions program, costs savings of approximately 14%, or an average of $146, per year using mail service instead of retail pharmacies for a brand-name drug were realized. The General Accounting Office (GAO) has also confirmed the cost savings due to pharmacy benefit management techniques. In the January 2003 study of the Federal Employees' Health Benefits Program, the GAO concluded that the average mail-order price was 27% lower for brand-name drugs and 53% lower for generic drugs than the average cash-paying customer price. The PACE Program could reduce drug cost by 10% if using competitively priced mail service pricing - and dispensing fees with only 60% of brand-name drugs switching from retail.

- ***Expanding Pharmacy management technological tools are key to the management of health care.*** Pharmacy benefit managers are proficient in developing, installing, communicating, and maintaining complex prescription drug benefit structures for large groups of beneficiaries. While capabilities are expanding, costs are declining.

  As shown above, by effectively managing the drug benefit, the government can spend less and improve integrated health care for Medicare beneficiaries. If PACE used all of the marketplace innovator tools, it could cut costs by 40%. Additionally, better management of prescription drugs can help reduce medical expenditures, including hospitalizations and emergency care due to adverse drug events. Proven management tools will help the federal government provide a more valuable prescription drug benefit and improve the quality of life for Medicare beneficiaries.

Acknowledgments

Associates & Wilson wishes to acknowledge the many people and organizations that made this report possible. First and foremost we thank the American Association of Health Plans (AAHP) and its members for giving us the opportunity to present ideas to important decision makers at a time when the United States is moving forward on healthcare policies. What happens this fall, as Congress works to reconcile differences in the bills passed by the House and Senate, will have far-reaching effects on both the national economy and the healthcare of older Americans.

Special thanks goes to marketplace innovators listed in this report as well as all those who are committed to improving care quality. To complete this report we drew upon their ideas and the words they wrote. We encourage all to read the thoughts of others referenced in the "For more information" sections that appear throughout the report.

In addition, we would like to acknowledge Loren Lipson, M.D. for generously contributing his time and expertise during our lifetime collaboration on retiree healthcare improvements.

Introduction

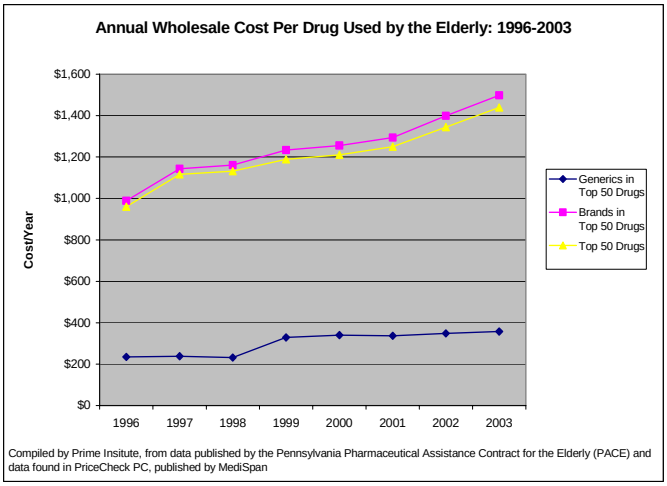
In July 2003, Families USA published a report entitled *Out-of-Bounds: Rising Prescription Drug Prices for Seniors* using data from the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE) program. Focusing on the 50 drugs most frequently used by this elderly population (See Exhibit 1), the findings include:

- Prices rose 3.4 times the rate of inflation in 2002.
- On average, prices for generics rose less rapidly than brand-name drugs while generics also cost significantly less. It is important to note that there is significant variability in price increases between drugs.
- Only 15 of the 50 most frequently used drugs were generics.

The PACE program has been suggested as a model for a Medicare drug benefit, but the program does not use most pharmacy benefit management techniques. This paper focuses on the drugs highlighted in the Families USA report to show how the use of prescription drug benefit management tools developed by marketplace innovators can reduce cost substantially while improving the quality of care and safety for beneficiaries.

The PACE Program as an Example

The *Out-of-Bounds: Rising Prescription Drug Prices for Seniors* report recently published by Families USA provides useful information about the cost of medications taken most frequently by seniors.
The report is based on the drug market basket for the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE) with information compiled by the PRIME Institute at the University of Minnesota.



- PACE has been a leader in many pilot and research projects, yet it uses few of the pharmacy benefit management tools used by a variety of other organizations to manage health care quality and cost.

If PACE used all of the marketplace innovator tools, it could cut costs by 40%.

- The outlook for increased use of pharmacy benefit management tools is promising. On May 29, 2003, the Pennsylvania Governor's Office of Health Care Reform and the Management and Productivity Council announced several changes to the PACE program that will focus on negotiating more competitive drug prices.

For more information:
- Visit www.familiesusa.org for a copy of publication No.03-106.
- Visit www.aging.state.pa.us/aging/lib/aging/pace_01annl.pdf for a copy of the Annual Reports to the Pennsylvania General Assembly for the PACE program.

The PACE program provides limited prescription coverage for low to moderate income older Pennsylvanians. Its sister program PACENET (Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier) extends coverage to a higher income levels with somewhat different copays but subject to the same management features. Established in 1984, with an on-line claims adjudication system implemented in 1991 and the addition of PACENET in 1996, PACE is the largest public pharmaceutical program for seniors. Some key design features include:

- Predominately uses independent and chain pharmacies. Pharmacies who deliver by mail including retail stores who register as mail service providers must enroll and meet special requirements
- Supplies limited to 30 days or 100 pills - whichever is less.
- $6 copay per script for PACE and $8 for generics and $15 for brand-named medications for PACENET.
- Generic substitution for multi-source brands is required wherever there is an FDA A-rated generic.
- Specific prospective drug utilization review criteria are used for the maximum initial dose, the maximum daily dose, and the duration of therapy or duplicate therapy. In order for reimbursement to occur under the program for any claim subject to a prospective drug utilization message, the physician or the pharmacist must document the medical necessity.

Important Factors in Healthcare Delivery

Disease Management Programs

Education, compliance programs, and the avoidance of drug interactions contribute to improved quality of care. Pharmacy Benefit Managers (PBMs) have been involved in many successful disease management programs designed to improve compliance with specific pharmaceutical regimens, such as treatments for beta-blocker therapy post acute myocardial infarction, and depression treatment. For example, asthma education programs can improve care by fostering the use of effective anti-inflammatory drugs and other long acting medications. A recent study by Merck-Medco found that overall health care costs were decreased, mainly due to decreased use of asthma inhalers (short-acting beta-agonists)[1]. Other studies confirm this and document the reduction in emergency visits and hospitalizations after appropriate interventions[2].

Verizon, together with a pharmacy service organization, has developed a program to identify members at risk of hip fracture or diagnosis of osteoporosis. These patients are then screened for medications that are known to increase the risks of fall, such as painkillers, sleeping aids, and antidepressant drugs. Communications including information on prevention of falls and alternative drug therapies are sent to both the member and physician for consideration. This type of program reduces health care expenditures while improving quality of life for seniors[3].

PBMs can use pharmacy claims data to identify patients as risk for noncompliance and share this information with treating physicians who can use the data to improve care of their patients[4]. Centralized data collection for pharmacy claims can also help prevent potentially harmful drug interactions; AdvancePCS was able to avoid three million potential adverse drug interactions through the use of their on-line process with immediate drug utilization review[5].

Healthcare Quality

Each year, an estimated 44,000 to 98,000 people die from medical errors. That's more than the number of people who die from car accidents (43,458), AIDS (16,516), or breast cancer (42,297). The statistics in recent studies are concerning – 25% of outpatients had an adverse drug event, 13% were serious and 20% were preventable (See Exhibit 2). Seniors are particularly at high-risk. The Institute of Medicine (IOM) suggests a systems-driven solution: "Human beings, in all lines of work, make errors. Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing. In healthcare, building a safer system means designing processes of care to ensure that patients are safe from accidental injury."

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[1] Feifer, RA, Gutierrez B, Verbugge RR. Impacts of a PBM-based Disease Management Program on Asthma Medication Use. American Journal of Managed Care 2001; 6: 460-467. (Medco)

[2] Owens GS. Measuring Outcomes of Asthma Patients after Clinical Pharmacy Educational Intervention. AMCP Annual Meeting, October 1996. (FHP)

[3] Rabinowitz E. Preventing Falls and Fractures, Verizon program monitors senior medications. HealthPlan Nov/Dec 2002; 16-18.

[4] Bieszk N et al. Detection of Medication Nonadherence Through review of pharmacy claims data. Am J Heath-Syst Pharm 2003; 60 (4): 360-366. (Henry Ford Health System)

[5] AdvancePCS Patient Safety Study Finds Alerts to Pharmacists avoided 3 million potential adverse drug reaction in one year. CNET.com February 27, 2003.

Generics
Generics have chemically identical active ingredients, are available from multiple manufacturers, cost less, and are equally effective as brand-name drugs. Marketplace innovators use generics whenever they can and make them the cornerstone of drug classes to deliver cost-effective, quality care. Many employers and state Medicaid plans encourage generic drug use as a part of their fiduciary and management responsibilities. With significant numbers of brand-name patents due to expire in the near future, we expect more plans to get even more aggressive in encouraging use of generics.

Increased Direct-to-Consumer Advertising
The pharmaceutical industry spends billions of dollars each year to market its products. Studies show pharmaceutical advertising is working: the 25 most advertised drugs account for 40% of recent increased spending on drugs. Increased attention to direct-to-consumer advertising encourages employers, states, and health plans to seek value for their money.

Health Plan Focus on Patient Safety and Quality of Care
There has been a significant increase in attention to patient safety since the Institute of Medicine (IOM) released its report, To Err Is Human: Building a Safer Health System, in 1999, highlighting the magnitude of this problem. The IOM report estimates that medication errors account for over 7,000 deaths annually. Incidence rates of adverse drug reactions vary from 2 per 100 admissions to 7 per 100 admissions among hospitals that have conducted such studies according to the Agency for Healthcare Research and Quality.

Health plans believe that patient safety is a critical component of quality of care and actively address patient safety concerns as part of their efforts to improve health care quality. By design, health plans have an infrastructure that can support patient safety. As part of this infrastructure, health plans employ tools that support physicians and other caregivers and systematically identify patients at risk for medication errors, contraindications and pharmacy recall—at the time when the patient goes to the pharmacy and fills the prescription to help to prevent potential problems before patients begin taking the medications. These activities have been purposely created to reach one of the many IOM safety recommendations: implementing proven medication safety practices that include systematic tracking of drug interactions and dosing.

Management Tools – Their Effect

While the PACE program uses some unique concurrent drug utilization review screening techniques, it employs few of the cost and quality management tools used by health plans and other States in their prescription drug programs. Those tools include formularies with designs that either encourage use of a preferred drug or require a preferred drug as first-line treatment unless care would be compromised. Additionally, PACE does not utilize step-therapy or prior authorization, which are both key management tools in health plans. PACE uses retail pharmacies almost exclusively, and the prices it pays to retail pharmacies are substantially higher than payments made by other entities, including employer-sponsored programs or health plans. Another potential opportunity is the substantial savings from mail service efficiencies.

To address the impact of some of these management tools, we have reviewed the drug utilization data for the top 50 drugs under the PACE program and have attempted to quantify, where appropriate, the potential cost savings on a per user basis for:

- the use of an alternative, but equally effective drug
- lower negotiated prices through dispensing pharmacies
- mail service efficiencies

.

The following treatment examples illustrate potential savings using the management tools: cholesterol-lowering statin agents; proton pump inhibitors that are used to treat various digestive disorders; cardiac medications to treat hypertension; Plavix, used to prevent heart attacks; and drugs used to increase bone mass and prevent/mitigate osteoporosis.

A Word about Calculations

Pace/Families USA Reported Annual Cost:
This represents the annual cost of the drug as documented in the July 2003 "Out-of-Bounds" report that was produced by Families USA.

Alternative Annual Cost:
This number was calculated for a drug viewed as an effective therapeutic alternative to the drug used under the PACE program. We used the drug's per pill/capsule Average Wholesale Price (AWP) as reported in the July 2003 Drug Topics Red Book. The per pill AWP was multiplied by either 365 (one pill once a day) or 730 (one pill twice a day). The result was reduced by 13% for a brand or 55% for a generic drug to produce a conservative proxy for a negotiated annual ingredient cost for a retail purchase in a managed health plan for a maintenance medication. $36.00 was added to this discounted ingredient cost to account for pharmacy dispensing and administrative fees.

Negotiated Cost:
This number was calculated for the drug utilized under the PACE program using the drug's per pill/capsule AWP as reported in the July 2003 Drug Topics Red Book. The per pill AWP was multiplied by either 365 (one pill once a day) or 730 (one pill twice a day). The result was reduced by 13% for a brand or 55% for a generic drug to produce a conservative proxy for a negotiated annual ingredient cost for a retail purchase in a managed health plan for a maintenance medication. $36.00 was added to this discounted ingredient cost to account for pharmacy dispensing and administrative fees.

Cholesterol Drugs

The cholesterol-lowering drugs of the statin class are the most prescribed medication for any age group. They are also among the most expensive. The accompanying chart illustrates the PACE usage ranking for the statins. It is important to note that the generic lovastatin (Mevacor) is not on the list of the 50 most prescribed drugs.

Families USA	
Drug Ranking (by claims)	**Drug Name**
1	Lipitor 10mg
8	Zocor 20mg
11	Lipitor 20mg
31	Zocor 40mg
34	Zocor 10mg
38	Pravachol 20mg

Drug management is especially important for this class of drugs, as often, these very powerful cholesterol lowering drugs are prescribed when the patient only needs a 10%-20% drop in LDL cholesterol. Additionally, every cholesterol-lowering statin drug has the potential for serious side effects on liver and kidney function and muscles, and the potential side effects are of great concern for elderly beneficiaries.

This class of drugs represents an exceptional opportunity for step therapy. Since the lowest dose possible presents the lowest risk, step therapy suggests that the patient start with a low dose. After inspecting the results and monitoring any side effects, the physician and the pharmacy benefit manager can move the patient up to a higher dose if necessary. This procedure protects patient health and saves money.

Drug Name	Pace/ Families USA Reported Annual Cost	Alternative Drug	Alternative Annual Cost	Annual Savings Per User
Lipitor 10mg	$871.00	lovastatin 20mg	$425.00	$446.00
Lipitor 20mg	$1,330.00	Lipitor 20mg	N/A	N/A
Pravachol 20mg	$1,124.00	lovastatin 20mg	$425.00	$699.00
Zocor 10mg	$959.00	lovastatin 20mg	$425.00	$534.00
Zocor 20mg	$1,674.00	lovastatin 40mg	$737.00	$937.00
Zocor 40mg	$1,674.00	Zocor 40mg	N/A	N/A

The chart to the left illustrates the cost savings if an alternative drug is used. Conservative savings estimates range from $446 to $937. Lovastatin was not subject to competitive market forces at the time of this data collection; however, it is presently a multi-sourced drug and additional savings can be realized.

Drug Name	PACE/Families USA Reported Annual Cost	Negotiated Cost	Annual Savings Per User
Lipitor 10mg	$871.00	$794.00	$77.00
Lipitor 20mg	$1,330.00	$1,193.00	$137.00
Pravachol 20mg	$1,124.00	$1,014.00	$110.00
Zocor 10mg	$959.00	$871.00	$88.00
Zocor 20mg	$1,674.00	$1,492.00	$182.00
Zocor 40mg	$1,674.00	$1,492.00	$182.00

The annual savings shown to the left are conservative estimates of savings obtained by negotiating rates for retail pharmacy dispensing. Taking advantage of the efficiencies of mail service would reduce costs further.

Proton Pump Inhibitors (PPIs)

Proton Pump Inhibitors (PPIs) reduce acid formation in the stomach, and this therapy is FDA approved for up to eight weeks for the treatment of Gastroesophageal Reflux Disease (GERD) (For more serious but relatively infrequent conditions, use is continuous). However, if the patient is still experiencing GERD symptoms after eight weeks, it may be a sign of a more serious disease. Step therapy programs help identify patients' needs and focus appropriate care based on symptoms and previous experience. A PPI step-therapy program can also be used to recognize and cure stomach problems caused by the bacteria H. pylori.

Families USA	
Drug Ranking (by claims)	**Drug Name**
5	Prilosec
9	Prevacid
26	Protonix
33	Nexium

Actively managed prescription drug benefit plans who utilize step therapy recommend OTC products for occasional heartburn. More severe cases warrant the use of a generic like ranitidine (Zantac) in prescription strength.

Drug Name	PACE/Families USE Reported Annual Cost	Alternative Drug	Alternative Annual Cost	Annual Savings Per User
Nexium 40mg	$1,614.00	Protonix 40mg	$1,282.00	$332.00
Prevacid 30mg	$1,690.00	omeprazole 20mg	$718.00	$972.00
Prilosec 20mg	$1,684.00	omeprazole 20mg	$718.00	$966.00
Protonix 40mg	$1,282.00	omeprazole 20mg	$718.00	$564.00

Step therapy programs can reduce drug spending between 15% and 25% for most classes of drugs while increasing patient safety and reducing potentially harmful side effects.

Omeprazole shown in the table above as a formulary preferred drug choice is the newly approved generic for Prilosec – once the gold standard in the PPI class. As more generic manufacturers are approved, prices will fall. This will produce even larger savings than those shown above, ranging from $500 to more than $900 per patient.

Drug Name	PACE/Families USA Reported Annual Cost	Negotiated Cost	Annual Savings Per User
Nexium 40mg	$1,614.00	$1,430.00	$184.00
Prevacid 30mg	$1,690.00	$1,522.00	$168.00
Prilosec 20mg	$1,684.00	$1,501.00	$183.00
Protonix 40mg	$1,282.00	$1,141.00	$141.00

An additional tool is negotiating more competitive pricing at retail. These are conservative estimates, and actual experience in the competitive market will vary.

Plavix

Plavix is the fourth highest utilized drug on the PACE/Families USA list, with an annual cost of $1,539 per beneficiary. The drug is an anti-platelet agent used for the secondary prevention of an atherosclerotic event. Common aspirin has been shown to be clinically equivalent to Plavix. See Exhibit 5 on page 31 for more information on the drug.

Families USA	
Drug Ranking (by claims)	**Drug Name**
4	Plavix 75mg

Management tools in PACE could reduce cost of Plavix by about $8 million – or 2% of its *total* program drug costs.

Plavix use in actively managed prescription drug plans is typically limited to patients who have pre-existing cardiovascular problems such as stent placement, heart attack or stroke, or patients who are allergic to aspirin.

Typically, in a plan that utilizes benefit management techniques would classify Plavix as a non-formulary drug that requires prior authorization. This system protects patients who do could achieve equal health benefits with aspirin from the risk of potentially dangerous side effects.

Additionally, lower negotiated prices at retail pharmacies would save the taxpayers and beneficiaries an additional $214 annually, if Plavix is taken continuously. Mail service efficiencies could decrease annual drug costs by an additional $100.

Drug Name	PACE/Families USA Reported Annual Cost	Negotiated Cost	Annual Savings Per User
Plavix	$1,539.00	$1,325.00	$214.00

Bone Building Drugs

Families USA Drug Ranking	Drug Name	Pace/Families USA Reported Annual Cost	Negotiated Cost	Annual Savings Per User
3	Fosamax 70mg	$894.00	$859.00	$35.00
32	Evista 60mg	$895.00	$858.00	$37.00

For many health conditions, there is definitive drug treatment with a presumptive diagnosis. This is often the case with bone loss. In many health plans, these drugs are prescribed even though less than 50% of the time there is no definitive need as evidenced by a bone density test. Additionally, if these drugs are not taken properly, the individual will often take a PPI to counter stomach irritation. Effective marketplace innovators utilize alternative, effective treatments, including:

- Preventing bone loss through lifestyle changes, and
- Minimizing the risk of broken bones by reducing the risk of a fall. Often this involves eliminating drugs that cause dizziness or instability of gait.

Hypertension Treatment

Drugs used to treat hypertension are the most common types of medication prescribed for the elderly population. The PACE/Families list is interesting because it does not contain any ACE inhibitors, and diuretics are at the bottom of this list. With the new practice guidelines just released by JNC7, diuretics whose cost is less than $100 per year still are the preferred treatment for those with uncomplicated situations – producing better outcomes than new medications.

Families USA	
Drug Ranking (by claims)	**Drug Name**
2	Norvasc 5mg
7	furosemide 40mg (Mylan)
10	Norvasc 10mg
13	Toprol XL 50mg
19	metoprolol tartrate 50mg (Mylan)
23	metoprolol tartrate 50mg (Teva)
27	Cozaar 50mg
28	atenolol 25mg
30	furosemide 20mg
37	atenolol 50mg
40	Toprol XL 100mg
42	hydrochlorothiazide 25mg
45	furosemide 40mg (Geneva)
49	Diovan 80mg

Norvasc, in positions 2 and 10 in magnitude of utilization, is a calcium channel blocking agent that causes arteries to expand and drops blood pressure. Other drug categories are preferred over calcium channel blocking agents because they produce better outcomes. Geisinger, a Pennsylvania health plan identified as a marketplace innovator, has a preferred drug list that does not contain calcium channel blockers, and most of the other drugs used to treat hypertension are generic. What makes this so compelling is that Geisinger has such a low rate of hospital admissions (.8 per 10,000 members) for hypertensive patients. Geisinger, and many health plans that use prescription drug management tools, review the use of Angiotensin II inhibitors like Cozaar and Diovan, and coverage is granted in circumstances where an improved outcome is likely to be produced.

This point about some drug classes like calcium channel blockers having no preferred drugs on formulary is an important one regarding management control. For example, if the final bill reported out of the Medicare conference committee requires one drug in each class, there will be never ending pressure to further subdivide therapeutic classes in ways that will not provide added value to beneficiaries. The arguments could be endless – is a Cox II really a different class with different outcomes than non-steroidal anti-inflammatory drugs (NSAID)? If judged yes, it will get 100% of the market and its advertising budget will promote its exclusive position.

While these drugs are not as expensive as newer drugs in other categories, money can still be saved while improving outcomes (see chart below). These savings are on an order of magnitude of $100 to $300 per patient with hypertension. Given the prevalence of hypertension in the PACE population, this could translate to billions.

If we saved *only* $100 annually per patient through better management of hypertension drugs, that's $1.2 billion to spend on other beneficiaries who need prescription drug coverage.

Drug Name	PACE/Families USA Reported Annual Cost	Alternative Drug	Alternative Annual Cost	Annual Savings
Angiotensin II Inhibitors				
Cozaar 50mg	$553.00	enalapril 20mg	$286.00	$ 267.00
		lisinopril 40mg	$294.00	259.00
Diovan 80mg	$567.00	enalapril 20mg	$286.00	281.00
		lisinopril 40mg	$258.00	309.00
Beta Blockers				
Toprol XL 50mg	$277.00	metoprolol tartrate 50mg	$128.00	149.00
Toprol XL 100mg	$416.00	metoprolol tartrate 100mg	$167.00	$ 249.00
Calcium Channel Blockers				
Norvasc 5mg	$549.00	Sular 20mg	$417.00	132.00
Norvasc 10mg	$794.00	Sular 40mg	$417.00	377.00

For drugs treating hypertension, there is less opportunity to reduce costs through pricing negotiation since the initial cost of the drug is less. However, the total savings are significant because of the number of people treated for hypertension. Since about 70% are not treated to an acceptable blood pressure goal, these savings can be spent on treating more people and treating them more effectively.

Drug Name	PACE/Families USA Reported Annual Cost	Negotiated Cost	Annual Savings
Angiotensin II Inhibitors			
Cozaar 50mg	$553.00	$541.00	$12.00
Diovan 80mg	$567.00	$528.00	$39.00
Beta Blockers			
atenolol 25mg	$298.00	$172.00	$126.00
atenolol 50mg	$304.00	$241.00	$ 63.00
metoprolol tartrate 50mg	$405.00	$128.00	$277.00
Toprol XL 50mg	$277.00	$277.00	$ ----
Toprol XL 100mg	$416.00	$398.00	$18.00
Calcium Channel Blockers			
Norvasc 5mg	$549.00	$512.00	$37.00
Norvasc 10mg	$794.00	$725.00	$69.00
Diuretics (loop)			
furosemide 20mg (Mylan)	$52.00	$47.00	$5.00
furosemide 40mg (Mylan)	$59.00	$51.00	$8.00
furosemide 40mg (Geneva)	$57.00	$51.00	$6.00
Diuretics (Thiazide)			
hydrochlorothiazide 25mg	$29.00	$28.00	$1.00

Additional Cost Savings from Mail Order

Throughout this section, we have mentioned that marketplace innovators have negotiated contracts with retail drug stores – or buy and distribute using their own pharmacies – producing costs even lower than the conservative estimate of "negotiated cost." Further, most experience even greater savings when utilizing the efficiencies of mail service dispensing. Costs are significantly lower than retail costs even if retail can dispense a 90-day supply through plan design.

In the PACE example, they could reduce drug cost by 10% if using competitively priced mail service pricing - and dispensing fees with only 60% of brand-name drugs switching from retail.

Prescription cost of ten drugs commonly prescribed for seniors (Retail vs. Mail)[6]

The average savings is 14% or $146 per year on a branded drug

Drug	30 day Retail	90 day Retail	90 day Mail	Savings per 90 days	Annual Savings	Percentage Savings
Pravachol	$121	$365	$325	$40	$160	11%
Lipitor	98	293	261	33	130	11
Lisinopril (g)	22	67	60	7	28	10
Lotensin	33	99	85	14	56	14
Plavix	112	336	302	34	142	10
Metformin (g)	31	92	86	6	24	6
Protonix	104	313	253	60	240	19
Fosamax	76	229	180	49	196	21
Premarin	26	79	57	22	88	28
Zocor	123	368	328	40	160	11

The General Accounting Office (GAO) has also confirmed the cost savings due to pharmacy benefit management techniques. In the January 2003 study of the Federal Employees' Health Benefits Program, the GAO concluded that the average mail-order price was 27% lower for brand-name drugs and 53% lower for generic drugs than the average cash-paying customer price.[7]

Some Conclusions

If PACE had utilized all of the management tools used by marketplace innovators, its costs could have been reduced by as much as 40%. Since the program is funded largely by the state, this would reduce the cost to taxpayers and it could be used to expand the program. On May 29, 2003, Pennsylvania announced plans to expand the groups covered by the PACE program and to negotiate changes in drug purchasing contracts. This is one of many steps that will allow PACE to save money through smarter purchasing. Other steps may focus on eliminating waste and change the mix of what is delivered through the program – not just the price they pay for it. Assuring the use of prescription drug management tools in the Medicare prescription drug benefit will reduce the cost to the government and directly help beneficiaries through higher quality care.

[6] Data derived from PacifiCare of California pharmacy claims January – March 2003.

[7] United States General Accounting Office, Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies. January 2003.

Marketplace Innovators

In this section, we briefly highlight entities that address health management and delivery using all of the tools available within the sophisticated pharmacy management arena to improve quality. Since health plans usually integrate prescription drug benefits and medical care, they actively work to promote appropriate drug use to reduce medical costs, including hospitalizations and emergency care.

Health Plans

Below are two health plans (PacifiCare and Geisinger), selected because of their unique characteristics. However, they use many common practices concerning pharmacy benefit management. These plans, whether serving their own health plan, or providing management services to other health plans or employers, provide a host of management services delivered through their pharmacy management unit including:

- Targeted disease intervention programs from Attention Deficit Hyperactivity Disorder (ADHD) to Syndrome X (the insulin resistant state)
- Focused initiatives and education for improved Health Plan Employer Data and Information Set (HEDIS) measurements from asthma to post heart attack
- Specialty pharmacy disease therapy management
- Formulary development and management including the groups that support their Pharmacy and Therapeutics Committees having members with varied specialized training and expertise to insure clinically-sound and cost-effective options
- Prior authorization based upon evidence-based guidelines to insure safe, appropriate, and cost-effective use of prescription medications
- Health outcomes research, epidemiological studies, predictive modeling, decision analysis, and a host of other services that look to future improvements.

PacifiCare Health Systems serves more than 3 million health plan members. The Secure Horizons division of PacifiCare is one of the nation's largest Medicare risk programs, with more than 700,000 members enrolled in its Medicare + Choice plan.

PacifiCare's pharmacy program is managed by Prescription Solutions, a wholly-owned PacifiCare subsidiary. Prescription Solutions serves 5 million beneficiaries, about 55% are from PacifiCare's health plans and 45% represent external clients. Prescription Solutions uses a contracted network of retail pharmacies along with company owned and operated mail service facilities to supply members with their required drugs. Prescription Solutions uses in-house developed coverage management systems and techniques to minimize member risk, utilization and cost. Its generic utilization rate is approximately 55% for its commercial business and almost 60% for its senior products. Additional information on PacifiCare can be found at their website: www.pacificare.com. Information on its pharmacy benefit manager, Prescription Solutions is at www.RxSolutions.com.

Geisinger Health Plan is among the largest rural health care plans in the nation and covers a 20,000 square mile area in northern and central Pennsylvania. Many of the residents in the area participate in the PACE Program reported in the Families USA Study. Geisinger Health Plan serves residents in 40 of Pennsylvania's 67 counties with a variety of health plan options.

Geisinger Health Plan created its own Pharmacy and Therapeutics committee to develop and maintain a specific list of preferred drugs. After using the services of an outside pharmacy benefit manager, it decided to develop its own capabilities, buying support services on an as-needed basis. Its current generic utilization rate is now 57%. Additionally, it has the enviable position of producing some of the best outcomes in the Pennsylvania Healthcare Cost Containment Council report, having the lowest hospital admission rate for hypertension of 0.8 per 10,000 members. More information on Geisinger can be found at: www.thehealthplan.com.

Employers

Health plans are not the only driving force behind the healthcare management tools that are being used to manage rising costs and improve quality of care. As the financier of the majority of Americans' health benefits, employers have a critical role. With double digit annual healthcare cost increases and drug cost trends in excess of 20%, employers need to maintain their ability to continue offering affordable, quality healthcare benefits. Successful and innovative employers develop tools that encourage cost effective and appropriate healthcare use and encourage employees to be smart healthcare consumers (see Exhibit 3 for one company's explanation of "What is a Preferred Drug List?").

Verizon Communications is the largest providers of wireline and wireless communications in the United States. A Fortune 10 company with approximately 190,000 employees, and 900,000 individuals covered by its health care programs, Verizon's global presence extends to 45 countries in the Americas, Europe, Asia and the Pacific.

In 2002, Verizon spent more than $2.4 billion on direct healthcare costs – slightly more than 3.5% of annual revenue. Spending for prescription drugs is over $600 million. Verizon's team is constantly evaluating and implementing new ways to provide quality healthcare that is cost effective for both employees and shareholders. Initiatives include:

- **The Leapfrog Group -** Verizon is a founding member of this group of large healthcare purchasers committed to improving healthcare. Leapfrog initiatives include paying incentive bonuses to hospitals that implement the following changes:
  - ➔ Computerized prescription orders in hospitals to avoid adverse drug events. Requiring hospital doctors to use a computerized order entry system would reduce the errors from hard-to-read handwriting.
  - ➔ Evidence-based hospital referrals.
  - ➔ Attention to critical care.

- **The Dx on Rx Initiative –** This initiative was drafted by Verizon's healthcare team and endorsed by the Pharmacy Council of the Washington Business Group on Health (WBGH). *Dx on Rx* is a proposal to place the diagnosis on a prescription. This can prevent medical errors by making sure that the dose matches the diagnosis and by eliminating the confusion caused by drugs with similar names and different uses. Medical plans won't pay medical claims without this information, and prescription drugs should be treated in a similar manner.

- **HEDIS and Beyond –** The Health Plan Employer Data & Information Set (HEDIS) is a data reporting system that has become an industry standard. And Verizon was one of 3 pilot cases to refine its original work. In the coming years, Verizon plan members will receive data on health plan quality ratings that can help inform their purchasing decisions.

- **The Pennsylvania Project –** This program, run in conjunction with Omnicare, Inc, a geriatrics healthcare company, addresses appropriate drug use and safety through pilot pharmaceutical case management projects. These include:
  - ➔ **Cisapride –** integrated pharmacy data identified patients and reduced the use of cisapride linked to adverse events in seniors, including death. The analysis of Verizon data found the odds of cisapride users dying was nearly 62% higher than for non-cisapride users, and cisapride users had 85% higher total medical and prescription drug costs (see Exhibit 4 for a description). This project produced fact-based information to share with physicians necessary to facilitate a change in drug treatment. It raised awareness that many of the current review protocols are not sufficient and/or appropriate for many individuals (in this case, seniors). Specifically, it raised awareness about cisapride and subsequently the FDA severely restricted use of this product.
  - ➔ **Heart Failure –** a project to increase physician prescribing of ACE inhibitors to retirees with a history of heart failure. It was based on analysis that showed two-thirds of Verizon's retirees and dependents with heart failure were *not* receiving these drugs, which are considered the standard of care under the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC7). The analysis also found that the odds of an ACE inhibitor user with congestive heart failure dying are 25% lower than they are for non-users.
  - ➔ **Falls and Fractures –** Approximately 350,000 hip fractures occur annually in seniors, and the mortality rate of these hip fractures is 25%. Long-term disability, including depression, occurs for an even greater percentage. The Verizon program aims to prevent falls and fractures in seniors by reducing the use of specific drugs linked as contributors to these events, often due to side effects such as dizziness or instability of gait. The specific drugs identified through this project were based on patient data.

States' Initiatives

Innovation is not limited to health plans and leading edge employer initiatives. States, either individually or collectively, are using proven techniques to make evidence-based decisions in selecting drugs covered under their programs with or without the need for more information. Many of the initiatives are driven by Medicaid, but all focus on spending money wisely so that programs can continue to serve the greatest number of beneficiaries with the highest quality of care. Managing drugs better also reduces other health care costs.

Drug Effectiveness Review Project – a Multi-state Initiative - States are leading the way among governments in finding ways to maintain and improve quality while purchasing drugs more economically.

In order to control costs and maintain quality, states are showing a growing interest in head to head comparisons of effectiveness in drugs within classes (e.g. between the various cholesterol lowering drugs known as statins or between the various anti-inflammatory drugs know as non-steroidal anti-inflammatories).

To obtain accurate information, the Institute for Evidence-based Policy at Oregon Health and Science University is leading a collaboration among interested states to commission evidence-based systematic reviews of worldwide research to find which drugs within a given class are most effective. The reviews are conducted by Evidence-based Practice Centers (EPCs). EPCs are research organizations designated by the U.S. Agency for Healthcare Research and Quality as fully qualified to perform evidence-based reviews for the U.S. Government. These reports are then used by the participating states to determine which drugs to cover for first line treatment. Since evaluation and selection is based on the facts presented in peer-reviewed studies, states using the information in the drug management process can be confident about the quality of the drugs selected. They can then encourage price competition among drug companies with similar products.

Among the top 50 drugs listed in the Families USA article, in classes already reviewed under the state-driven initiative the states found that:

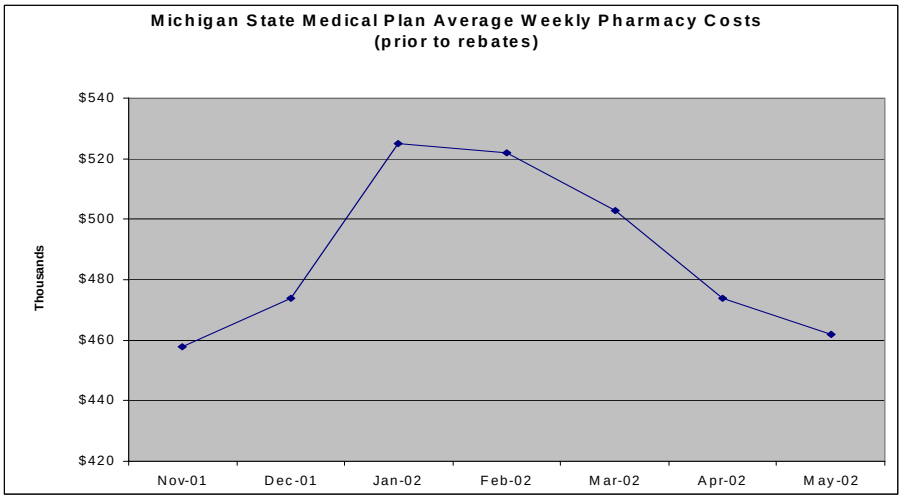
- Among cholesterol-lowering statin drugs lovastatin, a generic, was found to have equal to or better outcome data for the vast majority of individuals than all brand-name drugs in the same class at a fraction of the cost.
- Among proton pump inhibitors to prevent stomach acid formation, all agents had similar outcomes so states could confidently buy the least expensive of the class.
- Non-steroidal anti-inflammatory drugs—far more expensive brand-name medications showed virtually no significant additional benefit in reducing pain and inflammation than over-the-counter medications costing one-tenth as much.

For more information:

- On the results of the evidence-based reviews of therapeutic classes visit www.OregonRx.org and click on the "Reports" hyperlink in the middle of the page. There is also a hyperlink from www.AARP.org to the same material.

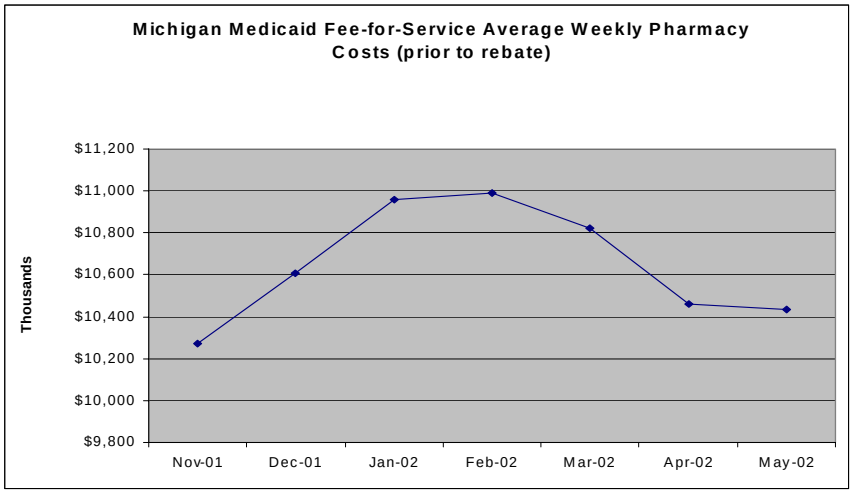
Michigan Pharmaceutical Best Practices Initiative

In 2001, Michigan was spending $1.1 billion in annual drug expenditures for beneficiaries covered under the Michigan Department of Community Health Program. Additionally, Medicaid recipients were growing at a rate of 10,000 per month.



The State decided to implement a "Pharmaceutical Product List" as a statewide drug program management tool to: maintain clinical efficacy in State drug program, improve health outcomes and patient quality of life, increase the number of recipients served and improve cost efficiency and overall healthcare cost management**.**

It accomplished this task by creating a Pharmacy & Therapeutic (P&T) committee, establishing and maintaining a pharmaceutical product list, managing start-up activities and prior authorization volumes and criteria.



Since the implementation of the Michigan Pharmaceutical Product List, the weekly pharmacy expenditure for the Medicaid fee-for-service and the State Medical Program has declined steadily and are over $620,000 below the average weekly expenditures of January 2002. Additionally, the average claim cost has been reduced by over $3.60 per claim.

For more information:

- For information presented by James K. Haverman, Jr. – Director, Michigan Department of Community Health at the October 26,2002 meeting of the National Conference of State Legislators see: www.kaisernetwork.org/health_cast/uploaded_files/MI-Rx-Viele-02Jul.pdf
- See www.michigan.gov for the Michigan Pharmaceutical Product List (MPPL)

Summary

When the federal government begins providing prescription drug coverage for Medicare beneficiaries, the government will have the power to influence the delivery system to provide the most appropriate care. By effectively managing the drug benefit, the government can spend less and improve integrated health care for Medicare beneficiaries. Additionally, better management of prescription drugs can help reduce medical expenditures, including hospitalizations and emergency care due to adverse drug events. Proven management tools will help the federal government provide a more valuable prescription drug benefit and improve the quality of life for Medicare beneficiaries.

Exhibit 1 – Cumulative price change of the top 50 drugs (by number of claims) used by the elderly (PACE program)

Rank by # of claims	Drug Name	Strength	Therapeutic Category	Cumulative Change 1998-2003	Multiple of CPI 1998-2003	2003 Cost/Year
1	Lipitor	10 mg	Lipid-Lowering Agent	30.80%	2.6	$ 871.00
2	Norvasc	5 mg	Calcium Channel Blocker	16.50%	1.4	$ 549.00
3	Fosamax	70 mg	Osteoporosis Treatment	nm	nm	$ 894.00
4	Plavix	75 mg	Anti-Platelet Agent	nm	nm	$ 1,539.00
5	Prilosec	20 mg	Gastrointestinal Agents	22.50%	1.9	$ 1,684.00
6	Celebrex	200 mg	Anti-Inflammatory/Analgesic	nm	nm	$ 2,102.00
7	furosemide	40 mg	Loop Diuretic	135.20%	11.4	$ 59.00
8	Zocor	20 mg	Lipid-Lowering Agent	25.20%	2.1	$ 1,674.00
9	Prevacid	30 mg	Gastrointestinal Agents	33.30%	2.8	$ 1,690.00
10	Norvasc	10 mg	Calcium Channel Blocker	0%	-	$ 794.00
11	Lipitor	20 mg	Lipid-Lowering Agent	29.20%	2.5	$ 1,330.00
12	Klor-Con M20	20 meq	Potassium Replacement	nm	nm	$ 386.00
13	Toprol XL	50 mg	Beta Blocker	42.80%	3.6	$ 277.00
14	Xalatan	0.005%	Glaucoma Treatment	34.80%	2.9	$ 186.00
15	Vioxx	25 mg	Anti-Inflammatory/Analgesic	nm	nm	$ 1,050.00
16	Lanoxin	0.125 mg	Cardiac Glycoside	36.60%	3.1	$ 88.00
17	Synthroid	0.1 mg	Synthetic Thyroid Agent	63.60%	5.4	$ 153.00
18	Synthroid	0.05 mg	Synthetic Thyroid Agent	63.80%	5.4	$ 136.00
19	metoprolol tartrate	50 mg	Beta Blocker	15.80%	1.3	$ 405.00
20	isosorbide mononitrate	30 mg	Anti-Anginal Agent	nm	nm	$ 407.00
21	Digitek	0.125 mg	Cardiac Glycoside	nm	nm	$ 69.00
22	isosorbide mononitrate	60 mg	Anti-Anginal Agent	nm	nm	$ 429.00
23	metoprolol tartrate	50 mg	Beta Blocker	20.30%	1.7	$ 405.00
24	Synthroid	0.075 mg	Synthetic Thyroid Agent	63.60%	5.4	$ 150.00
25	Zoloft	50 mg	Antidepressant	19.60%	1.7	$ 966.00
26	Protonix	40 mg	Gastrointestinal Agents	nm	nm	$ 1,282.00
27	Cozaar	50 mg	Angiotensin II Inhibitor	25.30%	2.1	$ 553.00
28	atenolol	25 mg	Beta Blocker	16.40%	1.4	$ 298.00

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Exhibit 1 – Cumulative price change of the top 50 drugs (by number of claims) used by the elderly (PACE program)

Rank by # of claims	Drug Name	Strength	Therapeutic Category	Cumulative Change 1998-2003	Multiple of CPI 1998-2003	2003 Cost/Year
29	Premarin	0.625 mg	Estrogen Replacement	88.50%	7.5	$ 324.00
30	furosemide	20 mg	Loop Diuretic	136.40%	11.5	$ 52.00
31	Zocor	40 mg	Lipid-Lowering Agent	25.20%	2.1	$ 1,674.00
32	Evista	60 mg	Osteoporosis Treatment	23.90%	2	$ 895.00
33	Nexium	40 mg	Gastrointestinal Agents	nm	nm	$ 1,614.00
34	Zocor	10 mg	Lipid-Lowering Agent	25.20%	2.1	$ 959.00
35	Combivent	1 mg	Respiratory Agent	54.00%	4.6	$ 10,868.00
36	Miacalcin	200 IU/act	Calcitonin Replacement	43.60%	3.7	$ 7,132.00
37	atenolol	50 mg	Beta Blocker	12.80%	1.1	$ 304.00
38	Pravachol	20 mg	Lipid-Lowering Agent	49.40%	4.2	$ 1,124.00
39	Paxil	20 mg	Antidepressant	31.70%	2.7	$ 1,031.00
40	Toprol XL	100 mg	Beta Blocker	42.80%	3.6	$ 416.00
41	Celexa	20 mg	Antidepressant	nm	nm	$ 880.00
42	hydrochlorothiazide	25 mg	Thiazide Diuretic	360.50%	30.5	$ 29.00
43	Glucotrol XL	10 mg	Oral Antidiabetic Agent	27.20%	2.3	$ 308.00
44	Klor-Con M10	10 meq	Potassium Replacement	72.10%	6.1	$ 342.00
45	furosemide	40 mg	Loop Diuretic	123.70%	10.4	$ 57.00
46	potassium chloride	10 meq	Potassium Replacement	81.50%	6.9	$ 221.00
47	Lanoxin	0.25 mg	Cardiac Glycoside	36.60%	3.1	$ 88.00
48	Claritin	10 mg	Non-Sedating Antihistamine	51.20%	4.3	$ 1,178.00
49	Diovan	80 mg	Angiotensin II Inhibitor	nm	nm	$ 567.00
50	HCTZ/triamterene	25-37.5 mg	Potassium Replacement	0%	-	$ 137.00

Notes:
nm - Not marketed during part or all of the period indicated

Data from the July 2003 Families USA Report. Source of data: Compiled by PRIME Institute from data published by the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE) and data found in PriceCheck, PC, published by MediSpan.

Exhibit 2 – Adverse Drug Events

Medication Errors
Evidence from three recent medical journal articles suggests patients, insurers and plan administrators should give a careful consideration to the issue of medication errors.

- Seniors are especially likely to suffer from medication errors. According to the April 2, 2003 issue of the *Journal of the American Medical Association*, elderly patients hospitalized for drug toxicity, such as hypoglycemia, digoxin toxicity, or hyperkalemia were up to 20 times more likely to have been prescribed an interacting drug in the week before hospitalization.
- Outpatients are at an even higher risk then hospitalized patients of some kind of medication error, says a study in the April 17, 2003 issue of the *New England Journal of Medicine*. 25% of the patients in the study had adverse drug events; 13% of these events were serious and 20% were preventable. Beneficiaries who are prescribed drugs outside of the hospital are not under constant supervision, they see their doctors sporadically, and they may not report all of their symptoms, side effects, and other medications. This is especially problematic when the patients are seniors, on several medications at once, and fill their prescriptions at different pharmacies or have memory problems.
- According to an editorial in the same issue of the *New England Journal of Medicine*, preexisting conditions such as Parkinson's or diabetes may increase the likelihood of medication errors.

In 1994, nearly 5% of all hospital admissions (for individuals of all ages) were attributable to drug reactions and interactions. Studies show at least 20% (some show almost 30%) of hospital admissions for Medicare-eligible patients are due to a medication error.
Causes are varied and include:

- Taking too many of one drug
- Taking too few or none of a prescribed drug
- Taking them inappropriately (before or after meals, with alcohol, etc.)
- Allergic reactions
- Drug-to-drug reactions
- The wrong product for the individual's health status

Seniors are more likely to have complications from taking medications. Complications may be minor or they may be severe and may result in death (see *Exhibit 4 - Propulsid*). The more drugs seniors take, the more complications they have. Many seniors take 1,000 pills a year. Repeated studies have identified drugs that should never be used by those 65 or over because of their side effects. Yet more than 15% of all prescriptions for seniors are for inappropriate drugs.
For seniors it is especially important to screen for duplicate therapy, adverse interactions with other prescription drugs, and contraindications of health conditions being treated by different doctors. OTCs, herbs and home remedies create additional complexities

Because of the imperfections of the medical system, patients must be smart healthcare consumers. They must:

- Monitor themselves carefully and report all symptoms to their doctors
- Disclose all medications that they are currently on, both prescribed and over-the-counter
- Help their doctors communicate with each other
- Realize that the drugs contained in their medicine cabinets can both save and cost lives.

Exhibit 2 – Adverse Drug Events

For More Information:

- See "Patient Safety: Adverse Drug Events in Ambulatory Care," *New England Journal of Medicine*, April 17, 2003, Vol. 348, No. 16
- See "Adverse Outpatient Drug Events – A Problem and an Opportunity," *New England Journal of Medicine*, April 17, 2003, Vol. 348, No. 16
- See "Drug-Drug Interactions Among Elderly Patients Hospitalized for Drug Toxicity," *Journal of the American Medical Association*, April 2, 2003, Vol. 289, No. 13

What Can Help

One way of remedying human mistakes is to increase the use of technology in medical settings. An article in the same issue of the *New England Journal of Medicine* states that "computer-based decision support can improve physicians' performance and, in some cases, patient outcomes." The IOM also urges a "paperless" healthcare system. Technology can monitor patients, analyze the data, compile it, and even suggest a course of action to the doctor. It can identify potential problems before a medical professional notices them. With technology, there can be fewer problems from calculation errors, patient mix-ups, drug interactions, doctors' infamous illegible handwriting, and more. However, this technology isn't perfect yet, so other problems in the system must be addressed too. Yet the one area which grew up in the technology age is outpatient pharmacy management. Here eligibility, coverage management and claim payment plus tens of thousands of edits on drug interactions and dosing are all handled electronically.

For More Information:

- See "A Broader Concept of Medical Errors," *New England Journal of Medicine*, December 12, 2002, Vol. 347, No. 24
- See *Crossing the Quality Chasm: A New Health System for the 21st Century*, Committee on Quality Health Care in America, Institute of Medicine, 2001.
- See "Errors Today and Errors Tomorrow," *New England Journal of Medicine*, June 19, 2003, Vol. 348, No. 25
- See *Fostering Rapid Advances in Health Care*, Committee on Rapid Advance Demonstration Projects: Health Care Finance and Delivery Systems, Institute of Medicine, 2003.
- See "Improving Safety with Information Technology," *New England Journal of Medicine*, June 19, 2003, Vol. 348, No. 25
- See "Patient Safety: Views of Practicing Physicians and the Public on Medical Errors," *New England Journal of Medicine*, December 12, 2002, Vol. 347, No. 24
- See *Priority Areas for National Health Action: Transforming Health Care Quality*, Committee on Identifying Priority Areas for Quality Improvement, Institute of Medicine, 2003.
- See *To Err is Human: Building a Safer Health System*, Committee on Quality Health Care in America, Institute of Medicine, 2000.

Exhibit 3 – Verizon Formulary Description

What is a Preferred Drug List? (a.k.a. "Formulary")

Background

The "sustainability" of comprehensive prescription drug coverage requires the integration of multiple plan components designed to align the clinical and financial interests of patients and plan resources. In brief – to encourage patient utilization of prescription medications on the same basis as if they were spending their own money while, at the same time, providing patients:

- Clinical support – about treatment options that (a) they may not be familiar with, and/or (b) that might be harmful to them, and
- Economic support – especially for an increasing number of high cost medications that patients might otherwise forego if drug coverage was not available.

The multiple plan components include:

- A commitment of coverage for safe, appropriate, and cost-effective prescription medications;
- Effective use of Retail and Mail Order resources – to balance both acute care and maintenance medication needs cost-effectively, and
- Effective use of (a) preferred, and (b) generic drugs when appropriate for the patient.

This supplement provides supporting information regarding **What is a Preferred Drug List (a.k.a. "Formulary")** as part of "sustainable" prescription drug coverage.

Preferred Drug List

The purpose of the proposed 'preferred' drug concept is to focus both prescribers and patients on the most clinically appropriate and cost-effective medication when there are multiple similar ("me too") medications available. Given a preferred drug list, plan design can work in two ways:

- to limit plan coverage to drugs on the list, unless a patient has gone through a review process to determine coverage eligibility, or,
- to provide lower patient co-payments for 'preferred drugs', and correspondingly, a higher patient share for 'non-preferred' drugs.

The first approach is what is commonly referred to as a "closed formulary" –limiting prescription coverage to only 'preferred' medications – with the exception that if the listed drugs are not effective for the patient, a non-listed drug becomes preferred. The "preferred' approach (second alternative) differentiates the patient's share of prescription costs – with patients responsible for a higher share of covered, but 'non-preferred' medications.

Exhibit 3 – Verizon Formulary Description

Preferred Drugs: The List

Any 'preferred' drug list does not limit patients to a single drug, a single manufacturer, or just a few options for each drug type. The list usually indicates a variety of 'preferred' drugs – often with considerable cost variance.

- Additions to the list of 'preferred' drugs are made as new branded products (or limited-use-generics that treat rare conditions) are approved by the Food and Drug Administration (FDA). Following FDA approval, drugs are evaluated for coverage and management in accordance with best-practice clinical guidelines, the plan's coverage criteria, etc. and may be selected for addition to the 'preferred' drug list.
- Deletions can also occur – drugs previously designated as 'preferred' can be moved to a 'non-preferred basis' – frequently when a new medication is found to be more effective or offer a higher value.

The 'preferred' or 'non-preferred' status will influence the patient's share of the prescription expense – but does *not* exclude coverage for 'non-preferred' drugs for those for whom it is deemed medically necessary on a "closed formulary," or for anyone on an increased cost formulary.

Preferred for Some Patients

Notations concerning appropriateness of use can also change from time-to-time as information about use for the broad population becomes available. In addition, as problems are identified with use in a particular population, a product that is generally 'preferred' could be footnoted as *not* preferred for children or seniors. For example, a footnote might indicate: *"Use by people 65 and older is generally not recommended. The side effects may not be obvious, but may be serious. Safer medication may be available. If used, lower dosages are recommended."*

Sometimes there may be other references footnoted in the 'preferred' drug list – to aid prescribers such as to caution a reduction in dose below the usual guidelines printed in the FDA-approved labeling. This type of footnote often results from experience concerning a drug's use after the clinical trial phase done to secure FDA approval. Pharmacy managers also use reports and clinical findings based on broad, population-based experience. In this case a footnoted text might be something such as *"The recommended dose for children under age 12 – or weighing less than 60 pounds – is often lower than the manufacturers' usual dosing guidelines."*

'Preferred' drug lists may also contain additional information including the best practice guidelines recommended by the body of experts for a specific condition such as hypertension, elevated cholesterol, mild, or moderate or severe asthma. For example, for hypertension, the 'preferred' drug list might show treatment recommendations from The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7). The explanations could be detailed including various degrees of hypertension (mild to severe), and with or without other conditions (diabetic, previous heart attack, etc.).

Costs such as indicators of relative costs of specific drugs or actual costs for a typical supply (such as $ or $$$$) are included in some preferred drug lists to assist physicians and plan members in making cost-effective choices appropriate for their condition.

Exhibit 4 – Pharmacy Intervention to Reduce Medication Risk

Reducing Cisapride Use Through a Targeted, Evidence-Based Intervention in At Risk Retirees of a Telecommunications Company.

W. Gary Erwin[1], Patricia L. Wilson[2], James A. Astuto[3]; [1]Omnicare, Inc., [2]Associates & Wilson, [3]Verizon Communications, Inc.

Purpose. This initiative was conducted to reduce risks of cisapride (Propulsid®)-associated arrhythmias in a telecommunications company's Medicare-eligible plan members with medical and/or drug risk factors. The telecommunications company, a founding member of The Leapfrog Group, undertook this initiative to improve the safety and overall value of its healthcare benefit for retirees. **Methods**. Cisapride was chosen because of its Unacceptable rating for treatment of GERD by Omnicare's *Geriatric Pharmaceutical Care Guidelines®*. An analysis of death rates between Medicare-eligible indemnity plan members who used cisapride (N=445) and members who did not (N=17,732) demonstrated that for those with both a medical and drug risk factor, the odds of a cisapride user (N=163) dying were 62% higher than for a non-cisapride user (N=4202) ($p<0.09$). Intervention "cases" were selected based upon presence of a medical risk factor (ICD9) and drug risk factor (NDC). Cases were forwarded to Omnicare pharmacists, who called targeted prescribers to request discontinuation of cisapride. If the prescriber could not be identified, the retiree was called directly. If the prescriber refused without sound clinical justification, a geriatrician then called. Drug therapy changes resulting from the intervention were forwarded to Verizon's pharmacy benefit manager. **Results**. 144 retiree cisapride users were identified with both medical and drug risk factors. Cisapride was discontinued in 112 (77.8%). At the close of the intervention, 15 (10.4%) prescribers had been contacted but had yet to make a change, 3 (2.1%) refused to discontinue without providing clinical justification, and 2 (1.4%) chose to continue the drug providing informed clinical justification. In 5 (3.5%) cases, no prescriber could ever be identified. **Conclusions**. A targeted, evidenced-based intervention by Omnicare pharmacists changed prescriber behavior by reducing the use of cisapride in at-risk retirees, thus improving the safety of a telecommunications company's drug benefit. The at-risk retirees, when called directly, were fully supportive of the intervention, forthcoming in their discussions, and thankful for the telecommunications company's efforts.

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Exhibit 5 – Plavix drug summary

How it works	FDA approved uses	FDA recommended dosing/PDR
• Keeps blood platelets from sticking together and forming clots • Shown to work only somewhat better than Aspirin	• The reduction of atherosclerotic events (myocardial infarction, stroke, and vascular death) in patients with atherosclerosis documented by: - recent stroke - recent myocardial infarction or - established peripheral arterial disease	• Recommended dose is 75 mg once daily with or without food • No optimal length of dosage provided in PDR • Only strength approved for manufacture is 75 mg • Average wholesale price (AWP) for 30 pills of 75 mg each is $114

Some FDA precautions (see attachment for full FDA labeling insert)

- While clinical trial data was deemed statistically significant, the results were marginal when compared with aspirin. Trial data is:

Outcome Events

	Plavix	Aspirin
Ischemic stroke*	438	461
Myocardial infarction*	275	333
Other vascular deaths	226	226

*fatal or not

Note: The event is the time to first occurrence of the new event

- For clinical trial "recent" was deemed to be:
  - within 6 months for stroke (with at least a week of residual neurological signs)
  - 35 days for myocardial infarction
- For clinical trials, peripheral arterial disease was objectively established
- Should be discontinued 7 days prior to surgery
- Should not be used when the patient has a tendency toward conditions that cause bleeding such as peptic ulcers or intercranial hemorrhage
- Patients should be notified that it takes longer than usual to stop bleeding and that they should report any unusual bleeding to their physician

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Exhibit 5 – Plavix facts and experience

Facts	Experience
Aspirin has been shown effective in reducing the recurrence of heart attack and stroke if taken daily	• Studies suggest aspirin alone has been shown to limit the formation of blood clots, reducing the risk of heart attack, stroke, or death by 30% in people with heart disease
Effectiveness of Plavix in preventing heart attack and stroke has been tested against over-the-counter aspirin (CAPRIE Study – Clopidogrel vs. Aspirin in Patients at Risk of Ischemic Events)	• Patients with recent history of heart attack, stroke, or arterial disease were separated into two groups – one given Plavix (75 mg/day), the other aspirin (375 mg/day) Patients received randomized treatment averaging 1.6 years • The overall incidence rate of heart attack and stroke for these patients was 10.6% for the aspirin group and 9.8% for those on Plavix. In other words, of these patients, 10.6% of those who took aspirin had recurrences to only 9.8% of those on Plavix. • Statistical significance of the relative reduction in risk by using Plavix vs. Aspirin was borderline, however (p=.045)
Researchers in the New England Journal of Medicine have recently conducted a study of the cost-effectiveness of aspirin and Plavix as a preventative measure in patients with coronary heart disease	• Plavix costs $3.22 per pill while aspirin is roughly $0.04 • Using a computer simulation of the United States population with relevant coronary heart disease rates, researchers found the following: - Extending aspirin therapy from its current level to all eligible patients (those for which aspirin isn't contra-indicated, or about 95% of the population) would cost about $11,000 per quality adjusted year of life gained - Giving clopidogrel to that 5% of the population that can't take aspirin would cost about $31,000 per quality adjusted year of life gained - If, however, you were to give clopidogrel to everyone, the tremendous additional cost combined with the relatively minimal positive outcome would cost more than $130,000 per quality adjusted year of life gained • These researchers therefore suggest, on the basis of relative cost effectiveness, the prescription of clopidogrel only in cases where the patient cannot take aspirin for some reason

Sources:

- New England Journal of Medicine; June 6, 2002 "Cost Effectiveness of Aspirin, Clopidogrel, or Both for Secondary Prevention of Coronary Heart Disease." Gaspoz, Coxson, Goldman, et al.

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Written Statement Submitted to

Department of Health and Human Services

Office of the Secretary, Office of Public Health and Science, Office of Disease Prevention and Health Promotion

on

National Action Plan to Assure the Appropriate Use of Therapeutic Agents in the Elderly

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May 2002

Part 1

You have asked for comments identifying the most important priorities to be considered in the development of a national action plan to assure the appropriate use of therapeutic agents by elderly Americans. We regret that many competing priorities precluded us from submitting comments earlier. However, we subscribe to "better late than never." We are now pleased to contribute our thoughts developed based on full careers as individuals (Loren Lipson as a patient-caregiver, researcher and teacher and Pat Wilson as a consultant to employers and health plans) and in our more than 15 years of collaboration on aging issues. Since drug overuse, underuse and misuse contribute to or impairs the health status of seniors, much of our work involves managing pharmacy to manage health.

Introductory Comments

When looking at large populations, use of healthcare services increases with age and services change from acute health episodes to continuous treatment of chronic conditions. Medicare beneficiaries tend to have more chronic health conditions, resulting in more physician visits and prescriptions, than younger individuals. Drugs are the primary treatment for most chronic conditions –hypertension, heart conditions, diabetes, etc. While drugs can be beneficial, they can also harm if they are not appropriate for a specific individual. Interactions, overmedication, doses too high, side effects like instability of gait, confusion– all of these endanger health and raise overall healthcare costs. And because the side effects of a particular drug, or combination of drugs, begets more side effects, more drugs are prescribed. It is a never-ending cycle. And those that suffer most are seniors.

Any Federally sponsored program has a significant effect- both positive and negative- on the economy and on health status. By providing the money, the financier dictates what will be delivered. Providing too much money for whatever the healthcare system and its myriad of practitioners want to deliver, is a formula for disaster. The disaster is both in terms of care and in terms of cost to taxpayers and beneficiaries.

Most of us have our own experiences with the effect of too many or the wrong drugs for our aging relatives. Unfortunately, many of these misadventures ended in death. If you have no experience, just go read the first paragraph of the Executive Summary of The Institute of Medicine's report *To Err is Human*. That report deals with a healthcare system that needs fixing. Two of the three medical misadventures used to make its points real to all of us, deal with drugs. And while this report focuses on problems in hospitals, drug "management" outside is no better. Various reports, including HHS-sponsored studies, document that for the Medicare-eligible population, between 20% and 30% of all hospital admissions result from a drug misadventure. The wrong drug, too high a dose, failure to take a needed medication are some examples, but the list goes on.

No one intends harm. They just don't know what they don't know. Additionally, the healthcare practitioners are not supported by *systems* that have as their goal helping them do their jobs better. Sometimes that means preventing errors. Sometimes that means helping pick products appropriate for Aunt Sophie, given her various medical conditions and the current mix of drugs deemed necessary by her various caregivers. Other times that means picking the least costly drug that will be effective for Cousin Ed.

In the design of a new Medicare program, we believe that money should be treated as a precious resource. Spending money on healthcare services and supplies that deliver value to the patient is a worthwhile goal. Spending money on healthcare services and supplies that do harm to patients is just dumb! And doing it in a program that at its core is based on electronic patient- and drug-specific data that is instantaneously accessible and usable, is the dumbest of all. A *smart system* can know all about Aunt Sophie and can know all about the side effects of different drugs, as they are likely to pertain to *her*. A *smart system* can support caregivers in choosing cost-effective products that work for Aunt Sophie. The choices made for her can be quite different than for Uncle Jim. The result is that care is better, value is delivered and money is not wasted on needless and harmful services.

With the graying of America, more services are needed. Few physicians specialize in geriatric medicine. As recent reports have so well documented, there aren't enough of these specialists to provide adequate service to seniors today much less to the aging baby boomers. And of those who specialize in geriatrics, only some specialize in managing drugs. However, most retirees go to general practitioners that may be not as well equipped to monitor prescription drug use and are currently not incented by Medicare to coordinate care with others attending to patient needs. Retirees tend to see multiple doctors and often no one has all of the important facts – not even the patient or a family member. *Smart systems* can help. And a Medicare-sponsored program can either lead or impede their development. For the benefit of all, we hope you will lead.

Important Priorities

You have asked that those contributing to the debate be selective in making suggestions about the most important priorities for a national program. We suggest the following five:

- Design for an electronic infrastructure
- Look at the service or supply you cover – you should set the rules
- Develop your own formulary. Close it. And develop rules that allow appropriate expansions of coverage in individual circumstances
- Use generics whenever you can and make them the cornerstone of drug classes wherever you can
- Be creative, flexible and take nothing for granted.

1. Design for an electronic infrastructure - When card and mail plans were first introduced, plan sponsors were looking for discounts on drugs and lower administrative fees than were paid for the paper claim approach. That's all. Nothing more. Few understood the value of data and what is at the heart of every PBM- electronic networks, infrastructures and computer-driven data manipulation. Remember that what now goes under the name of Medco Health Solutions started as a small division of CSC (Computer Sciences Corporation). The speed with which data is captured and used is mind boggling.

Today, PBMs are not all the same in how they view their job. Some view their job as being efficient claims processors, but do little to judge whether claims are eligible for coverage. A script written is a claim paid, albeit one that is tracked electronically. Some view themselves as drug managers. And some as health managers who help physicians select products that are

effective for their patients within the context of coverage rules. The coverage rules would include effective for the condition, supported by evidence and practice guidelines, safe, least costly etc.

The technology that PBMs use captures important data that can easily be transformed into useful information. Current uses vary from: determining eligibility for benefits, to what are the covered benefits, to prices to be paid to pharmacies and fees to be collected from plan members. But with more data, more is possible. For these reasons some employers and PBMs are looking to use the existing and new information in creative ways to manage their drug and medical plan and to improve the quality of care for patients. HHS should understand the possibilities and expand on them as the basis of coverage decisions. Some easy requirements that would benefit HHS management, improve efficiency and the likelihood that supplies meet the coverage rules to be established are to require:

- The diagnosis on the script
- The directions for use (e.g. *bid*, short for *bis in die* and meaning for us non-Latin scholars twice a day) be included as part of the electronic claim, along with the quantity and strength dispensed
- Special training or certification in a specialty for certain drugs treating complex conditions (whether as a consultant or as the script writer).

Electronic processing costs less than the antiquated paper claims approach and it allows drug utilization review (DUR) to occur before the script is filled – screening for allergies, interaction with other drugs the patient may be taking, age appropriateness, etc. It also creates a drug record for each patient which can be used to target disease management, wellness programs, and for additional DUR after the script is filled – screening for fraud, abuse and therapeutic evaluation. Coupled with patient-specific data even more important screenings can occur to identify and eliminate potential problems.

The relationship between prescription drug programs and medical plans and the data that each has is important for managing costs and care. The goal of integrating all components of the healthcare system is to decrease costs for a disease and improve care and quality outcomes. The development of electronic data interchange creates the ability to integrate medical and pharmacy data. Integrated plans can have one vendor who manages the medical and drug components, or they can have different vendors who share data. The number of vendors is not the issue, but rather how sophisticated their systems are and how well the vendors perform. HHS as a design sponsor can influence the development of *smarter systems*.

2. Look at the service or supply you cover- you should set the rules - To manage anything well, you must go beyond both the price for any service or supply and how much, if any, of it gets delivered (utilization). To get at the heart of the health cost problem requires managing not only *who pays*, but *how much* and *for what*. Management doesn't really exist unless you know exactly what you are purchasing. And care is compromised if the unit of service or supply is not what the patient needs. This focusing on the unit of service provided - a factor most overlook - we believe is the essence of an effective healthcare plan. A unit of service could be a lab test, a surgical procedure, a drug etc. Most efforts to reduce price and utilization have assumed that the

unit of service remains constant; in reality, it is continually changing. Those that focus on price and utilization are not asking questions like:

- Is the service or supply necessary for Aunt Sophie?
- Will she benefit and if so, in what way?
- Is it a generally accepted practice?
- Is it a new approach, but well grounded in science and likely to provide significant benefit?
- Is it elective, cosmetic or a custodial treatment not treating an illness or injury and not an eligible charge covered under the plan? etc.

In the case of drugs, the unit of service is constantly changing. From an H2RA to lifetime therapy with PPIs. From ibuprofen to COX 2s. From ACE inhibitors to angiotensin II receptor blockers. In many cases, the patient is no better off. But, because of dynamic pressures, exerted by those with an interest in influencing providers and patients, care changes because someone – the plan sponsor or funder of services – allows it to change. They are not exercising an appropriate but different pressure on the dynamic marketplace. This failure to anticipate dynamics and respond appropriately leaves the marketplace subject to special-interest pressures.

We approach healthcare with a few simple premises. Whenever evidence indicates that the newer therapy delivers value, it should be covered. Wherever there is no evidence and it costs more, as most new things do, it should not. Congress and the federal government are the funders of the Medicare program in that they collect dollars from various taxpayers and funnel it to various providers for covered services. State legislatures and administrations are sponsors of the Medicaid programs. As such, all should have a say in establishing coverage rules, if they simply have the resolve to set them.

Analyzing the unit of service goes beyond defining physical parameters or looking for unbundling, etc. It raises issues of quality and appropriateness of care. Both affect the rate of growth in health benefit costs. So as we consider expansion of drugs under the Medicare program, it is important to define what you cover and establish the rules for how you will determine if the rules are satisfied. Fortunately you have an electronic and data-driven system so this can be done efficiently *if you* set the rules.

Do not assume that a PBM will do it for you. You must tell them. Focus on what you mean by "medically necessary" or skip the term altogether and go to the elements of coverage. Things like "must treat an illness that the individual has" are made easy because you now have the diagnosis on the script. One rule that should be important for a plan administered by HHS is that the individual should have a condition for which the FDA has approved the use of the drug. Off label use should only be covered when there is sufficient evidence to indicate that it is effective. The evidence should be such that those who are tied to the pharmaceutical manufacturers do not unduly influence it.

Just as it is important to set the rules for what you cover, you should set the rules for what you don't. Listed below are the most common exclusions from employer and managed care plans.

Most common plan exclusion:

- Drugs that don't meet the coverage criteria (e.g. appropriate and effective for the individual etc.)
- Drugs used for experimental purposes
- Drugs for cosmetic purposes including Rogaine, Vaniqua, Solage and Retin-A when used for age spots and as a wrinkle cream
- Weight loss aids
- Drugs that don't treat an illness or injury
- Prescription and OTC vitamins
- Nicotine gum and other smoking deterrents whether OTC or prescription
- Drugs that are highly elective. This could include Viagra, Lamisil for toenail fungus, etc.
- Fertility drugs
- Biologicals unless they are a named inclusion

But the devil is the details. There is significant discrepancy between *how* plans are actually administered by the various administrators- in this case a PBM. For example, you could exclude either experimental drugs or drugs used for experimental purposes, and cover growth hormones for dwarfism but deny coverage to increase muscle mass in the bedridden elderly. Similarly plans might cover Botox for cervical dystonia because it would generally fall under the definition of an illness but deny claims for galbellar lines. No to wrinkles!

There are important distinctions between *exclusions* where a particular drug or type of drug is not covered at all and *restrictions* where use of a drug is limited in some way. It is often hard to enforce these rules in an indemnity plan because information about the use of the drug is often not captured. For example, in many plans, prescription vitamins are only covered during pregnancy, but information about whether or not the patient is pregnant is not captured during drug claim processing. Or, a drug may be FDA approved for a certain use, but experimental for treatment of another condition and the claims processor doesn't know which is applicable. By having the diagnosis on the script, it will be mush easier to efficiently process claims and to deny those that should not be covered under the program. That gets us back to Priority 1 and the importance of a data-driven system. - **Dx on Rx** is the mantra**.**

3. Develop your own formulary. Close it. And develop rules that allow appropriate expansions of coverage in individual circumstances. - A formulary is described by most folks as a list of preferred drugs for use in a specific plan. If properly developed, it is useful in managing both care and its cost. Negotiated manufacturer rebates may also lower cost but may not be a factor in a national plan. If a factor, the rebate should only be an issue in determining the cost of a drug to compare to another choice to determine where the most value is delivered. Formularies – whether or not manufacturer rebates continue or are dealt a fatal blow - are important management tools for drug plans and influence drug selection by doctors and patients.

Any formulary as currently conceived and established only addresses the issue of treatments that are *generally* safe and effective. On a patient by patient basis, this is an irrelevant concept. The only important issue is what is safe and effective for me, or for Cousin Jim or Uncle Bruce. So

while the most cost-effective treatment for most cases will come from Formulary Drugs X, Y and Z, if there is evidence that another treatment is necessary, it should be covered. But to quote a client, the reasons can't be based on "might as well healthcare".

Drug manufacturer marketing both to physicians and to patients makes the closed formulary an important design tool. But given the clout of the pharmaceutical industry, it may be difficult to implement. Yet without it, we believe you doom a national program to failure. We cannot afford a program that simply allows patients to fill prescriptions for whatever a physician chooses to prescribe. Just turn on the television or flip through a magazine and you'll find pharmaceutical companies advertising their drugs directly to the public. The ads direct patients to ask their doctor about their product and may even include a list of doctors or a monetary incentive to see a doctor. The ads never mention costs and often the information about side effects, effectiveness and when using the drug would be inadvisable is in small print and may not even appear on the same page as the advertisement. This advertising is causing patients to ask their doctors for the miracle drugs they've read about or ask why they prescribed one medicine and not the other they saw advertised. The problem is that many of these drugs are no better than older alternatives. Switching to them means we can't gain the advantage of a competitive marketplace with multiple manufacturers.

As you contemplate the design of a national program, you may assume that patients may find the answer "it's not on your formulary" unacceptable. While patient resistance is an issue, it's only one factor. An equally important factor is the continued sustainability of the plan itself. Without controls inherent in the initial plan, you doom it to failure.

4. Use generics whenever you can and make them the cornerstone of drug classes wherever you can - Generics have chemically identical active ingredients, are available from multiple manufacturers, are not patent-protected, and cost less – in many cases, significantly less. Given our premise that money is a precious resource, paying more than you have to for something that is no better - or even marginally better - is imprudent.

Employers and state Medicaid plans have learned the lesson. Plans who only gently encourage generics are a dying breed. More forceful tactics are required. Dying are the days where plan sponsors are reluctant to influence a doctor's decision in any way. While resolve to tackle the issues has been slow in coming, many are exercising their fiduciary and management responsibilities and duties. With significant numbers of brand name products' patents due to expire, we expect even more plans to get even more aggressive in encouraging use of generics in the future.

Some employers' plans call for generic substitution unless the prescription is marked DAW (Dispense As Written). In some states this is permissible, in other states the physician must actually prescribe a generic for it to be dispensed. But all too often the physician just writes DAW for the brand with only a belief, based largely on drug company marketing, that the generic is inferior. But you already have some effective tools to use to counter the ill founded beliefs. We particularly like the one from the inside back cover of the September-October issue of FDA Consumer.

"If you're experiencing anxiety about taking your

generic drug,

read this ad and repeat as needed.

The FDA ensures that your generic drug is safe and effective. All generic drugs are put through a rigorous, multi-step approval process. From quality and performance to manufacturing and labeling, everything must meet the FDA's high standards. We make it tough to become a generic drug in America so it's easy for you to rest assured.
Visit www.fda.gov/cder/ or call 1-888-INFO-FDA to learn more.

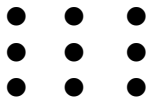
Generic Drugs: Safe. Effective. FDA Approved."

The following chart shows the methods managed plans most typically use to encourage generics.

How plans encourage generics:

- Copay/coinsurance is less for generics
- Closed formulary that is based on generics only in many classes(H2RAs, Ace Inhibitors)
- Charges for branded drugs limited to cost of generic- member pays the full difference in cost even if the physician indicates that the Brand is to be Dispensed as Written(DAW)
- Communicate about price differences- to both patients and physicians
- Communicate about quality control of generic manufacturing process
- Establish a *short* list of drugs that are available as Brands and as generics for which the patient will not be penalized by having to pay more for the Brand. Publish the list and describe why these drugs are treated differently
- Establish procedures to handle the exception for the patient who can't take the generic – when a nonformulary brand is the preferred agent for Aunt Sophie
- Pay pharmacist a higher dispensing fee for generics

5. Be Creative, Flexible And Take Nothing For Granted - Here's a problem we've seen used many times: How do you connect all these dots with just four lines – without lifting your pencil from the paper?



If you're like us, you may forget the solution. You'll have trouble finding it if you're constrained by what you think are the rules of the game or if your focus is too narrow. The key to this puzzle lies in looking outside the grid of nine dots. There's a lesson here for those of us grappling with rising healthcare costs- particularly for those 65 and over. The healthcare system is dynamic, and the rules are constantly changing. To be effective, our thinking must be creative and flexible.

A creative approach to benefit cost management is looking for ways to buy better medical services for less money. There's much room for improvement in the quality of retiree healthcare. The elderly tend to be over-medicated, over-dosed, and over-scalpeled – and their care tends to be under-coordinated. Improving quality of care – and reducing the price you pay for it – takes the resolve to deal with providers – including drug manufacturers, physicians, pharmacists, etc. - not as adversaries but as cooperative business partners, like any other supplier of goods and services.

Healthcare has become big business, and plan financiers who drive the system – governments, employers, etc. - can gain advantages by following sound business practices in dealing with providers. They must use their purchasing power, negotiate, and shop for the best value and exercise their responsibility to say what the plan covers. Retirees can also play a role in improving the quality of care they receive – if all help them become better healthcare buyers.

One way to control retiree healthcare liability is to give more of the financial responsibility to retirees. Another way is to broaden focus beyond the dollars which finance care to the care itself. By managing the type, number and quality of services delivered to retirees or purchased by them, plan financiers – including the U.S. Government can create a win-win situation for themselves and plan beneficiaries.

Closing Comments

In providing financing of drug coverage for Medicare beneficiaries, the government also has the power to influence the delivery system to provide more appropriate care to covered groups. He who has the gold makes the rules! By spending *smarter*, we can spend less – and improve quality of life. Better management of prescription drug benefits can help eliminate other expenditures; for example, hospitalizations due to inappropriate medications, or extended hospital stays from overuse of sedatives. If you fail to exert your power – some would say your responsibility – and you simply expand coverage without addressing what's wrong with how care is now delivered, we all assuredly will spend more. And older Americans will continue to lose out in a healthcare system that doesn't serve their needs as well as it should.

The health and security of our retired American's should be assured through thoughtful, informed change to our current system. This call for ideas before you finalize plans represents but a first step in that process – a process in which we all should become involved.

An Example - Neurontin (gabapentin)

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Office of the Secretary, Office of Public Health and Science, Office of Disease Prevention and Health Promotion

on

National Action Plan to Assure the Appropriate Use of Therapeutic Agents in the Elderly

Part 2

Earlier this year, we responded to Health and Human Service's call for ideas on the most important priorities to consider in developing a national action plan to assure the appropriate use of medications by seniors. In our previous statement, we suggested the following top five priorities for a national program:

- *Design for an electronic infrastructure*
- *Look at the service or supply you cover – you should set the rules*
- *Develop your own formulary. Close it. And develop rules that allow appropriate expansions of coverage in individual circumstances.*
- *Use generics whenever you can and make them the cornerstone of drug classes wherever you can*
- *Be creative, flexible and take nothing for granted*.

We selected those ideas formulated during a lifetime of work involving identifying and solving problems. We tried hard to choose words to make the concepts real to readers. As is usually the case, *the linkage* between ideas is as important as each idea is as a unique concept. In other words, what is possible manifests itself when the ideas are linked together and put into practice.

The national debate to develop a sustainable expansion to Medicare's existing comprehensive physician and hospital benefits was center stage in the recent 2002 elections. The specific initiative has yet to be developed in sufficient detail so that a sustainable drug benefit becomes a reality. In part that program would deliver medications appropriate for covered individuals.

Examples make concepts clearer. This paper is an example of how the 5 selected priorities come into play using just one drug- Neurontin (gabapentin). It is intended to illustrate how our suggestions promote better healthcare and appropriate coverage and could be used in an environment where pharmacy is managed in a systematic way to deliver benefits appropriate for a covered individual. In part that means we will point out how things work now in the "managed" pharmacy environment. And to provide additional clarity, we will mention how some could think things work, but don't.

We do not presume in this paper to cover all of the details concerning the drug's specifics. Nor do we presume that the readers of this paper have, or should have, a medical background - in fact one of its authors has no medical school, nursing or pharmaceutical training. Yet it is important to look at some information about a drug and its coverage under any plan of benefits (whether Medicare, Medicaid or an employer or union-sponsored program) if the goal is to provide coverage for care appropriate for the individual and an expense appropriate for coverage under any benefit plan. We have created summaries to help readers become familiar with background on the drug, with additional references for those who want to read more. We welcome edits and improvements and other thoughts that contribute to the goal of appropriate coverage of medications for all.

Neurontin

Background on the Drug

Under the standards established to safeguard Americans, the Food and Drug Administration (FDA) is responsible for determining if medications (whether drugs or biologicals) are generally safe and effective for use. As part of the initial investigation, whenever a medication is found to be unsafe for use for any subset of the population, information is presented in the labeling approved by FDA. This might relate to use:

- During pregnancy
- By someone with another condition (like kidney problems)
- While taking another medication where a severe interaction has been identified, etc.

Doctors can (and do) prescribe drugs in any way they believe will best help their patient. The prescribing may be for conditions that have not been approved by the FDA as both safe and effective. This is called off-label prescribing. The hope is that there is:

- Fact-based evidence readily available to the prescriber of the benefits of a non-FDA approved use
- Time for the prescriber to review it
- No undue influence by those who benefit from use
- Value delivered to patients for the treatment selected by the physician
- No harm done to the patient.

While it is legal for the prescriber to write scripts for off-label uses, it is, however, illegal for a drug maker to actively promote a medicine for conditions where it has not been demonstrated to the FDA that it is safe and effective for that purpose.

Until recently the only FDA approved use of Neurontin was as adjunctive (add-on or in addition to) therapy in the treatment of partial seizures for patients with epilepsy. Recently (June 2002) the FDA approved Neurontin for postherpetic neuralgia (the treatment of pain after herpes). According to a lawsuit, Warner-Lambert (which has since been acquired by Pfizer) has been actively marketing Neurontin for 11 specific off-label uses. The FDA has now approved one of those 11 uses. There are reports that the off-label marketing was often supported with nothing but anecdotal evidence often sponsored or created by the drug company, with little or no hard data. For some conditions they also promoted dosages that exceeded FDA-approved guidelines. See the next section for more on the misconduct allegations and the attached documents with more drug specifics.

Why we chose it as our example

1. It's in the news - It's topical. In part that means that some readers can relate to the information presented here because it is not new. Others who have not read recent articles about Neurontin can easily search out information for themselves. Here are some of the actions reported in articles in *The New York Times*[1], the *Wall Street Journal*[2] and in *Worst Pills Best*

[1] The New York Times. Melody Petersen: March 14, 2002, May 15,2002 and October 29, 2002
[2] The Wall Street Journal. Rachel Zimmerman: November 8, 2002

Pills News[3], a publication of the Public Citizen Health Research Group. Reports were based on interviews, basic legwork and court documents in the lawsuit brought by Dr. David P. Franklin, a former Warner-Lambert employee. The allegations are:

- In exchange for money, physicians allowed pharmaceutical sales reps into their examining rooms to meet with patients, review medical charts and recommend off-label use.
- Marketing executives at Warner-Lambert urged their superiors to let them promote Neurontin for unapproved uses rather than perform the clinical studies needed to prove the medicine was safe for such patients. They recommended against doing studies because of the short time that they expected the company to be able to sell the drug exclusively before the patent expired. They recommended that Neurontin be promoted for the unapproved condition through educational courses.
- Warner-Lambert tried to influence doctors who wrote medical journal articles about Neurontin by paying them, sometimes secretly, and hiring a marketing company to write first drafts. Warner-Lambert hired two marketing firms to write articles about the unapproved uses of Neurontin and to find doctors willing to sign their name to them as authors. According to an invoice from one of the marketing firms, Warner-Lambert agreed to pay the firm $12,000 for each article and $1,000 for each doctor willing to serve as author. Internal memos detail how the marketing firm often wrote a first draft, but sometimes had problems finding an author. The articles were then reviewed and approved by Warner-Lambert before they were sent to journals for publication.
- Warner-Lambert gave financial incentives to hundreds of doctors to prescribe Neurontin for unapproved uses by inviting them to dinners and weekend trips to resorts. They also paid doctors to speak about Neurontin and to prescribe it to patients who were enrolled in the company's clinical trials.
- Warner-Lambert tracked prescriptions written by doctors after they attended dinner meetings paid for by the drug company at which Neurontin was discussed. Doctors attending the dinners wrote 70% more prescriptions for Neurontin than doctors who did not attend.
- Although Neurontin is approved as adjunct therapy for epilepsy, a marketing executive at Warner-Lambert in a recorded voice-mail message that is part of the lawsuit told sales reps to promote monotherapy.

In a public interview, Dr. Franklin, a former research fellow at Harvard Medical School said he was most troubled by the company's insistence that he press doctors to prescribe Neurontin in much higher doses than had been approved. Several marketing executives had told him that because Neurontin appeared to be safe in high doses it was reasonable to encourage doctors to try it for almost any neurological condition "just to see what happened."

The list of reported questionable tactics goes on and the drug manufacturer will answer charges in court. At the very worst, much of the evidence of effectiveness is tainted. That in turn may have resulted in harm being done to those who used the drug. At the very best, individuals and firms who often appeal to us as working to improve patient care and reduce suffering, come off as a Ron Popeil competitor for the marketing genius award for the year. But marketing pills is not the same as marketing chicken rotisseries.

2. We got snookered (a technical term). Making a mistake should always be a learning experience. This time perhaps others can learn by seeing where we went wrong. What we did

[3] Worst Pills, Best Pills News. May and September 2002

was to violate one of our work standards - take nothing for granted when it comes to managing pharmacy to manage health. It is so important that we selected it as one of only five for your consideration.

Here is what we did. Several years ago we looked at use of Neurontin because it moved into the top 20 for drug spend. Seeing that at that time its only approved use was for epilepsy, we *presumed* that further management should not be a high priority. Reasoning went like this. Most patients were under the care of neurologists. Neurologists were managing use so that it was both standard- and fact- based and the resulting care was appropriate with costs being an eligible expense under either employer-sponsored and self-insured ERISA medical plans or health plans where we provide consulting services.

What should we have done? Some simple calculations to determine if experience is reasonable! According to the U.S. Bureau of Vital Statistics there are about 5.1 epileptics per 1,000 Americans. One client has 537,000 lives in all 50 states covered under several plans but managed by one PBM. That means we could expect about 2,738 epileptics. If we wanted to cross check the number based on the age characteristics of the group, we would expect about 2,937. And then not all of the epileptics would use Neurontin as part of their therapy. If the number is even as high as 50%, that would mean that we should expect about 1,400 users. We could further refine the process for sexes and geographic characteristics but all are in the same ballpark.

So how many Neurontin users are there in this population? 8500! It is interesting to note that this is right in line with the quoted off- label use-83% here vs 78% referenced in articles and court documents. Having identified inconsistencies, we would then have looked further to explain the experience. We did not because **we took for granted** that all users were epileptics and that treatment is evidence-based and appropriate. Had we not violated an important principle (Take nothing for granted) we should not have had to rely on the testimony from the court case now pending to determine that use was off by many multiples of what was reasonable. We believe that experience under any plan is a result of what many do or fail to do. By checking the experience, we can determine the factors driving it and whether the experience is reasonable given current plan provisions and the goal of appropriate care under a sustainable plan of benefits.

Medicaid got snookered too! Since epilepsy prevalence is not linear and is most prevalent in young children and in older seniors (the two groups who make up the largest numbers of covered lives under any Medicaid program), their reasonable estimate would be based on age bands– perhaps with some adjustment for economic variables. Then they too would have known that use was out of kilter and they should look further to explain the experience. They would not just now be trying to recoup inappropriately billed charges.

3. It's a big number and it matters. In 2000, Neurontin earned $1.3 billion. Media reports that as much as 78% of these sales were for non-FDA approved uses without evidence that the drug was safe and effective. *Drug Topics*, a magazine for pharmacists, and based on statistics from Scott-Levin, lists 2001 Neurontin sales in retail drugstores:

- $1,485,674,000(ranked 16th for $s)
- 13,261,000 scripts(ranked 31st for scripts)
- Average price per Rx of $112.

4. It's not just about money and whether it is wasted. It's about care appropriate for all, including Aunt Sophie.

Given the side effects of this product, use by some is likely to cause problems that may continue if not linked back to the drug. Those side effects may be attributed to other things including depression. The prevalence of both dizziness and drowsiness are significant. It would appear that it is this side effect that takes the edge off, that may cause it to have been promoted for these off-label uses like ADD, pain, and bipolar disorder. Yet for seniors, both of these side effects are more significant since they can lead to a slip and a fall with a resulting fracture.

While the labeling suggests that dosing should be carefully selected in seniors, the maximum dose edit in pharmacy benefit manager (PBM) systems are set at what we refer to "as kill a horse" levels-3600 mg per day. Anything less than this and no edit is triggered even if the member is age 80. Further there is no distinction between dosing appropriate for epilepsy or postherpetic neuralgia. Why? Because the PBM does not routinely know the diagnosis. And even if they did also have the medical claims with its codes, the PBMs have not refined their systems to make smart edits that go beyond the general rules. Nor have they demanded that the vendors from whom they buy their basic screening modules, do it differently. Nor is there any edit for an initial script where the starting dose is at maintenance level rather than at the recommended starting dose. It would be reasonable to assume that many of these edits are built in as system safeguards. They are not and because they are not, Aunt Sophie may get more than she should.

Applying our 5 priorities to Neurontin

Here is how the Neurontin example applies to each of the 5 important priorities we previously submitted.

1. ***Plan for an electronic infrastructure***: An electronic infrastructure provides many tools for checking for appropriate and safe use of medications. Using a smart systems' approach, here are some ways to identify appropriate use of Neurontin that should be covered as an expense under a plan:

- Identify all patients taking the drug who are on other epilepsy (Neurontin is recommended as add -on treatment) or herpes drugs. Those scripts could process without further inquiry - whether done by the system or involving physician outreach. For other scripts, establish procedures to ask questions about its intended use.
- If you planned ahead and required the diagnosis on the script (**Dx on Rx**) check the diagnosis against one or two tables input in the claims adjudication software. One table could contain only the FDA approved uses. Another could contain uses that might be approved by various groups as appropriate treatment. For example, if you accepted *Facts and Comparisons* as a source for generally accepted off-label uses, your table for acceptable off label use would contain the following:
  - tremors associated with multiple sclerosis
  - neuropathic pain
  - bipolar disorder
  - migraine prophylaxis.
- Identify the patient's age and determine if the dose is within guidelines. This might require multiple dosing tables for different conditions and for other circumstances-with age being the

most prevalent. Effectively the smart system would have a 3 dimensional array of tables containing dosing information and the patient's characteristics would pick the appropriate one.

- Periodically review the drug data against other significant medical events. For example, look at the Part A data for frequency of slips and falls with a resulting broken bone. We suspect you would find more than you expect. Why? Because the dose may be too high for seniors and the side effect profile, much like sleeping pills, is such that it contributes to the fall and the resulting broken bone.
- Identify the prescriber as an individual licensed to write scripts in the U.S. If not licensed, the claim is denied.
- Identify the *sig* and correlate the quantity dispensed for a specific duration of time (say 30 days) to the number of pills being dispensed. Further check this against the drugs dosing recommendations to determine if it is reasonable. For example, if 30 pills are being requested for 30 days of treatment, yet dosing guidelines are for multiple pills a day, there is a disconnect. Too much product is just as much an issue as too little. Yet this is a simple edit, made possible by the *sig* if the goal is appropriate care. Further if the ultimate sharing of costs between beneficiaries and CMS is a flat dollar copay design instead of a percentage coinsurance, this is an important edit to preclude stockpiling and other fraud.

The list goes on. The important point is that if the system planned for an electronic infrastructure, it could provide a diagnosis code, *sig* code and other important data that could be used to screen for appropriate use, inappropriate off-label use, etc. Systems/programs (coverage review, denial/appeal process, etc.) could then be designed to determine when and under what circumstances coverage of a drug is acceptable in a Federally sponsored program when that drug has not been sanctioned by the FDA as safe and effective for that use. The end result is data connected in an on-line, real time system, creates improvements in care.

A second important point is that drug choices are expanding (with both new chemical compounds and DNA derivatives) at a time when there is significant time pressure on physicians. Many physicians are not able to stay current with these rapid changes. The electronic infrastructure supports them in getting the information they need to make the best choice for each of their patients.

2. *Look at the service or supply you cover – you should set the rules:* The FDA is the primary resource for determining coverage criteria in terms of approved uses and dosage. Off-label use may be appropriate when endorsed by sub-specialties or a broad or common consensus. One example is DESI drugs. They are still currently used by many and should be considered as covered drugs under a federally sponsored plan, even though they may not have been approved by the FDA.

Off-label use should only be covered when there is sufficient evidence to indicate that it is effective. And the evidence should be such that those who are tied to the pharmaceutical manufacturers do not unduly influence it. In the Neurontin case currently pending, allegedly the drug manufacturer illegally and falsely represented the drug's benefits to doctors and patients who then use it so that it becomes an accepted off-label use. The current evidence for off-label use for Neurontin does not pass the sniff test.

CMS should set the rules for coverage. Those rules should also address the strength, step dosing and administrative rules for routine follow-up. For example, Neurontin is recommended to start at a low dose and then be titrated up. These rules can all be easily built into the electronic infrastructure that adjudicates claims. The design of a Medicare-sponsored drug program can make it happen. Alternatively, Medicaid can set requirements for PMBs who process their claims.

In setting rules you can look to the literature to determine where value is delivered and for which subsets of the population it becomes a covered product. The litmus test is that it is appropriate, treats the illness or injury, evidence-based, in accordance with generally accepted guidelines, least costly effective therapy, etc. These become the general coverage criteria used to guide all future decisions about coverage rules in specific circumstances. The point is that Neurontin - as an example of any product - is not always covered or always excluded. The rules will determine that. But you should set the rules that are administered by any PBM. This also ensures that coverage will be the same based on similar facts and circumstances and the rule you establish rather than the vagaries of one administrator who may administer your program in a specific geographic area.

3. ***Develop your own formulary. Close it. And develop rules that allow appropriate expansions of coverage in individual circumstances:*** A thorough review by a national P&T committee set up for this purpose would be necessary to determine whether Neurontin would be on a formulary for a senior population. Currently the drug is being used off-label as a chemical restraint in nursing homes. While with proper dosing and monitoring this may be beneficial to a select population, there have been reports of egregious abuse of this drug in nursing homes. One case alleges that high dose (off-label) usage contributed to lethargy, loss of appetite and dehydration, which lead to immobility, bedsores, and eventually amputation of both legs.

Neurontin also has significant side effects that can lead to serious complications for seniors. See the attached *Neurontin – facts and experience* for more information on side effects. It's likely that inclusion of Neurontin on a formulary for seniors would be limited to a select population, low dosages and require proper monitoring-including creatinine levels. Currently many PBMs set a single *kill a horse dose* for Neurontin that applies for all uses and for all groups, including the elderly. An edit is not triggered unless this maximum dosage is exceeded. Dosing edits need to be customized so that each individual gets the right amount. The system knows lots about covered individuals. That information can be used in improved systems of care that make it appropriate for Aunt Sophie.

Purepac Pharmaceuticals, a subsidiary of Alphapharm, is in approvable status to manufacture a generic. Once the generic is available, you need to decide whether Neurontin™ would then continue to be covered or whether it would be considered non-formulary and then either excluded (if a closed formulary as we suggest) or subject to a different copayment structure. If it continued to be on formulary, would it affect the price the covered individual would pay if they chose the brand over the generic. You might conclude that even in a closed formulary when the drug is used currently by a Medicare beneficiary to treat epilepsy or another seizure disorder that you judge as appropriate, you would cover the brand for existing patients. All new patients would however start on the generic. Price is an issue because it contributes to the sustainability of the program. But appropriateness is the overriding issue.

Drug development and sales is a business, and the product pipeline is important. The pipeline includes both new innovative products with lifesaving benefits as well as marginally different products with few, if any benefits. These new drugs are sold with highly-effective marketing to physicians and users. Most often these new products are brought to market just in time to precede loss of exclusivity for a marginally different drug. Pfizer has been working on pregabalin, the replacement for Neurontin (gabapentin). In 2000 press releases, Pfizer anticipated filing in 2001 in the US for 7 major indications. Some are for the 10 off-label uses of Neurontin. Clinical trials are also under way for today's big money making "illnesses" – generalized or social anxiety disorders. According to Pfizer's September 6, 2002 press release, pregabalin will now not be submitted to both the FDA and European regulators until 2003. CMS's coverage decision about the new drug when available, should be made in light of the then existing brand Neurontin and its generic gabapentin. Cost is one issue, since there is no money to waste. But equally important is the rules under which each product becomes the covered preferred agent.

4. ***Use generics whenever you can and make them the cornerstone of drug classes wherever you can.*** Currently this priority doesn't directly impact the Neurontin example. The patent is due to expire in 2003. However our guess is that now that it is a blockbuster drug (number 16 on the top 200 brand-name drugs by retail sales in 2001 with total retail sales exceeding 1.4 billion dollars), Pfizer will employ the usual drug manufacturer machinations to extend the patent and delay the generic. A 30-month extension could get them beyond an anticipated approval date for pregabalin, the presumed pipeline replacement drug. But when in consort with priorities 2 and 3 you could determine that gabapentin is the preferred drug, with both the brands (Neurontin and the to be determined trademarked name for pregabalin) generally not covered. You could also set a HCFA (when will the name change to CMS MAC?) MAC sooner rather than later, so that you benefit from a competitive price even though there may be only one generic manufacturer.

Coverage exceptions could be made where evidence exists that either brands are the preferred agent for subsets of the population. In all cases, system-edits should be put in place in the electronic infrastructure (priority 1) to check for a dose appropriate for Cousins Jim and Bruce or Aunt Sophie.

5. ***Be creative, flexible and take nothing for granted.*** The healthcare system is dynamic and the rules are constantly changing. As drug companies change the rules, health plans must be prepared to identify the behind the scene moves and refine the plan to adapt. As claims for Neurontin rose well beyond the incidence of epilepsy, alarms should have gone off and set in motion a review procedure and actions to adapt to the change. We got snookered and failed to identify the significant off label use that should have been subject to further scrutiny.

Neurontin is a perfect example of *take nothing for granted* and the consequences of not adhering to this principle.

- Do not take for granted that you know what it is used for, and that its uses will be appropriate for any one individual.
- Do not assume that the off-label use has been or should have been approved by a physician specialty group as acceptable therapy.

- Do not assume that dosing will be checked in any PBM system so that someone is checking for excessive dosing for seniors.
- Do not take for granted that any PBM system will check dosing for children even though the label contains specific recommendations.

Closing Comments

While drugs provide safe and effective treatment options that improve well being for those in specific circumstances, they are not necessarily safe and effective for any one individual. Drug manufacturers are doing what any business should do. They develop a product and market it as well as they can to generate sales. Financiers- whether it is Medicare, Medicaid, an insured health plan or a self- insured employer or union ERISA plan- need to decide when the product meets its coverage rules. Doing that effectively is the challenge. But it can be done in a way that supports physicians in the care they deliver to their patients. And failure to do it dooms any drug benefit – even one sponsored by Medicare. Besides seniors deserve better.

A post script about capture and use of patient data

The Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations are causing both head scratching and some steps backward in the managed pharmacy area. PBMs and retail pharmacies are at odds about what data they can and should capture as part of the electronic claim submission in light of HIPAA. Some are posturing under the guise of outright prohibition of even the most basic data. It may however represent a desire to spend less time on entering data. But data specific to the individual is necessary not only to determine if the drug for Aunt Sophie is an eligible claim under the health plan, but also to determine if it is safe and appropriate. We presume that clarification is needed since it was never your intent to force coverage of ineligible charges (an ERISA violation) or to process claims that may do harm. We assume that the Institute of Medicine's (IOM) ideas as outlined in its reports (To Err is Human and Crossing the Quality Chasm) will proceed unimpeded by HIPAA. Their thrust, like ours, is for data-driven systems, supporting physicians, to improve quality of care.

Neurontin (gabapentin)

How it works	FDA approved uses	FDA recommended dosing/PDR
• How it works in unknown – either to manage nerve pain after herpes or as a supplemental epilepsy treatment • Not metabolized by the body therefore it is not likely to have a negative effect on the liver • Excreted unchanged by kidneys	• Epilepsy as an add on therapy to other epilepsy drugs * * * • Pain after herpes (postherpetic neuralgia)[1]	• Epilepsy - Pediatric patients (3-12 years): 10-15 mg/day in 3 divided doses. Maximum interval time between doses should not exceed 12 hours - Adult patients (>12): 900 – 1800 mg /day given in divided doses (3x a day) using 300 or 400 mg capsules or 600 or 800 mg tablets. Starting dose is 300 mg 3x/day • Postherpetic neuralgia - 300 mg on day 1 – single - 600 mg on day 2 – divided in 2 doses - 900 mg on day 3 – divided in 3 doses - Can be increased as needed for pain relief to a daily dose of 1800 mg • Neurontin is given orally with or without food

Some FDA precautions (see attachment for full FDA labeling insert)

- Due to decreased kidney function, take care in dose selection for the elderly. Creatinine clearance values should be routinely checked
- Neurontin may cause dizziness, somnolence and other symptoms and signs of CNS depression. Accordingly patients should be advised not to drive a car or operate other complex machinery until they have gained sufficient experience on Neurontin to gauge whether or not it affects their mental and/or motor performance adversely
- Should be used in pregnancy *only if* the potential benefit justifies the risk to the fetus
- Should be used in nursing mothers *only if* the benefits clearly outweigh the risks

Notes:

[1]From www.pfizer.com, under *Health, Medicines & Lifestyles*, and then under US Prescribing Information, its posted labeling for Neurontin also lists this condition. Note: this has not yet been listed in the Physicians Desk Reference (PDR) or on the Food and Drug Administrations website (www.FDA.gov) because it has just been approved for this use.

Neurontin – facts and experience

<table>
<tr><th>Facts</th><th colspan="5">Experience</th></tr>
<tr><td>Clinical trials comparing Neurontin to a placebo showed a reduction in participants level of pain resulting from herpes</td><td colspan="5">• Using a scale of 0 (no pain) to 10 (worst possible pain) when the dose was increased, the approximate pain scores were:
- Placebo 6
- Neurontin 4
• Additionally between 29% and 34% (depending on the study) of individuals reported a 50% or more reduction</td></tr>
<tr><td rowspan="13">There are significant side effects in adults.</td><td rowspan="2">Side Effect</td><td colspan="2">Post herpes pain (from Pfizer website)</td><td colspan="2">Epilepsy (from FDA labeling)</td></tr>
<tr><td>Neurontin</td><td>Placebo</td><td>Neurontin</td><td>Placebo</td></tr>
<tr><td>Ataxia (involuntary muscle movement)</td><td>3.3%</td><td>0%</td><td>12.5%</td><td>5.6%</td></tr>
<tr><td>Abnormal gait or coordination</td><td>1.5%</td><td>0%</td><td>1.1%</td><td>.3%</td></tr>
<tr><td>Constipation</td><td>3.9%</td><td>1.8%</td><td>1.5%</td><td>.85</td></tr>
<tr><td>Diarrhea</td><td>5.7%</td><td>3.1%</td><td>---</td><td>---</td></tr>
<tr><td>Dizziness</td><td>28.0%</td><td>7.5%</td><td>17.1%</td><td>6.9%</td></tr>
<tr><td>Drowsiness</td><td>21.4%</td><td>5.3%</td><td>19.3%</td><td>8.7%</td></tr>
<tr><td>Dry mouth</td><td>4.8%</td><td>1.3%</td><td>1.7%</td><td>.5%</td></tr>
<tr><td>Fatigue</td><td>---</td><td>---</td><td>11.0%</td><td>5.0%</td></tr>
<tr><td>Nystagmus (rapid involuntary eye movement normally associated with dizziness)</td><td>---</td><td>---</td><td>8.3%</td><td>4.0%</td></tr>
<tr><td>Peripheral edema (fluid buildup under the skin)</td><td>8.3%</td><td>2.2%</td><td>1.7%</td><td>.5%</td></tr>
<tr><td>Tremor</td><td>---</td><td>---</td><td>6.8%</td><td>3.2%</td></tr>
<tr><td colspan="5">In the adult population, during clinical trials (but without measurement against a placebo), the following side effects were mentioned by patients and were characterized by the clinical investigators as frequent:
- Malaise - Bruising related to physical trauma - Hypertension
- Vertigo - Anxiety - Pneumonia - Abnormal vision</td></tr>
</table>

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Associates & Wilson

Neurontin – facts and experience

<table>
<tr><th>Facts</th><th colspan="3">Experience</th></tr>
<tr><td rowspan="6">When used in children, there are also significant side effects. Other than drowsiness they are different than the effects on adults</td><td colspan="3">Where Neurontin was used in clinical trials as in-addition-to therapy to treat epilepsy, in children 3-12 significant events include:</td></tr>
<tr><td>Side effects</td><td>Neurontin</td><td>Placebo</td></tr>
<tr><td>Viral infection</td><td>10.9%</td><td>3.2%</td></tr>
<tr><td>Fever</td><td>10.1%</td><td>3.1%</td></tr>
<tr><td>Drowsiness</td><td>8.4%</td><td>4.7%</td></tr>
<tr><td>Bronchitis</td><td>3.4%</td><td>.8%</td></tr>
<tr><td rowspan="4">Some side effects (like dizziness and drowsiness) are more of a problem with seniors because they are leading causes of falls. Fall are then a leading cause of fractures which in turn, significantly increase the rates of death.

Additionally, drowsiness may lead to inactivity which presents a whole host of different problems for seniors (loss of muscle, bedsores, etc.)</td><td rowspan="2">Trials</td><td colspan="2">Difference between Neurontin and Placebo</td></tr>
<tr><td>Dizziness</td><td>Drowsiness</td></tr>
<tr><td>Post herpes pain study (from Pfizer website)</td><td>20.5%</td><td>16.1%</td></tr>
<tr><td>Epilepsy (from FDA approved labeling)</td><td>10.2%</td><td>10.6%</td></tr>
<tr><td>For adults whose kidneys are not functioning normally, extra care should be taken with Neurontin because the drug may be in their body longer than for individuals with fully functional kidneys

Neurontin is not metabolized by the body. Rather it passes through the body and is eliminated through urination</td><td colspan="3">A drugs half-life is the period of time that half of the product is in your body. For adults with kidney problems, Neurontin’s half-life increases from a mean of about 6.5 hours to 52 hours. With continuous dosing, the drug builds up in the system.</td></tr>
</table>

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Associates & Wilson

Neurontin – facts and experience

Facts	Experience
Actions by representatives of Warner Lambert (the drug company who developed the drug) and its new owner (Pfizer) are now the subject of litigation for illegally marketing the uses of the drug to physicians. 11 non-FDA approved uses have been cited in newspapers and court documents	The uses being promoted by the drug company but for which there is not FDA approved use indication include: • Bipolar disorder • Pain syndrome peripheral diabetic neuropathy • Stand alone treatment for epilepsy (FDA approved use of Neurontin in addition to other primary epilepsy drugs) • Reflex sympathetic dystrophy – pain or tenderness following a traumatic injury to an arm or leg • Attention Deficit Disorder • Restless leg syndrome • Trigeminal neuralgia • Essential tremor periodic limb movement • Migraine • Drug and alcohol withdraw Severe pain following herpes virus infection was cited in the court case as inappropriately promoted but a FDA indication has just been granted. New studies (and therefore not listed in the court cases) are now appearing to sing the praises of Neurontin as a treatment for hot flashes. This is a lucrative market because of concerns raised about Premarin.

Sources:

- www.pfizer.com under US Prescribing Information for Neurontin
- www.fda.gov and Physician Desk Reference labeling for Neurontin
- New York Times articles on March 14, May 15 and October 29, 2002
- Worst Pills, Best Pills News, May and September 2002, a publication of The Public Citizens Group
- John McMahon et al vs. Guardian Post-acute Services, Contra Costa Superior Court, #MSC01-00471

Tel: 610-519-0602
Fax: 610-519-0605

CMS-4068-P-1226

Submitter : Mr. Chuck Bell **Date & Time:** 10/04/2004 08:10:00

Organization : Vital Care, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Pls see attached comments

CMS-4068-P-1226-Attach-1.doc

Dear Sir or Madam:

Vital Care Home Infusion Services is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Vital Care is a system of individually owned and operated infusion pharmacies specializing in providing high-tech services to rural and urban patients throughout the United States. With over 120 locations in 14 states, Vital Care can provide fast, efficient, and personalized to patients across the nation. Vital Care is based in Meridian, Mississippi and has been treating infusion patients since 1986. To date, Vital Care has treated approximately tens of thousands of patients. Vital Care was established for the purpose of providing a comprehensive scope of high-quality infusion therapies for stabilized patients in the home setting.

Vital Care appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home

administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B *has not resulted in additional access to home IVIG under Medicare*. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm.

CMS should establish **specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies** to ensure adequate enrollee access to home infusion therapy under Part D.

CMS should require **specific standards for home infusion pharmacies** under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

CMS should adopt the **X12N 837 P billing format** for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

CMS should **mandate that prescription drug plans maintain open formularies for infusion drugs** to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Chuck Bell
CEO\ COO
Vital Care, Inc.

Submitter : Ms. Margaret Thomas **Date & Time:** 10/04/2004 08:10:07

Organization : Horizon HealthCare Services

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-4068-P-1227-Attach-1.doc

Horizon Healthcare Services is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Horizon Healthcare services the home infusion needs of thousands of patients in south central Pennsylvania every year including many Medicare recipients. Founded in 1984, our highly trained healthcare professionals have the experience and skills necessary to create positive clinical outcomes for the patients we serve while at the same time conserving scarce healthcare dollars by treating patients at home and avoiding costly hospitalizations.

Horizon Healthcare Services appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

* Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm <http://www.nhianet.org/perdiemfinal.htm> .

* CMS should establish specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require specific standards for home infusion pharmacies under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the X12N 837 P billing format for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should mandate that prescription drug plans maintain open formularies for infusion drugs to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Margaret F. Thomas RN

Intake Coordinator

Horizon Healthcare Services
2106 Harrisburg Pike, Suite 101
Lancaster, PA 17601

CMS-4068-P-1228

Submitter : **Date & Time:** **10/04/2004 08:10:19**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I support increased utilization of generic prescriptions, when available. I would also like to see a "universal" card for Medicare (drug benefits) recipients. With this universal card, the customer could go to any pharmacy and receive the same benefit. Give pharmacist "Provider" status, so that when performing DURs (drug utilization review) of patients prescriptions, the pharmacist will have some real power to act on duplicate therapy and make therapy changes, instead of just making or noting meaningless comments in the patient's profiles.

Many other health care professionals have been given provider status, and I feel that pharmacist should also be given this same status because the pharmacist is the one "Provider" that a patient has easy access to w/r/t other healthcare professionals (i.e physician, nurse, etc.) and pharmacists receive numerous calls/questions from patients on a daily basis..much more so than many other "providers".

CMS-4068-P-1229

Submitter : Dr. Mark Riley **Date & Time:** 10/04/2004 08:10:15

Organization : Arkansas Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment from the Arkansas Pharmacists Association.

CMS-4068-P-1229-Attach-1.doc

Arkansas Pharmacists Association

417 South Victory • Little Rock, Arkansas 72201 • (501) 372-5250 • Fax (501) 372-0546

Mark S. Riley, Pharm.D.
Executive Vice President

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Sir or Madam:

I am writing today on behalf of the Arkansas Pharmacists Association concerning the proposed rules for Medicare Part B. I have several serious concerns about the rules as currently written.

Any Willing Provider/Access to Community Pharmacies

While the bill includes "any willing provider" language to explicitly address Congress' intent for access, the proposed rules pose problems in accomplishing this intent. TriCare Access standards will be circumvented if PDPs and MA-PDs are allowed to "average" the standards across a region. Many Medicare beneficiaries will have unequal access in all three designated areas: urban, suburban, and rural. By averaging the standard, Congress' intent for access is by-passed.

TriCare Access standards and any willing provider intent will also be avoided if plans are allowed to create "preferred" and "non-preferred" networks. Spreading the total savings across the whole network can maximize plan savings. PDPs and MA-PDs will attempt to meet TriCare Access standards with the network as a whole yet proceed to build a "preferred" network that may not meet those standards at all. Medicare beneficiaries in rural areas would be severely limited in their ability to receive the greatest possible savings.

In determining travel distances involved in meeting TriCare Access standards, "commercially traveled routes" should be applied, not the shortest distance between two points.

Level Playing Field for Mail Order Pharmacies and Community Pharmacies

Based on the medication received, rebates from drug manufacturers should be applied and passed on to the Medicare beneficiary equally in both mail-order and community pharmacy. In no case should the mail-order pharmacy employed by the plan be allowed to reallocate rebates received based on community pharmacy prescriptions in a way that would make the mail-order pharmacy seem less expensive. Many PDPs will be pharmacy benefit managers (PBMs), which own their own mail-order houses and will have a vested interest in routing prescriptions to them. Also, PBMs will employ numerous "games" to make discounts appear larger than they really are.

Conflict of Interest in the Use of Mail-Order Pharmacies

Plan sponsors who own mail-order houses SHOULD NOT be allowed to use their own mail-order pharmacies. This practice causes sponsors to attempt to unfairly disadvantage community pharmacies in order to move the prescriptions to their mail-order pharmacies (i.e. self-dealing).

Medication Therapy Management (MTM)

A minimum standard should be defined in the rules so that any Medicare beneficiary can be assured of the same care in the implementation of these services.

Minimum eligibility standards for MTM should be established (i.e. the number of medications and chronic conditions diagnosed for the patient). Without these minimum standards, eligibility could vary greatly between regions.

Payment for these services should be defined so that payment levels are not so low that pharmacies would not be able to afford to supply them. Lack of definition would force patients to receive their MTM services by telephone or some other method inferior to face-to-face care. Again, face-to-face care seemed to be the intent of Congress.

I thank you for allowing comment on these regulations and for your careful consideration of my concerns. Medicare beneficiaries should be allowed freedom of choice for their pharmacy providers. Survey after survey supports that senior patients want and expect that freedom.

Sincerely,

Mark S. Riley, Pharm.D.
Executive Vice President

CMS-4068-P-1230

Submitter : Mr. David Rogers **Date & Time:** 10/04/2004 08:10:18

Organization : Idaho Department of Health and Welfare

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

attached are our comments related to this proposed regulation.

CMS-4068-P-1230-Attach-1.doc

October 4, 2004

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid
Department of Health and Human Services
Attention CMS-4068-P
P.O. Box 8041
Baltimore, MD 21244-8014

Re: Medicare Prescription Drug Benefit – Comments to Proposed Rules

Dear Dr. McClellan:

The State of Idaho, Department of Health and Welfare respectfully submits the following comments regarding the proposed Medicare Prescription Drug Benefit Regulations, published in the Federal Register on August 3, 2004. Idaho recognizes CMS efforts to bring prescription coverage to our Medicare population and appreciates the opportunity to comment on these proposed regulations. Idaho's overriding concern is that the proposed regulations have the potential to increase administrative and financial burdens on the State.

Phase-Down Provision:

1. Section 423.910 (d) requires the States to submit an electronic file to CMS identifying each full benefit dual eligible enrolled in the State for each month with Part D coverage that is also determined to be full benefit eligible by the State for full Medicaid benefit.

   Issues related to this section:

   A. The process for submission has yet to be identified. The submission process is identified in the proposed rule as "a manner specified by the Secretary". Without knowing the manner or process that will be used the States cannot estimate what if any additional costs are going to be associated with this requirement and cannot determine how and when they can comply with this

requirement. The process needs to be identified and communicated as soon as possible so that States can meet the implementation timeline and identify new costs associated with this new process.

B. MSIS data is being used to establish the baseline however this process that will be identified by the Secretary will presumably not be from the MSIS reports. There is concern that once operational, the data used to determine phase down payments will not be consistent with the data used to develop the baseline.
C. In the preamble to the proposed rule it is estimated that this new process will place an additional burden on the States which is estimated to be 100 hours per State for start up and an ongoing burden of 122 hours per State per year. Since the manner/process is yet to be defined the actual burden on the States is really unknown. In fact Idaho has spent this amount of time preparing the baseline data – which has yet to be completed. This estimation appears to be exceedingly low.

2. Section 423.902 of the proposed rule states that the growth factor will be based on the most recent National Health Expenditure (NHE) projections for the years involved.

   Issues related to this section:
   A. The overall NHE projections do not reflect the inflation rate experience by Idaho or any specific Medicaid agencies.
   B. Using a national number, even if specific to Medicaid programs, is insensitive to the growth rates that have actually been experienced in each State. In affect, States that have made little or no effort to control the rate of growth of drug costs will be rewarded while States that have worked diligently to control drug costs will be punished.

      Using the Calculation of Phase-down Monthly Contribution for 2006 as described in the proposed regulations, best available data and the cumulative growth factor that we have experienced over the past 3 years we would estimate a monthly payment in 2006 of about $720,000. Each additional percent increase/year above our actual inflation experience represents an additional cost to Idaho of over $21,000 per month. For example, and estimated 11% inflation rate would cost Idaho an additional $65,416 per month or a total of $785,000 for calendar 2006.

3. Section 423 of the proposed rule states that 2003 calendar year is the base year upon which the monthly phase down payments will be based. There will be no adjustments made once this base year calculation is determined.

   Issues related to this section:
   A. Having a complete list of included and excluded costs are paramount for the States to determine the correct baseline rates. Without an approved list of

included and excluded drugs, as just one example, there is no way to determine an accurate baseline.

B. Since drug costs have experienced wide swings over the past few years – using a single year as the baseline and not allowing for any adjustments does not appear to be a fair approach for the States. See comments related to the rebate adjustment factor.

4. Section 423.910 (f) states that the Secretary establishes the rebate adjustment factor using total drug expenditures made and drug rebates received during calendar year 2003 as reported on CMS 64 Medicaid expenditure reports for the four quarters of calendar year 2003 that were received by CMS on or before March 31, 2004.

   Issues with this section:

   A. The assumption is that all of the rebates received during calendar year 2003 and prior to March 31, 2004 are related to the drug expenditure in calendar year 2003. This is an erroneous assumption as rebates can and are collected well after the actual drug expenditure. Baseline year calculation will not be accurate.
   B. The assumption is that the amount of rebates that States receive as a percentage of drug expenditures is a static number. This again is an erroneous assumption as the amount of rebates received by our State has continued to increase. Idaho has experienced over a 2.2% increase in rebates as a percentage of total drug expenditure between CY 2002 and CY 2003. This is not atypical for Idaho as the cumulative increase is over 8% from 1998 through 2003. Each percent difference in the rebate adjustment factor represents additional costs to Idaho of approximately $118,000 for the first year of the phase-down contribution.
   C. The rebate adjustment factor is figured on the total drug expenditure for the State – not just the dual eligible population. This population traditionally has higher drug utilization and presumably would represent a higher percentage of the rebates that the State receives, comparatively speaking. We request that an adjustment be made so that the rebate adjustment factor is more representative of the population in question.

Eligibility/Enrollment

1. Section 423.772 discusses family size. It is unclear what degree of relationship to the applicant is required to include an individual in family size.

2. Section 423.782 refers to cost sharing subsidy. Are individuals eligible for Medicaid HCBS considered “institutionalized individuals” for purposes of no cost sharing? This is not clear in the proposed regulations.

3. In section 423.904 – should the reference to the notice requirements be to 423.34(c) instead of 423.34(d)? Reference appears to be in error.

4. Section 423.904 states that the State agency must make eligibility determinations and redeterminations for low-income premium and cost-sharing subsidies. Section 423.906(a) specifies that regular Federal matching applies to eligibility determinations and notification activities for this Federal program. The State believes that an enhanced federal match should accompany the State's activity that supports this Federal program.

5. Section 423.42 (d) of the proposed rules provides that PDPs may disenroll participants for various reasons. Additionally and individual who is disenrolled for failure to pay monthly PDP premiums, disruptive behavior, or misrepresentation of third party reimbursement will not be provided a Special Enrollment Period permitting him/her in another PDP. Idaho encourages a thoughtful review of this section of the rule for the following reasons:

    A. Because Medicaid can no longer receive federal financial participation for paying for prescription drugs, dual eligible individual beneficiaries who are involuntarily disenrolled would face a significant hardship.
    B. The proposed rule creates a significant opportunity for a very vulnerable population to be denied access to needed medications. Without needed medications the participants, in particular those with mental health issues, have the potential to become unstable and may end up utilizing additional public funds to deal with crisis situations, institutional care, or imprisonment.
    C. Disruptive behavior is not defined in the proposed regulation. Disruptive behavior that is related to the participant's underlying diagnosis should not be a reason for disenrollment. Language used in 42 CFR 438.56(b)(2) that refers to managed care arrangements would also be appropriate in this setting. Without the addition of more defining language too much latitude will be given to the PDPs and there will be the potential that participants will be denied the medications they require to stabilize their condition.

Auto Enrollment

Section 423.34(d) states that full benefit dual eligible individuals who fail to enroll in a PDP or MA-PD plan during their initial enrollment period or special enrollment period under section 423.36(c)(4) will be automatically enrolled. The initial enrollment period is identified as November 15, 2005 through May 15, 2006.

Issues related to this section:

1. The actual process for auto enrollment is not identified in these regulations. The relationship between Federal and State responsibilities is not identified. Process,

roles and responsibilities for the State and Federal government must be defined as soon as possible.

2. Because Medicaid can no longer receive federal financial participation for paying for prescription drugs that are included in Part D, full benefit dual eligible individuals must be enrolled in a PDP by January 1, 2006. This provides a more limited period of the time for these beneficiaries to select a PDP of their choice. This seems to be in some conflict with section 423.859 "Assuring access to a choice of coverage."
3. Only a 45 day window exists for selection of a PDP or auto enrollment and the process is yet to be defined. Given the large volume of enrollment activity, there is significant opportunity for a number of full benefit dual eligible individuals, a vulnerable population, to have not be enrolled for part D benefits. Most importantly lack of prescription coverage for this vulnerable population could have a negative impact on their health. This could result in higher utilization of more expensive resources at additional costs to both the Medicare and Medicaid programs.
4. Not only will full-benefit dual eligibles not qualify for part D benefits if not enrolled, but also federal matching funds would no longer be available to the states for prescription drug coverage under Medicaid. As a result, this can have a significant financial impact on the states. It is imperative that the auto-enrollment process for full-benefit dual eligible individuals by completed by December 31, 2005.

Formulary

Section 423.120 of the proposed regulations covers access to covered Part D drugs. PDP or MA organization formulary must include at least two Part D drugs within each therapeutic category and class of covered Part D drugs. The covered Part D drug list is not included in these regulations.

Issues related to this section:

1. There will not be a single formulary for covered Part D drugs; rather each PDP will have their own formulary that need only include at least two Part D drugs within each therapeutic class of covered Part D drugs.
    A. A single formulary required of all PDPs would be an enormous aide to the States that desire to develop a wrap around drug program for dual eligible individuals.
    B. This approach is insensitive to a significant population of full benefit dual eligibles who are on multiple medications.

2. Recent correspondence from CMS (letter to Medicaid administrator dated September 9, 2004) has proposed a drug list for covered Part D drugs to be used only for the development of the program's baseline. It is explicitly stated in this correspondence that this is not the list that is to be used when the program is operational.

A. To coordinate drug benefits and assure adequate care for the dual eligible population the States need to know what drugs will be included and excluded in Part D as soon as possible. The coordination of State and Federal benefits will require system development and coordination that will take a significant amount of time. This cannot begin until the States have the included and excluded drug lists.
B. It is unclear to the State how having one list of included drugs for the development of the baseline year and a different list of included drugs for the actual Part D program can result in accurate calculation of Phase Down payments.

The State of Idaho appreciates the opportunity to comment on the Medicare Part D program proposed regulations. We are concerned that the proposed regulations have a significant opportunity to reduce the current drug benefit that is being experienced by full benefit dual eligible participants through State Medicaid programs. The proposed regulations do not define processes that will be an integral part of the Medicare Part D program and without this definition the cost to the States cannot be projected. It is our concern that the additional burden placed on the States may result in increased costs to the States and, in some cases, decreased benefit to the Medicare dual eligible population.

Sincerely,

DAVID A. ROGERS
Administrator

DAR/PL/ksl

cc: Karl Kurtz

Submitter : Mrs. Tammy Higgins **Date & Time:** 10/04/2004 08:10:07

Organization : Horizon Healthcare

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-4068-P-1232

Submitter : Kathryn Kuhn **Date & Time:** 10/04/2004 08:10:23

Organization : National Community Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

See Attachment

CMS-4068-P-1232-Attach-1.doc

National
COMMUNITY
PHARMACISTS
Association

Formerly NARD, the National Association of Retail Druggists

NCPA
205 Daingerfield Road
Alexandria, Virginia
22314-2885
phone
703.683.8200
fax
703.683.3619

www.ncpanet.org

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Proposed Rule—Medicare Program; Medicare Prescription Drug Benefit (CMS-4068-P)

To Whom It May Concern:

On behalf of the National Community Pharmacists Association (NCPA), I would like to submit the following comments regarding CMS-4068-P.

We support the use of a facilitator (FAC) in the processing of TrOOP and COB claims. Without a FAC, the burden placed on PDPs and claims processors could be exponential due to the complex nature of these claims (i.e., from reversals, resubmissions, etc.).

While we favor the FAC model, we also have some concerns with respect to using a prominent switch company (e.g., NDCHealth or another single entity) as a FAC. Our concerns primarily revolve around the net effect on pricing and freedom of choice with regards to switch companies.

1) Pricing - Today, the majority of pharmacy transactions are single switch transactions (provider - payer - provider). A small percentage of transactions require multiple switches (e.g., COB). The FAC model inherently involves a multitude of multiple switches to various payers, thus theoretically increasing the cost associated with full processing of a claim. Our concern for pharmacy, in general, is the fees associated with these complex processes. One common concern in the industry with respect to the Medicare Drug Program is the decreasing margins at the pharmacy level. While this logic is debatable, adding a higher switching fee for these types of complex claims would only add more fuel to the fire and continue to further decrease pharmacy margins.

2) Switch Providers - The fact that NDC is eyeing the opportunity to serve as a FAC concerns us as well. NDC is well known in the industry as the leader in claims switching (however, competitors such as eRx and WebMD continue to gain ground in this area). Our concern with placing a prominent switch company in the role as a FAC is the potential for an unfair advantage in the switch marketplace. This could result in decreased competition and create an environment susceptible to price increases for general claims switching services. Provisions would need to be made to allow equal access to the FAC by all switching companies so that no one switch provider would be placed at an economic disadvantage. In addition, measures should be taken to prevent any switch company serving as a FAC from creating a monopolistic environment.

The National Community Pharmacists Association (NCPA) represents the nation's community pharmacists, including the owners of 24,000 pharmacies. The nation's independent pharmacies, independent pharmacy franchises, and independent chains represent a $78 billion marketplace, dispensing nearly half of the nation's retail prescription medicines.

Thank you for the opportunity to provide these comments. Please feel free to contact me if I can provide you with any further assistance concerning this issue.

Sincerely,

Kathryn F. Kuhn, R.Ph.
Senior Vice President, Pharmacy Programs

CMS-4068-P-1233

Submitter : Ms. Lisa M. Getson **Date & Time:** 10/04/2004 08:10:17

Organization : Apria Healthcare

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

Please refer to Apria Healthcare's formal comments on this subject as found in the attached Word file.

CMS-4068-P-1233-Attach-1.doc

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Re: Comments on CMS-4068-P
The Proposed Rule for the Medicare Prescription Drug Benefit

Dear Dr. McClellan:

On behalf of Apria Healthcare Inc., I am pleased to submit these comments regarding the proposed rule to implement the new Medicare Part D prescription drug benefit. Specifically, these comments pertain to the recent notice published in the *Federal Register* on August 3, 2004.[1]

Apria is a leading provider of integrated home care services and products. Apria offers a full range of home infusion drug therapy, as well as home medical equipment and home respiratory therapy. Through 30 wholly-owned, licensed and JCAHO-accredited infusion pharmacies, Apria serves adult and pediatric patients with a wide range of infectious diseases, nutritional disorders, cancer and chronic illnesses such as Lou Gehrig's Disease and multiple sclerosis. Aside from the thousands of people covered by private managed care organizations who benefit from Apria's home infusion services, the company also cares for a significant number of elderly patients throughout the United States who have complex medical problems and multiple co-morbidities who require home infusion therapy and are covered by Medicare Advantage (MA. formerly Medicare+Choice) plans.

These comments are divided into the following sections:

I. General
II. Dispensing Fees for Home Infusion Drug Therapy
III. Contracting with Home Infusion Drug Pharmacies
IV. Formulary Development

[1] Medicare Program; Medicare Prescription Drug Benefit; 69 *Fed. Reg.* 46632 (Aug. 3, 2004).

I. General

We wish to commend CMS for engaging in the research necessary to understand many of the unique characteristics of home infusion drug therapy. These findings are reflected in the preamble of the proposed rule, which summarizes the various services and functions that are required to provide home infusion drug therapy safely and effectively in the home care setting.

We applaud CMS for recognizing in the proposed rule the clinical and cost benefits of home infusion drug therapy, as well as the essential role this area of therapy plays in the private sector health system and under Medicare managed care programs. The proposed regulation describes an interpretation of the Part D benefit that would include the essential services, supplies and equipment that are integral to the provision of infusion drug therapy provided in the home (see discussion of "Dispensing Fee Option 3" below).

If Dispensing Fee Option 3 is adopted in the final regulation, as we recommend, then the Medicare fee-for-service program can offer coverage of home infusion drug therapy comparable to what private sector health plans and Medicare Advantage plans have offered for years. In doing so, Medicare would realize the significant system-wide savings that come from the provision of infusion drug therapy in the most cost-effective setting.

A. Home infusion drug therapy provides an opportunity for Medicare Part D to replicate the success achieved by private sector health plans and Medicare Advantage plans.

Currently, many of the infusion drug therapies used commonly in the private sector, such as antibiotic therapy used in the treatment of severe infections, are not covered under the Medicare Part B durable medical equipment (DME) benefit. Coverage under the DME benefit is based on the use of an item of DME – in this case, an infusion pump − and extends only to a few designated drugs, most of which are used in the treatment of cancer and intractable pain. As a result, Medicare beneficiaries who could have received infusion drug therapy at home have been forced into far more costly settings, such as acute care hospitals, hospital outpatient departments, hospital emergency rooms and long term care facilities.

In contrast to the limited coverage that exists under Medicare Part B, Medicare coverage of home infusion therapy has worked well under Part C with the Medicare Advantage plans. Many if not most Medicare Advantage plans provide coverage for a broad range of home infusion therapies and related services as a <u>medical</u> benefit. Examples include Aetna US Healthcare, Humana Health Plans, PacifiCare's Secure Horizons plans and Presbyterian Salud in New Mexico. Clearly, these plans would not provide this optional coverage unless they were convinced that coverage of home infusion therapy in the home setting is cost-effective.

For Medicare Advantage plans, home infusion has provided significant system-wide savings by enabling beneficiaries to receive infusion therapy without incurring hospital or nursing facility costs. Medicare Advantage plans cover the homecare pharmacy, nursing and other in-home services, supplies, equipment and same-day, in-home delivery/patient teaching necessary for the provision of home infusion therapy. The effectiveness of home infusion therapy under Part C, and the manner in which Medicare Advantage plans define and cover this therapy, can be a model for infusion coverage under Part D.

B. Specific requirements must be established by CMS to ensure that Medicare Part D makes use of home infusion drug therapy in the same fashion as private sector and Medicare Advantage plans.

Stand-alone Part D prescription drug plans (PDPs), in the absence of specific requirements or direction from CMS, will not embrace drug therapies such as home infusion drug therapy because the PDPs will be rewarded for contributing to system-wide savings on the drugs alone. As a result, the financial incentives that have driven private payer acceptance and use of home infusion drug therapy will not exist for stand-alone PDPs.

As a result, specific requirements and direction from CMS are necessary for the coverage of home infusion drugs to work properly. We urge CMS to ensure that the Final Rule contains provisions relating to home infusion drug therapy on the issues discussed in the remainder of these comments, including such issues as dispensing fees, pharmacy access, formulary provisions and the formatting of claims.

II. Dispensing Fees for Home Infusion Drug Therapy

A. CMS should adopt Dispensing Fee Option 3, which is the only proposed option that would adequately recognize the services and items that are necessary to provide home infusion drug therapy.

Congress' definition of prescription drugs under the statute clearly includes infusion drugs provided in the home, and the proposed rule likewise reinforces the fact that infusion drugs (other than the few drugs currently covered under Part B) are included in the Part D benefit.

However, for the coverage of home infusion drugs to be meaningful for Medicare beneficiaries, CMS also must cover the services, supplies and equipment related to the provision of these drugs. Limiting coverage to the drugs only without the services, supplies and equipment will not produce meaningful coverage of infusion drugs in outpatient settings. This is because infusion pharmacies will be unable to provide infusion drugs without adequate payment for the services, supplies and equipment.

The most appropriate mechanism for such coverage of infusion services, supplies and equipment provided under the proposed rule is the dispensing fee. In the preamble, CMS sets out three options for defining dispensing fees under the new benefit and invites comment on each.

- Option 3 comes closest to accurately recognizing the fundamental elements – including the services, supplies and equipment – that are essential for the provision of home infusion drug therapy. Option 3 is the only option that reflects the fundamental elements of home infusion drug therapy (see additional discussion in subsequent sections of these comments).

- In contrast, Option 1 only provides the perspective of retail pharmacies and does not meet the needs of Medicare beneficiaries requiring home infusion drug therapy.

- Although Option 2 captures the supplies and equipment used in the provision of home infusion drug therapy, this option falls far short of recognizing the essential professional services required to provide home infusion drug therapy because it does not recognize the professional services that are required to provide safe and effective infusion therapy in the home.

B. CMS should adopt Dispensing Fee Option 3 because it is consistent with the well-established standards of practice for home infusion drug therapy.

The major independent accreditation organizations, including the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), have established extensive, detailed standards regarding the patient management, support services, facilities, patient safety, policies, procedures and functions that must be provided by home infusion pharmacies. These standards, which address issues ranging from the requirements for sterile preparation of infusion drugs to the oversight of patient therapy, are significantly different from the standards governing traditional retail pharmacies.

Option 3 is the only dispensing fee option that adequately reflects the content of these national accreditation standards. For example, one major difference between retail pharmacies and home infusion pharmacies is the urgency surrounding the initial referral from a physician or hospital and the resulting home delivery/patient education requirements. Due to the severity of the patient's illness (such as a serious infection which has not responded to oral medications), pressures on hospitals to discharge patients as soon as possible, and stability/refrigeration requirements for many medications, home infusion pharmacy staff frequently have to deliver directly to patients' homes the same day as the referral. This is considerably more expensive than a retail pharmacy model where the patient or caregiver visits the pharmacy in person to pick up the drug. All of this must take place in conjunction with insurance verification, coordination with the nurse who will teach the patient, compounding by a home infusion pharmacist, and eventually, billing third party payors and collecting patient co-pays – all activities that are not applicable to the retail setting.

The well-established understanding of the professional services involved in providing in home infusion drug therapy is not merely an industry definition. Payers, clinicians, clinical societies, providers and accrediting organizations share a common understanding of what is involved in providing these therapies in outpatient settings.

C. CMS should adopt accreditation requirements under Dispensing Fee Option 3 as a straightforward means to protect Part D enrollees.

As the first homecare provider to seek and obtain JCAHO accreditation in the 1980s, Apria has a longstanding commitment to ensuring that the professional services and functions we provide meet a demanding set of quality standards. Apria recently completed its latest triennial survey cycle, with a successful outcome in all infusion pharmacies, respiratory and medical equipment locations. Our company has served as a pilot for innovative survey techniques developed by the JCAHO, and our management has formally served on advisory committees of the organization. Today, our quality standards meet or exceed JCAHO's requirements, which is a requirement of the over 2500 private sector managed care plans with which we contract to provide home infusion services.

In the final rule, CMS should address the qualifications of the infusion pharmacies that may provide the elements of care described under Dispensing Fee Option 3. We recommend that CMS require every pharmacy providing infusion services to be accredited as a home care pharmacy by a recognized national accrediting organization. We also recommend that every entity that provides nursing services to Part D infusion patients be either accredited as a nursing agency as an extension of their existing home infusion accreditation, or be a Medicare-certified home health agency.

Private sector plans require accreditation as a basic assurance that the pharmacists and nurses are experienced and the pharmacies are staffed properly to provide the necessary care. The quality standards required of home infusion pharmacies and nursing agencies by the accreditation organizations have become the community standard for the provision of home infusion therapy.

D. CMS should use a refined version of Dispensing Fee Option 3 to define the full scope of necessary professional infusion pharmacy services.

All infusion patients, whether or not they qualify for the home health benefit, require professional pharmacy services that again differ from those found in the retail setting. The general categories of such services are:

- Compounding medications in a sterile environment
- Dispensing
- Ongoing Clinical Monitoring
- Care Coordination with other agencies involved in patient care

- Provision of Supplies and Equipment
- Multiple Categories of Pharmacy Professional Services, such as pharmacokinetic drug monitoring or parenteral nutrition formula development
- Administrative Services
- In-home delivery, patient and caregiver education
- Third party billing
- Other Support Costs

These services are described in greater detail in a number of accreditation materials and other forums, including a document on the website of the National Home Infusion Association describing the "per diem" model.[2]

We propose a modification to Dispensing Fee Option 3 to more explicitly describe the pharmacy professional services that are needed for home drug infusion therapy. The pharmacy services referenced above in the model per diem definition (and generally described in Dispensing Fee Option 3) should be included in the dispensing fee for all Part D infusion patients. Most of these functions would be captured in the Option 3 definition of dispensing fees.

Both private payers and Medicare Advantage plans use per diem payments that are tied to the intensity level of the particular infusion therapy. For over 20 years, these plans have essentially developed resource-based relative value scales to capture the intensity, in terms of time and resources involved in providing each infusion therapy safely and effectively. Thus, the plans do not use a single per diem amount for all infusion therapies. We recommend that the PDPs follow this approach under Medicare Part D.

E. CMS can establish easily-administered safeguards to avoid any duplicate payments for nursing services

CMS raises a question in the proposed rule regarding how to ensure that the services captured in Dispensing Fee Option 3 are not reimbursed under the home health benefit or otherwise.

The potential area of concern involves the infusion patients who also qualify for the Medicare home health benefit. For this subset of infusion patients who also qualify for the home health benefit, it would be a simple matter to first determine whether a beneficiary qualifies for the home health benefit before reimbursing Part D funds for nursing services. The majority of beneficiaries who require infusion drug therapy do not qualify for the home health benefit, and their nursing services should be paid under the Part D benefit as part of the dispensing fee.

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[2] National Home Infusion Association. National Definition of Per Diem. June 2003. *Available at* www.nhianet.org/perdiemfinal.htm.

Importantly, the home health benefit does not cover any of the pharmacy services described in the preceding subsection of these comments.

By first identifying beneficiaries who qualify for the home health benefit, the nursing component, when medically necessary, should be reflected in the dispensing fee but only for beneficiaries who do not qualify under the home health benefit for nursing services. Importantly, nursing care is not included in the model per diem definition (discussed above) nor in the HCPCS "S" coding structure (discussed below) used by private payers.

Private payers typically separate out nursing from the pharmacy-related costs represented by the per diem. They share the Medicare program's natural concern about nursing costs, and these plans have concluded the best means of tracking and controlling nursing costs is to use a separate payment mechanism for nursing.

F. CMS can establish easily-administered safeguards to avoid duplicate payments under Medication Therapy Management Programs.

CMS asks for comments regarding how to ensure that the Medicare program avoids making duplicate payments if the PDPs pay for infusion-related dispensing fees as well as medication therapy management services.

Generally, the dispensing fee as defined in Dispensing Fee Option 3 will capture most of the services and functions described in our per diem model plus the nursing component, and there will not be a clear need for a separate payment to infusion pharmacies for additional medication therapy management services. We believe that the primary situation where medication therapy management services may be indicated is where an infusion pharmacy has to coordinate the activities of another pharmacy.

However, if CMS does not choose Dispensing Fee Option 3 for defining dispensing fees, then CMS should not consider the medication therapy management program as a substitute for covering the services, supplies and equipment required to provide infusion drug therapy. The limitations on the applicability of the medication therapy management program (*i.e.*, it is limited to patients with chronic conditions and multiple medications) make it a poor vehicle for capturing the clinical monitoring functions required of infusion pharmacies for all infusion patients.

III. Contracting with Home Infusion Pharmacies

A. CMS should establish separate and distinct requirements for PDPs to contract with sufficient numbers of home infusion pharmacies to ensure adequate enrollee access to home infusion drug therapy under Medicare Part D.

CMS should establish specific safeguards for home infusion pharmacies to ensure meaningful enrollee access to home infusion drug therapies. A number of important differences exist between home infusion pharmacies and traditional retail pharmacies that highlight the need to create separate requirements for the two types of pharmacies. For example–

- Home infusion pharmacies provide specific essential services that are not provided by the vast majority of retail pharmacies or mail order pharmacies.

- Home infusion pharmacies must maintain facilities, equipment and safeguards for compounding and storing sterile parenteral drug solutions, which is not common among retail pharmacies.

- Home infusion pharmacies are responsible for the care of their patients 24 hours a day, seven days a week, while retail pharmacies are not.

- Home infusion pharmacies are subject to separate state licensure, regulations and accreditation standards from retail pharmacies.

- The contracts used by private health plans for home infusion pharmacies are structured differently from the contracts used for retail pharmacies.

- The total number of traditional retail pharmacies in the United States far outweighs the total number of home infusion pharmacies.

These differences are echoed in the preamble of the proposed rule, where CMS discusses its findings regarding important distinctions between home infusion pharmacies and retail pharmacies.[3]

To ensure that Part D enrollees have sufficient access to home infusion drug therapy, CMS should adopt its proposal to establish distinct access standards for home infusion pharmacies in the Final Rule. This would be consistent with Congress' general mandate that CMS must ensure enrollees have convenient access to pharmacies, as access to a retail pharmacy does not by itself meet the needs of a beneficiary who requires infusion therapy.

B. CMS should require use of the ASC X12N 837 claims format for infusion drug therapy, consistent with CMS' recent determination, because infusion claims formats are different from retail pharmacy claims.

CMS' Office of HIPAA Standards has carefully reviewed how home infusion therapy is provided, and recently issued a Program Memorandum[4] and a Frequently Asked Question (FAQ)[5] document on the CMS website summarizing its conclusion.

[3] 69 *Federal Register* at 46648 and 46658.

For example, the FAQ document states:

> …Home infusion therapy typically has components of professional services and products that include ongoing clinical monitoring, care coordination, supplies and equipment, and the drugs and biologics administered – all provided by the home infusion therapy provider.

In a letter dated April 8, 2003, Jared Adair, director of the CMS Office of HIPAA Standards, wrote:

> …we have determined that home drug infusion therapy services are different from services provided by retail pharmacies, and that the business model for home drug infusion therapy providers is fundamentally different from a retail pharmacy for dispensing drugs…. We also acknowledge that a requirement to bill home infusion drugs using the NCPDP format would fail to meet the administrative, clinical, coordination of care, and medical necessity requirements for home drug infusion therapy claims." (emphasis added)

As a result, CMS determined that the National Council for Prescription Drugs Program (NCPDP) claim format, which is the HIPAA standard for the processing of retail pharmacy drug claims, is not appropriate for the filing of home infusion drug therapy claims. Instead, CMS instructed that home infusion claims, to be compliant with HIPAA, must be filed under the ASC X12N 837 claims format.

Please note that the description of infusion therapy as described in the FAQ tracks very closely with the language of Dispensing Option 3 in the proposed rule. We recommend that the specific wording already posted on CMS's FAQ be included as the infusion claiming requirement in Part D regulations. To do so will increase the level of administrative standardization in infusion claims transactions per the objectives of HIPAA, while also ensuring that home infusion providers and Part D payers comply with the HIPAA regulation when implementing Part D claiming transactions. If CMS does not require that Part D home infusion therapy claims be submitted on the 837, then it would open up the possibility for some Part D payers to ignore the fundamental differences of home infusion therapy from retail pharmacy and implement only NCPDP claiming—forcing infusion pharmacies to be out of compliance with HIPAA.

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[4] Centers for Medicare & Medicaid Services, Program Memorandum, Carriers, Transmittal B-03-024 (4/11/03), *available at* http://cms.hhs.gov/manuals/pm_trans/B03024.pdf.

[5] Centers for Medicare & Medicaid Services, Frequently Asked Questions (FAQs), "Are Drug Transactions Conducted by HIT Providers Retail Pharmacy Drug Claim Transactions Billed Using NCPDP Formats?" (Answer ID 1880) (3/31/03), *available at* http://questions.cms.hhs.gov.

This would deprive the PDPs and CMS of a valuable tool for tracking important patient-specific data. Consolidated 837 claiming would facilitate the consolidation of all drugs along with the professional pharmacy "per diem" services, equipment and supplies into single claims billed for infusion therapies, easily mapped into patient services utilization data bases for analysis—whereas the possibility of billing infusion drugs separately via the retail NCPDP claim format results in loss of this consolidated data for analysis.

C. CMS should recognize that infusion coding is different from retail pharmacy drug coding.

Since 2002 the Healthcare Common Procedure Coding System (HCPCS) provides approximately 80 "S" codes for home infusion therapy services. Most codes reflect a "bundled" per diem approach in which most or all of the supplies and services provided to a home infusion patient are billed under a single code. This complete system of "S" codes for home infusion therapy services is specifically designed for use by private payers, and are available for use by government payers that adopt this widely used private sector methodology for infusion coding and payment. These codes are not used in coding of retail pharmacy drug claims and are not permitted for HIPAA-compliant use on the NCPDP transaction).

Although CMS does not have a single HIPAA coding standard for drugs, we believe that the PDPs and CMS will find requiring NDC drug coding for Part D claims will provide best opportunity for patient utilization analysis and tracking of total Part D drug costs for CMS's program administration. We believe the Part D regulations should require that all claims for drugs be coded with NDC numbers.

D. Coordination of benefits.

In addition to these reasons for infusion claiming and coding consistency, the COB portion of the Part D program is also best implemented by CMS's establishing a requirement for 837 claiming and use of the established coding systems. The majority of COB will occur with commercial payers such as the Blues and other private health plans. As the private sector has already widely adopted the established coding systems described above, it will be important for CMS to require consistent coding adoption to make COB work, ensuring that the allocation of payment for services between Part D plans and other primary or secondary plans works well.

Since the private payer sector accepts home infusion therapy claims using the HIPAA-compliant X12 N 837 format, for COB to work effectively is another reason that CMS should require PDPs to use the 837 claim format for infusion claims. Because a very large majority of private infusion payers use the HIPAA-complaint *professional* 837 (837P) claim format, to make COB work we believe that CMS's Part D regulations should require PDPs to adopt the HIPAA-compliant 837P format only, excluding both the *institutional* 837 and NCPDP transaction from use.

E. CMS should clarify the any willing provider requirements with respect to home infusion drug therapy.

CMS should clarify that this access safeguard is to be applied to any willing provider of home infusion therapy meeting the infusion-specific quality standards (see below), as distinct from retail pharmacies. Such a requirement is consistent with the statutory language.[6]

In addition, for the purpose of the any willing provider requirements, CMS should clarify that prescription drug plans should have a standard contract for home infusion pharmacies.

These recommendations for the network access standards will help safeguard enrollee access by ensuring that the Medicare Part D benefit reflects common private sector practices for home infusion drug therapy. In addition, the recommended clarifications will not impose significant burdens on PDPs.

F. CMS should recognize that OBRA 1990 standards do not represent the standard of care for infusion pharmacies.

In the preamble, CMS refers to Section 54401 of the Omnibus Reconciliation Act of 1990, stating that the regulations issued pursuant to that section in 42 CFR 456.705 "describe currently accepted standards for contemporary pharmacy practice and our intent is to require plans to continue to comply with contemporary standards." CMS seeks comments on whether these standards are industry standards and whether they are appropriate for Part D.

The OBRA 1990 standards were written for retail pharmacies. The drafters of these standards did not attempt to address the standard of care for infusion pharmacies. Infusion pharmacies that are in compliance with the infusion-specific standards established by accrediting organizations meet the OBRA 1990 standards, but the OBRA 1990 standards do not reflect "contemporary pharmacy practice" for infusion pharmacies. The community standard of care for infusion pharmacies is found in the accreditation standards that are required by virtually every private health plan, as well as numerous MA plans, to participate in their provider networks.

The quality assurance standards followed by home infusion pharmacies—and as required for accreditation--far exceed the OBRA 1990 standards. Due to advances in newly-approved drugs and technology and additional laws and regulations established in the intervening years (such as HIPAA), and development of knowledge surrounding patient safety and medication management at home, the level of patient data collection, assessment and intervention in the infusion clinical model goes far above and beyond the quality standards currently used for Medicaid. Again we respectfully direct your attention to Jared Adair's April 8, 2003 comments concerning the key differences between retail and home infusion pharmacies.

[6] Social Security Act, Section 1860D-4(b)(1)(A).

IV. Formulary Development

A. CMS should mandate that PDP and MA-PD plan sponsors maintain an open formulary for infusion drugs to ensure this population of vulnerable patients has appropriate access to necessary medications.

Much of the MMA is based on the premise that Medicare can take advantage of cost-savings techniques commonly used in the private sector and still deliver quality services to Medicare beneficiaries. CMS should note that although private health plans commonly use restricted or preferred formularies for drugs delivered orally, via patch or other non-invasive methods, private plans rarely apply these formulary restrictions to infusion drugs.

As discussed in greater detail below, there are numerous clinical and operational barriers to establishing formularies for infusion drugs. As a result, with respect to infusion drugs, formularies should remain open.

B. CMS should recognize that PDPs and pharmacy and therapeutics committees are not well situated to evaluate infusion drugs.

It will be difficult for PDPs and traditional pharmacy and therapeutics committees (P&T committees) to evaluate infusion drugs in the same manner that they evaluate orally administered drugs.

P&T committees generally evaluate the relative safety, efficacy, and effectiveness of prescription drugs within a class of prescriptions drugs and make recommendations to a health plan for the development of a formulary or preferred drug list. Frequently, P&T committees focus on the "therapeutic equivalence" of different multisource drugs (*i.e.*, whether one drug will have the same desired clinical impact as another). However, such evaluations are performed in a context where the method of administering the drug is not significant.

In contrast to oral drugs, the method of administration for an infusion drug may have separate and significant clinical and cost implications. All infusion drugs require a device of some type to deliver the drug into the body, including various catheters temporarily or semi-permanently implanted in each patient depending on the anticipated duration of therapy, potential side effects of the drug and the patient's diagnosis itself. Various methods of drug delivery also exist, from IV bags hung on poles to sophisticated external or internal infusion pumps. A patient's clinical condition may determine not only what device is selected for delivery, but also what drug should be used. For instance, many patients receiving infusion therapy are at high risk of infection or complications from infection. Consequently, a physician may need to choose a medication that can be prepared in advance in a pharmacy clean room and administered once a day to reduce the risk of infection from preparation in the home or multiple intravenous access device manipulations.

Similarly, in selecting a medication for a patient, a physician often needs to consider administration access type and what delivery technology will be best suited for use in a particular patient's home. If the patient is capable of managing a portable infusion pump, drugs requiring longer infusion times may become more clinically appropriate. If other technologies are used, such as IV bags hung on poles, the patient may require more frequent nursing visits to monitor the risk of infection.

The typical P&T Committee would usually not have the experience to evaluate the administration technology or professional support requirements, such as nursing visits, in reviewing infusion drugs. Furthermore, such committees do not typically make decisions considering all available treatment options throughout the continuum. Drugs considered ideal in an inpatient setting are often not desirable in the home setting and visa versa, especially where the first dose of the drug is concerned. Examples include Taxol® for ovarian cancer, Lovenox® for deep vein thromboses and certain immune globulins.

In addition, most infusion drugs must be compounded by the pharmacy. Once compounded, these drugs lose stability over time or be impacted by changes in temperature. For oral drugs, the frequency of administration or stability issues usually do not pose challenges for a P&T Committees as they try to determine therapeutic equivalence.

Ultimately, the infrastructure for protecting patient interests in formulary decisions—the traditional P&T Committee—does not have the ability to evaluate the extra-pharmacological considerations that must be taken into account for infusion treatment, including the administration device, drug stability, proximity to a compounding pharmacy, available administration access site and infection risk. Typically, these factors would be addressed by a physician or pharmacist knowledgeable about an individual's patient's circumstances and history when selecting a drug and delivery device.

C. CMS should recognize home infusion patients as a particularly vulnerable population that requires additional protection.

Patients receiving home infusion therapy are one of the truly vulnerable populations of the Medicare population, and as CMS acknowledged in the Proposed Rule,[7] the medical needs of such populations necessitate that they receive special protection under Medicare Part D. Infusion drugs are used to treat some of the most severe illnesses, including cancer, severe infections, pain and loss of gastrointestinal integrity.

Although the Medicare Part D regulations do create an appeals process for patients if their physician's choice of medication is not on formulary, patients with these compromising illnesses are the least capable of exercising an appeals right. If a patient does not have a family member or physician willing to take on the burden of being an advocate, then the patient's care could be compromised.

[7] 69 Fed. Reg. at 46661.

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We commend CMS for its initial efforts to understand and accurately define home infusion drug therapy under Medicare Part D. There is an important opportunity for the program to replicate the successes achieved by private health plans and Medicare managed care plans. There is also a risk that in the absence of sufficient direction from CMS and some targeted safeguards, the benefits of home infusion drug therapy will be lost for both beneficiaries and the overall Medicare program.

We would be pleased to provide additional assistance regarding these important issues. Please contact Lisa Getson, Apria's executive vice president, at 949-639- 2021 if you have any questions or comments.

Sincerely,

Lawrence M. Higby
President and Chief Executive Officer

CC: Herb Kuhn
Leslie Norwalk

Submitter : Ms. Janet Schalansky **Date & Time:** 10/04/2004 08:10:44

Organization : Dept. Of Social and Rehabilitation Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-4068-P-1234-Attach-1.pdf

K A N S A S

JANET SCHALANSKY, SECRETARY

SOCIAL AND REHABILITATION SERVICES

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Dear Sir or Madam:

The Kansas Department of Social and Rehabilitation Services respectfully submits the following comments regarding the proposed rule on the Medicare Prescription Drug Benefit published Tuesday, August 3, 2004. Comments are grouped under section identifiers as requested in the proposed rule.

One general comment needs to be made. Because of the statutory and regulatory requirements regarding states' responsibilities in implementing and administering activities related to Part D, it is absolutely critical that access to federal data be provided in a timely and thorough manner. Specifically Kansas requests access to online real time entitlement and enrollment information for not only Part D and subsidy eligibility but also Part A and B. This should occur through access to the Common Working File.

Subpart B - Eligibility & Enrollment

Section 423.34 - <u>Enrollment Process</u>

Because of the level of information required for the auto enrollment process and the resources needed to carry it out, the State would recommend that the Centers for Medicare & Medicaid Services (CMS) take the lead for this process. Information will need to be obtained in order to better guarantee that the person is enrolled in an appropriate plan taking into consideration their living arrangement, specific drug needs, and available participating pharmacies. CMS is in the best position to accomplish this task with information provided from the states and SSA.

Section 423.36 - <u>Initial Enrollment Period</u>

The State is concerned regarding the impact of the initial enrollment period for persons who are fully dually eligible at the time of this enrollment process. Per section 423.906, a person who is eligible for Part D and also is a full benefit dual eligible, medical assistance under Medicaid is not available for drugs that could be covered under Part D. It appears that in order to protect drug coverage from lapsing as of January 1, 2006 for current Medicaid eligibles, the individual would need to enroll by the

end of December 2005. If this is correct, the period of time to accomplish such enrollment (November 15 through December 31) is not sufficient for the number of beneficiaries who will be impacted. The State strongly recommends that an additional period of 90 days or more following January 1 be provided for Medicaid to continue paying drug claims for consumers who have not yet been able to complete the Part D enrollment process.

This same approach will likely be necessary for consumers who newly apply for full Medicaid coverage during this initial enrollment period for Part D. For example, a person who has not yet enrolled for Part D applies for Medicaid on December 20, 2005 and would qualify as a fully dual eligible. If the Medicaid application is not processed until January 15 but Part D enrollment does not take effect until February, the person would again appear to be left without drug coverage for the month of January.

On an ongoing basis, this additional Medicaid coverage period may need to be applied in certain instances involving the individual's own initial enrollment period for Part D. Persons may apply and qualify for full Medicaid coverage and be not only currently eligible but also eligible for Medicaid coverage in the three prior months. If not enrolled in Part D during this period, again the person would be left without drug coverage until that enrollment is completed.

Lastly such an extended Medicaid coverage period may need to be applied in situations where retroactive Medicare entitlement is established. Per section 423.4, a Part D eligible is defined as a person who is entitled to or enrolled in Part A and/or Part B. There will be instances in which an individual is retroactively enrolled in Parts A or B because of a delayed approval for disability benefits. Such persons may have received Medicaid during this time and had their drug costs covered. Once approved for retroactive enrollment in Parts A or B, the person would now become a retroactive full dual eligible. As the person was not enrolled in Part D during this time, any retroactive drug coverage would potentially be in violation of these regulations. The regulations would appear to require the State to fully reimburse CMS for the coverage provided, yet do not allow the beneficiary to enroll in Part D retroactively.

Because of these and similar instances, the State strongly encourages CMS to provide for either retroactive Part D enrollment and coverage or permit an interim period of Medicaid drug coverage to account for such situations.

Subpart C - Benefits & Beneficiary Protections

Section 423.100 - <u>Definitions</u>

Prescription drug coverage under Part D has been limited for institutionalized consumers so that only

those residing in skilled nursing facilities are eligible. The State disagrees with this limitation and believes that all institutional settings including ICF-MR's should be included. In addition, persons accessing long term care services through home and community based services waivers should also be included. Individuals in these living arrangements should be assured access to coverage of all drugs through Part D.

Subpart P - Premiums & Cost Sharing Subsidies for Low Income Individuals

Section 423.772 - Definitions

The definition of full benefit dual eligibles includes persons who meet a medically needy spenddown in a month. Such definition is extremely problematic as the person will go in and out of full benefit classification on an ongoing basis making continuity of drug coverage next to impossible. There is also an issue with persons who meet spenddown in a prior period but who are back in spenddown status in the current month of application. The State proposes that medically needy individuals who meet spenddown be viewed as meeting the full benefit dual definition for a continuous period of up to 12 months even though going back into spenddown status during this time.

Section 423.773 - Requirements for Eligibility

The State strongly concurs with the inclusion of QMB, SLMB, and QI 1's as full subsidy eligible without the requirement for a separate determination.

Section 423.774 - Eligibility Determinations, Redeterminations, and Applications

The regulations provide for a duplicative application and determination process in which persons may apply for low income subsidies with either the State or Social Security Administration. As the subsidy is directly tied to Medicare coverage, this process is best handled as an SSA function. However, it is understood that many low income subsidy applicants may qualify for the Medicaid Savings Programs (QMB, SLMB, QI1) and thus automatically qualify for a subsidy. The State recommends that where an application is filed with the State and the person does not qualify for a Medicaid category that would result in automatic qualification for a subsidy, the information be provided to Social Security for a determination of subsidy eligibility. This can best be done by permitting SSA to use the State's application to make the subsidy determination. This would prevent the State from expending substantial funds and resources on modifying eligibility systems to handle the subsidy determination. That determination uses income and resource rules as well as family size definitions that differ substantially from Medicaid rules applied is in most states. SSA should also handle the redetermination and appeal process for all subsidy-only consumers. Information systems also need to be developed to better share information gathered between the two entities.

There do not appear to be any provisions regarding treatment of individuals who lose subsidy eligibility, particularly those who are deemed eligible by virtue of Medicaid eligibility. Processes need to be put into place for SSA to redetermine subsidy eligibility before the subsidy is eliminated. This may occur in instances where the individual has failed to return a Medical redetermination form or in which they have moved to another state and not contacted the new state agency for continued

Medicaid coverage. Proper and timely notification is critical before the subsidy is withdrawn.

Subpart S - Special Rules for States

Section 423.910 - <u>Requirements</u>

The baseline for determining the state's contribution doesn't take into consideration deductions for recoveries received as a result of such activities as estate recovery, medical subrogation, consumer overpayment recoveries, and third party collections. The State requests such activities be included in the baseline calculation.

We appreciate the opportunity to provide comments regarding these regulations.

Sincerely,

Janet Schalansky
Secretary

JS:BM:DZP:jmm

CMS-4068-P-1235

Submitter : Ms. M. J. Terrebonne **Date & Time:** 10/04/2004 08:10:37

Organization : Department of Health and Hospitals

Category : State Government

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

With the use of formularies, Medicaid recipients who are currently stable on medication therapies may not have continuity of care should they be switched to MA-PD or PDP preferred drug therapies.
A Medicare Part D beneficiary who is a Medicaid dual eligible should not be disenrolled from a MA-PD or PDP plan for any reason. This group of individuals in most cases do not have an alternative drug plan.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Part B drug claims which are denied covergae due to therapeutic inappropriateness, drug-disease contraindication, incorrect drug dosage, duration of drug treatment or for similar reasons related to meidal necessity should not be considered a Part D drug. Consideration should be given for coverage of drugs which are denied coverage under Part B as there may be clinical reasons for the coverage of these products.

Also, while there is much interface between drug coverage under Part B and Part D, use of the NDC number should be require in Part B billing to ensure rebate collections from drug manufacturers on federal and state supplemental rebates. Continuing the use of HCPCS codes makes it difficult to invoice drug manufacturers accurately for all drugs.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Should the auto-enrollment of dual eligibles end prior to 1/1/06? The dual eligibles should have an opportunity to choose the MA-PD or PDP plan prior to an auto-enrollment period.

Submitter : Ms. Linda Hanold **Date & Time:** 10/04/2004 08:10:47

Organization : NCC MERP

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

By Electronic Mail October 4, 2004

Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014

File Code: CMS-4068-P

Dear Dr. McClellan:

On behalf of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), I would like to take this opportunity to respond to the proposed rule for Title 1 of the Medicare Prescription Drug, Improvement and Modernization Act under Section 423.153(c) that requires providers of qualified prescription drug coverage to implement a quality assurance program. This includes quality assurance measures and systems for reducing medication errors, reducing adverse drug reactions, and improving medication use.

At its September 24, 2004, meeting, the Council had the opportunity to carefully review and discuss these sections of the proposed rule and offers the following comments:

? The Council supports the inclusion of drug utilization review, patient counseling, and patient information record-keeping as part of the quality assurance program.

? The Council supports inclusion of the proposed elements for quality assurance systems including electronic prescribing, clinical decision support systems, educational interventions, use of barcodes, adverse event reporting systems, and provider/patient education.

? The Council strongly cautions the Agency against the inclusion of error rates or the comparison of error rates in future quality reporting systems. In June 2002, the Council issued a statement against the use of medication error rates as a basis for comparing health care organizations noting that medication error rates for this purpose are of no value because of differences in culture, interpretation of error definition, differences in patient populations, and methods of reporting and detection. This document may be found in Attachment A. The Council suggests that there is

more value in encouraging the reporting of errors to a central location (e.g., national databases such as USP MEDMARX SM and FDA MedWatch). When errors are reported to an objective third party, these data can be broadly disseminated to help avoid recurrence. It is the Council?s contention that using these data for comparisons is a step backward that will resurrect the punitive ?culture of blame? identified by IOM as a major obstacle to safer patient care. Such comparisons also foster under-reporting and less than full disclosure about events which prevent the understanding of the causes of error.

Finally, the Council would like to point out that the definition of medication error that is quoted in the proposal was originally developed by the Council (see Attachment B) and later adopted by the Food and Drug Administration. It is important to note, however, that medication errors are preventable adverse events; but not all adverse events are preventable. All drugs have intrinsic toxicities that are unavoidable in some patients. Also, some patients have unanticipated allergic or idiosyncratic reactions to drugs that cannot be prevented.

A roster of NCC MERP member organizations and individuals is included as Attachment C. These comments reflect the collective opinion of the Council, but not necessarily of its individual members.

Thank you for this opportunity to provide input on this important issue. If you require additional information, please do not hesitate to contact me at 630-792-5916 or lhanold@jcaho.org.

Sincerely,

Linda S. Hanold
Chair, NCC MERP, c/o USP, 12601 Twinbrook Parkway, Rockivlle, MD 20852

CMS-4068-P-1236-Attach-1.doc

CMS-4068-P-1236-Attach-3.doc

CMS-4068-P-1236-Attach-2.doc

National Coordinating Council for Medication Error Reporting and Prevention

Statement from the National Coordinating Council for Medication Error Reporting and Prevention:

USE OF MEDICATION ERROR RATES TO COMPARE HEALTH CARE ORGANIZATIONS IS OF NO VALUE

The use of medication error rates to compare health care organizations is not recommended for the following reasons:

1. Differences in *culture* among health care organizations can lead to significant differences in the reporting of medication errors. Organizations that encourage medication error reporting by providing incentives and resources to report within a non-punitive, continuous quality improvement arena will likely report more medication errors than organizations that wish to conceal errors and punish individuals who report or are involved in errors.

2. Differences in the *definition* of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors. For example, some organizations may only consider actual errors that reach the patient as errors. Other organizations also will include potential errors and errors that do not reach the patient. The latter organizations will likely collect more medication errors, and information from reports of potential errors can sometimes be more useful in prevention efforts than reports of actual errors.

3. Differences in the *patient populations* served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations. For example, tertiary care hospitals generally may serve more severely ill patients than rehabilitation hospitals. In addition, the intensity of drug therapies, the types of drugs used, and the methods of drug distribution may be substantially different in these environments, thereby leading to differences in number and types of errors.

4. Differences in the *type(s) of reporting and detection systems* for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded. Passive reporting systems, relying upon voluntary reports from staff, are known to result in far fewer medication error reports than active surveillance systems are able to detect. Also, the number of error reports can be significantly different, depending on the type of active surveillance system (e.g., direct observation versus retrospective review of medical records versus computer-based data gathering from electronic medical records and order entry systems).

The National Coordinating Council for Medication Error Reporting and Prevention believes there is no acceptable incidence rate for medication errors. Use of medication error rates to compare health care organizations is of no value. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Health care organizations should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication use system to prevent future errors, and potential patient harm. The value of medication error reports and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the health care organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

Adopted by the National Coordinating Council for Medication Error Reporting and Prevention
June 11, 2002

The definition of “medication error” as developed by the Council and adopted by the Food and Drug Administration reads as follows:

“A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.”

The following national organizations, agencies, and individuals comprise the current membership of the NCC MERP:

AARP*

American Health Care Association

American Hospital Association

American Medical Association

American Nurses Association

American Organization of Nurse Executives

American Pharmacists Association

American Society for HealthCare Risk Management

American Society of Consultant Pharmacists

American Society of Health-System Pharmacists

Department of Defense

Department of Veterans Affairs

Food and Drug Administration

Generic Pharmaceutical Association

Healthcare Distribution Management Association

Institute for Safe Medication Practices

Joint Commission on Accreditation of Healthcare Organizations

National Association of Boards of Pharmacy

National Association of Chain Drug Stores

National Council of State Boards of Nursing

National Council on Patient Information and Education

Pharmaceutical Research and Manufacturers of America

The United States Pharmacopeia

David Kotzin, R.Ph., Director, Department of Pharmacy, Greater Baltimore Medical Center

Deborah Nadzam, PhD, FAAN, Director, The Quality Institute, The Cleveland Clinic

* AARP's opinion on the MMA Regulations is reflected in its own comments to CMS.

Submitter : Karla Fultz McHenry **Date & Time:** 10/04/2004 08:10:00

Organization : Iowa Medical Society

Category : Physician

Issue Areas/Comments

Issues 11-20

SPECIAL RULES FOR STATES

The MMA clawback provisions and eligibility determination requirements for dual eligibles under Part D have the potential to impact State Medicaid budgets significantly.

CMS-4068-P-1238

Submitter : Mr. Randy DeFrehn **Date & Time:** 10/04/2004 08:10:33

Organization : NCCMP

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find the comments filed by the NCCMP

CMS-4068-P-1238-Attach-2.doc

CMS-4068-P-1238-Attach-1.doc

VIA ELECTRONIC DELIVERY

October 4, 2004

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014
http://www.cms.hhs.gov/regulations/ecomments

Dear Sirs/Madams:

These comments are filed by the National Coordinating Committee for Multiemployer Plans (NCCMP) in response to the request for public comments by the Centers for Medicare and Medicaid Services (CMS) on the proposed rule to implement the new Medicare Prescription Drug Benefit authorized in section 101 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). This proposed rule was published in the Federal Register of August 3, 2004 (69 Fed. Reg. 46632).

The NCCMP is the only national organization devoted exclusively to protecting the interests of the approximately ten million workers, retirees, and their families who rely on multiemployer plans for retirement, health and other benefits. Our purpose is to assure an environment in which multiemployer plans can continue their vital role in providing benefits to working men and women. The NCCMP is a nonprofit organization, with members, plans and plan sponsors in every major segment of the multiemployer plan universe, including in the building and construction, retail food and service, and entertainment industries.

Most multiemployer plans today provide for retiree health benefits and many of those plans include some type of coverage for prescription drugs. As is well documented, the number of retirees covered by employer-sponsored health benefit plans today and in the future has continued to shrink, primarily because of the combination of accounting rule changes that force private sector employers to recognize the long-term liability of the retiree medical benefits and the rapidly escalating cost of providing that retiree health coverage.

Although facing the same marketplace cost pressures as other plan sponsors, employers and unions who have come together through collective bargaining to establish multiemployer plans have been less likely to drastically reduce or eliminate retiree coverage, in part because active workers in those industries where multiemployer plan coverage is prevalent have been willing to forgo some portion of their compensation to continue to subsidize the health benefits of their brothers and sisters who have retired. Even so, some multiemployer plans have been forced to alter the way benefits are financed in order to remain fiscally solvent. For some multiemployer plans, the rapidly escalating costs, the demographic trends, and the contraction of

the unionized workforce have required them to seriously rethink plan design and financing issues and to take steps to reduce or eliminate retiree benefits in ways that would have been unthinkable just a few years ago.

During the legislative process surrounding the passage of the MMA, the NCCMP urged Congress to consider carefully the structure of the new prescription drug program so as to avoid creating additional burdens on employer-sponsored plans and further incentives for them to reduce or drop prescription drug coverage for Medicare-eligible retirees. Although Congress incorporated an employer subsidy provision in the final legislation for plans that provided prescription drug benefits that were at least actuarially equivalent to the standard Part D drug benefit to encourage employers to continue providing retiree drug coverage, the overall structure of the new Medicare Part D benefit seriously disadvantages retirees with employer-sponsored coverage. This is particularly true with respect to the ability of retirees to meet the out-of-pocket limits that would trigger Medicare's catastrophic coverage. We recognize that CMS cannot through regulation remedy such a serious structural flaw in the statutory framework of the MMA, but we urge CMS to use its interpretive authority to ameliorate wherever possible the disadvantageous treatment of retirees with employer-sponsored coverage.

The statutory provisions of the MMA relating to employer-sponsored retiree prescription drug coverage are largely fashioned with a corporate health plan model in mind. Under this model, the plan sponsor is the employer who controls both plan design and financing decisions with little or no input from employees, unions or retirees. As you know, the world of multiemployer plans is quite different. Under applicable labor law, these collectively bargained plans are administered by a Board of Trustees consisting of equal numbers of representatives of labor and management. Under the Employee Retirement Income Security Act of 1974 (ERISA), the Board functions as both plan sponsor and the named fiduciary of the plan (and often the plan administrator as well) and therefore no individual employer can influence the operation or design of the plan because those decisions are reserved for the Board.

We appreciate the obvious effort that CMS has made in crafting its proposed rule to recognize that not all employer-sponsored plans are the same. We share your goals of maximizing the number of retirees retaining existing drug coverage, avoiding windfalls in which retirees receive a smaller subsidy from plan sponsors than Medicare would pay on their behalf, minimizing administrative burdens on beneficiaries, employers, unions, and plans, minimizing costs to the government of providing retiree drug subsidies and staying within the budget estimates. However, we believe that some of the rules that are being considered, particularly those directed at avoiding employer windfalls, may not be as relevant to multiemployer plans as they might be in a corporate plan setting, since it is the joint Board of Trustees that controls the design and financing of the retiree health plan, not any individual employer. This provides a degree of protection against potential manipulation that may be missing in other circumstances.

We have focused our comments on a handful of key issues raised in Subpart R of the proposed rule but we hope to open a dialogue with CMS staff on these and other issues of concern. Our detailed comments follow.

Comments Related to Subpart R – Payments to Sponsors of Retiree Prescription Drug Plans:

Section 423.882 Definitions

"Group health plan"

We support the use of the same definition of group health plan as found in section 607(1) of ERISA, 29 U.S.C. 1167(1). To further clarify the ability of multiemployer plans to qualify for the subsidy, we suggest also incorporating the definition of "multiemployer plan" found in section 3(37) of ERISA, 29 U.S.C. 1002(3)(37).

"Sponsor"

Although the proposed rule refers back to the definition of plan sponsor found in section 3(16)(B) of ERISA, we suggest that CMS confirm that in the case of a multiemployer plan (i.e., a plan established or maintained jointly by more than one employer and one or more employee associations), the plan sponsor is the board of trustees.

It would also be helpful for CMS to confirm how the employer subsidy provisions for prescription drug coverage operate in the context of a multiemployer health plan.

As we understand the statutory structure and legislative history of MMA regarding the employer subsidy for retiree prescription drug coverage, Congress intended for the Board of Trustees of the multiemployer plan to be the recipient of the employer subsidy since it is the plan that finances the retiree drug benefits (i.e., employer contributions and retiree contributions are placed in trust and those amounts, together with interest accumulated in the trust, are used to pay retiree prescription drug benefits). Therefore, as the entity claiming the subsidy, the multiemployer plan, not each contributing employer, will be responsible for meeting the procedural requirements to claim the subsidy, including providing the required disclosures to the Secretary and all eligible individuals (e.g., the notice of creditable coverage). The plan will apply for the subsidy (including furnishing the actuarial attestation and the list of qualified retirees covered under the multiemployer retiree prescription drug plan who are not enrolled in Medicare Part D). Once CMS has processed the application and verified the status of qualified retirees of all contributing employers, the subsidy would be paid to the multiemployer retiree prescription drug plan and these amounts would be credited toward future contributions to prescription drug coverage, by providing funds to cover costs that would otherwise have to be met through additional contributions. This approach eases burdens on CMS and individual contributing employers, while allowing the entity that pays the retiree prescription drug benefits (the multiemployer plan) to receive the subsidy and use it to cover retiree drug costs without incurring necessary administrative costs.

We would be happy to review with you the way that multiemployer plans operate and to furnish further detail why it is essential that the plan be treated as the plan sponsor for purposes of the subsidy, rather than individual contributing employers.

Section 423.884 Requirements for qualified retiree prescription drug plans

(a) Actuarial Attestation

Under the proposed rule, plan sponsors seeking to claim a subsidy for their prescription drug coverage must annually apply for the subsidy, no later than 90 days before the beginning of the calendar or plan year for which the subsidy is sought.

Although the proposed rule requires an actuarial attestation that the prescription drug benefits provided under the retiree prescription drug plan is at least actuarial equivalent to the standard Medicare Part D benefit, little guidance is given regarding the content of this attestation. CMS should consider developing a model form for this attestation, in which the plan's actuary could describe in simple terms how the determination of actuarial equivalency was made and what assumptions were used. A useful example of this type of standardized actuarial reporting for CMS to consider is the Schedule B to the Form 5500, the annual financial report that certain ERISA-covered pension plans must file with the U.S. Department of Labor. Of course, if CMS decides to promulgate a model form, its use should be considered a safe harbor for satisfaction of the attestation requirement and plan sponsors should be free to submit their own attestations in any other format as long as the required information has been included.

We think that CMS's proposal to require that an additional attestation must be filed with CMS no later than 90 days before a material change to the drug coverage that impacts the actuarial value of the coverage is generally reasonable, but we are concerned that the 90-day requirement may not be feasible in all situations.

The question of whether the 90-day deadline is feasible is interrelated with the issue of whether this deadline ought to be related to a calendar year or the plan year. CMS has indicated that it is leaning toward the use of a calendar year approach. Although most plan sponsors use a calendar year as the plan year, many do not. Clearly there are persuasive arguments favoring the use of a calendar year which can be made, however, we believe to reduce administrative burdens on plan sponsors, CMS should adopt a plan year approach.

Establishing actuarial equivalency

Under the MMA, the federal government will pay a cash subsidy to employers and other plan sponsors (including multiemployer plans) that provide retiree prescription drug coverage that is at least equal in value to the new Medicare Part D prescription drug coverage. The subsidy would be 28 percent of a retiree's total covered drug costs between $250 and $5,000 per year, which translates to a maximum subsidy payment to a plan sponsor of $1,330 per retiree. The subsidy would be payable for each retiree covered under the employer-sponsored plan who is not enrolled in Medicare Part D.

Although the cost of providing the new drug coverage under Medicare is partially financed by the Federal government, retirees enrolled in the new Medicare Part D benefit program will still be paying a substantial amount themselves for the coverage.

The standard Medicare Part D benefit design which will be offered through stand-alone prescription drug plans (PDPs) is as follows:

- Retirees will pay a monthly premium set by the PDP (estimated to be $35 per month in 2006 when the program begins, but expected to increase as costs increase);
- The PDP decides which prescription drugs to cover, as long as the PDP's formulary meets certain statutory requirements;
- Retirees must pay the first $250 in covered drug costs out of their own pocket (the standard deductible);
- Retirees pay 25% of covered drug costs between $250 and $2,250 during the year;
- Retirees pay 100% of covered drug costs between $2,225 and $5,100 during the year;
- Retirees pay no more than 5% of covered drug costs to the extent that those costs exceed $5,100. But to be eligible for this "catastrophic" coverage, an individual retiree must pay $3,600 (in 2006) in covered drug costs. Costs covered by a third-party, such as insurance or a group health plan, would not count toward this so-called "true out-of-pocket" amount (TrOOP).

To qualify for the 28% Federal subsidy, coverage provided by the employer-sponsored retiree medical plan does not have to be identical to the standard Part D drug benefit described above; it must be at least equal in value on an actuarial basis to the Part D coverage.

The MMA defines this measurement and comparison of the values of the two benefit design "actuarial equivalence." This test makes it possible to compare the value of different benefit designs. Actuarial equivalence looks at the expected cost of a benefit for a typical person, not how much it will actually cost for any given individual. This is important because a person who has greater health care needs obviously will cost more than one who is healthier.

The term "actuarial equivalence" is not defined in the proposed rule itself. CMS will have to create a standard for determining whether an employer retiree drug benefit is actuarially equivalent to the standard Part D benefit. However, in the preamble to the proposed rule, CMS has suggested a variety of differing approaches or tests to determine whether the employer-sponsored retiree drug plan is actuarially equivalent to the standard Medicare Part D prescription drug plan. CMS has asked for public comments on which, if any, of these standards is the right one and which may not be suitable. The standard CMS ultimately chooses will determine how generous a benefit employers have to offer retirees and how big a share of the benefit employers can require retirees to pay and still qualify for the federal subsidy.

Below is a brief description of each of the standards for which CMS seeks public comment:

- Single Prong Test: Under this test, also known as the "gross value test," an employer's benefit is good enough to qualify for a federal subsidy if, on average, the total value of

the benefit is at least equal to the total value of the standard Part D benefit. It does not matter what share of the benefit, if any, the employer pays. Under this test, the employer could contribute nothing and require the retiree to pay the full cost of the plan, yet the employer would still be paid the federal subsidy.

- Single Prong/No Windfall Test: As with the test above, an employer's benefit is good enough for a subsidy if on average the total value of the benefit is at least equal to the total value of the standard Part D benefit. However, the dollar amount of the subsidy paid to the employer cannot be greater than the dollar amount the employer pays toward the retiree coverage. The employer could design the plan so that it pays nothing towards retiree drug coverage after taking the federal subsidies into account.

- Two-Prong Test: This test begins with the single prong test but applies a second test (or "prong") in which the employer would also have to show it is paying for at least a specific minimum share of the total benefit. CMS offers several examples of the level at which it could set the minimum share or amount the employer must pay under the Two-Prong Test. These include:
    - The average per person amount Medicare would expect to pay as a subsidy to employers during the year, estimated by CMS to be $611 in 2006 when the program begins.
    - The expected amount of paid claims under the standard Part D prescription drug plan minus the monthly part D premiums paid by the retiree, estimated by the Congressional Budget Office to be approximately $1,200 in 2006.
    - The after-tax value of the average per person amount Medicare would expect to pay as a subsidy to employers during the year. For employers subject to the federal corporate income tax, this would be higher than the $611 estimated subsidy payment and will vary depending on the employer's tax rate.

One of Congress's policy goals under MMA is to ensure that the subsidy is used to preserve retiree benefits and not used simply to improve the employer's bottom line or for other non-health care uses. The preamble to the proposed regulation endorses the principle that the subsidy should be passed through to the retirees to pay for retiree prescription drug benefits. In particular, the proposed regulation states:

> "The intent of the MMA retiree prescription drug subsidy provisions is to slow the decline in employer-sponsored retiree insurance. By providing a special subsidy payment to sponsors of qualifying plans, the MMA provides employers with extra incentives and flexibility to maintain prescription drug coverage for their retirees. Our intention is to make these subsidy payments as reasonably available to plan sponsors as possible. We wish to take into account as much as possible the needs and concerns of plan sponsors, consistent with necessary assurances that Federal payments are accurate and in accordance with statutory requirements, that the interests of retiree-beneficiaries are protected, and that employers do not receive ''windfalls'' consisting of subsidy payments that are not passed on to beneficiaries."[1]

[1] 69 Fed. Reg. 46737 (August 3, 2004).

The structure of multiemployer plans assures that this policy goal is met.

After carefully considering each of the proposed standards, we have the following recommendations regarding the actuarial equivalence test that we believe are consistent with CMS's goals.

- CMS should adopt the Two-Prong Test for actuarial equivalence, which requires the portion of the prescription drug plan financed by the employer to be at least equal to the portion of the Part D benefit that is financed by Medicare. Only this test is consistent with the letter and intent of the MMA to provide for alternative drug coverage that is actuarially equivalent to the standard Part D benefit. In considering the portion of the plan that is financed by the employer, earnings on employer contributions held in trust as plan assets should be included. The comparison of the employer plan to the Part D benefit should be based on the benefits provided, not the cost.

- All of the other standards described by CMS in the preamble to the proposed rules could penalize retirees covered under a retiree drug plan and should be rejected. The Single Prong Test, the Single Prong/No Windfall Test, and the two versions of the Two-Prong Test that permit the employer to limit its contribution to the average subsidy amount it would expect to be paid from Medicare could all require a retiree to pay more for drug coverage than the retiree would if he or she were covered under a Medicare Part D prescription drug plan.

- Other tests being considered by CMS would allow for even greater windfalls to an employer. The Single Prong (or Gross Value) Test would allow for enormous windfalls to employers since it would permit an employer to pay nothing toward the drug benefit and still collect federal subsidies. This option has been roundly criticized in the press, is inconsistent with the intent of Congress, and would undermine the integrity of the Medicare drug program and therefore endanger the future of the program.

- In those cases in which a plan sponsor would be prohibited from claiming the largest possible retiree drug subsidy payable under the law due to the anti-windfall protections, CMS should provide a mechanism permitting the plan sponsor to claim the larger subsidy, so long as it passes through the value of the subsidy exceeding the windfall protections to the retirees. This is very important from a multiemployer perspective.

- Where a plan is fully insured, the regulations should require the insurance carrier to provide to the plan sponsor the information necessary to apply for the subsidy.

What is a "plan"?

As CMS acknowledges, many plan sponsors provide different levels and packages of benefits to different groups of retirees. In determining whether the coverage meets the actuarial equivalency test, one must first determine what the plan is that is being compared to the standard Medicare Part D prescription drug coverage. In its proposed rule, CMS indicates that it intends

to adopt a definition of "plan" that mirrors the current approach found in the Treasury regulations regarding the health insurance continuation requirements of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). Under those regulations, all health benefits provided by the plan sponsor are presumed to be under a single plan unless plan documents indicate otherwise.

As a result, actuarial equivalence would be determined by evaluating the plan as a whole, not on a benefit structure by benefit structure basis, and if, on average the actuarial value of the drug coverage equals or exceeds the value of the standard Part D coverage, the plan would satisfy the actuarial equivalency test.

We support the use of such an approach because it is one that is already familiar to plan sponsors and it provides flexibility without sacrificing retiree protections.

(b) Sponsor application for the subsidy payment

In general we support the approach taken by CMS that requires the plan sponsor to apply for the subsidy annually. As previously noted above, in the case of a multiemployer prescription drug plan, it is the plan itself, not each contributing employer that will file the application for the subsidy payment.

Under the proposed rule, plan sponsors must submit their subsidy applications no later than 90 days prior to the beginning of the calendar year for which the subsidy is requested. In order to receive the subsidy for 2006, applications with accompanying documentations must be submitted by September 30, 2005. For plans that begin coverage in the middle of a year, the plan sponsor must submit an actuarial attestation no later than 90 days prior to the date that coverage begins. For new plans that begin prescription drug coverage after September 30, 2005, the plan sponsor must submit an actuarial attestation no later than 150 days prior to the start of the program.

CMS also proposes to require that a plan sponsor submit a new actuarial attestation no later than 90 days before the implementation of a material change to the plan's drug coverage that impacts the actuarial value of the plan. A material change is defined as "any change that potentially causes the plan to no longer meet the actuarial equivalence test."

Although we generally support the proposed structure, we have concerns about the need to apply for a subsidy in the first year of the program by September 30, 2005. We are not sure whether the Boards of Trustees of multiemployer plans or other plan sponsors will be able to determine with certainty what alternatives there may be for retiree coverage other than simply continuing to provide benefits in the same way as in the past. For instance, some multiemployer plans may want to contract with qualified prescription drug plans (PDPs) to offer a coordinated or supplemental benefit. There is no guarantee that all the PDPs that might ultimately be offered in the region will be up and running by September 30, 2005. CMS should consider allowing plan sponsors who think they will be claiming the subsidy to file their application by September

30, 2005, but allow some flexibility in revising that application during a somewhat more extended period.

In addition, as previously noted in our comments on actuarial attestations generally, we think that CMS's proposal to require an additional attestation must be filed with CMS no later than 90 days before a material change to the drug coverage that impacts the actuarial value of the coverage is generally reasonable, but we are concerned that the 90-day requirement may not be feasible in all situations.

The question of whether the 90-day deadline is feasible is interrelated with the issue of whether this deadline ought to be related to a calendar year or the plan year. CMS has indicated that it is leaning toward the use of a calendar year approach. Although most plan sponsors use a calendar year as the plan year, many do not. Clearly there are persuasive arguments favoring the use of a calendar year which can be made, however, we believe to reduce administrative burdens on plan sponsors, CMS should adopt a plan year approach.

(c) Disclosure of creditable coverage

The proposed rule requires plan sponsors to disclose to retirees (and their Medicare-eligible spouses and dependents) whether the retiree prescription drug plan is actuarially equivalent to the standard Medicare Part D drug plan and therefore whether their coverage under the employer plan is creditable coverage. CMS has asked for input on a number of issues related to this requirement.

We encourage CMS to develop a model disclosure form that plan sponsors might use. We agree with CMS that it would be useful to consider as a model the approach taken by CMS, the Department of Labor and the Department of Treasury in their joint regulations regarding notices of creditable coverage under the Health Insurance Portability and Accountability Act of 1996, although the notice must be provided in a more timely fashion that would enable retirees to enroll in Part D if their plan is not actuarially equivalent.

CMS has also asked for comments regarding whether this disclosure could be incorporated into existing disclosures made to retirees in the normal course of plan operation or whether a separate notice should be required. In particular, CMS notes:

> We are soliciting comments regarding the types of materials that could provide an appropriate vehicle for this purpose, as well as ways to ensure that the notice is conspicuous and readily identified by recipients, particularly in those instances where the coverage is not creditable. 69 Fed. Reg. 46744.

Although we normally would oppose additional separate notices as unduly burdensome and would typically encourage CMS to allow plan sponsors to incorporate disclosure into existing types of dissemination, given the importance of the choice facing retirees, the need for timely disclosure of whether or not the plan's drug coverage is actuarially equivalent, and the

potential late enrollment penalties that retirees will face if they do not enroll in Part D when they are first eligible, we support requiring a separate notice regarding creditable coverage, unless the retiree prescription drug plan finds an alternative method of incorporating the notice with existing mailings or other forms of disclosure that assures that the notice will be conspicuous and readily identified by the recipients as important.

(d) HSAs, FSAs, HRAs, and MSAs

In the Preamble to the proposed rule, CMS requests input on whether the amounts used for prescription drug expenses under health savings accounts (HSAs) and other types of individual savings arrangements, including flexible spending accounts (FSAs), health reimbursement arrangements (HRAs) and medical savings accounts (MSAs) should be treated as group health payments for purposes of counting as incurred costs for purposes of meeting the Part D out-of-pocket threshold. 69 Fed. Reg. 46650. The general rule under Section 1860D-2(b)(4)(C)(ii) of the MMA is that any costs for which the individual is reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement do not count toward incurred costs.

CMS indicates that its "strong preference" is to treat HSA amounts differently so as to allow amounts reimbursed through an HSA to count towards incurred costs. Under this interpretation, a Medicare beneficiary could withdraw funds from his or her HSA, pay Part D drug expenses, and allow these expenses to count toward the beneficiary's out-of-pocket payments. Medicare catastrophic coverage would consequently begin sooner than if these payments were not counted toward TrOOP.

We strongly oppose creating a special exception for these payments. Although the Department of Labor has established a regulatory safe harbor for certain HSAs so that they may not be treated as group health plans under the Employee Retirement Income Security Act of 1974 (ERISA),[2] not all HSAs will fall into that safe harbor and some may, in fact, be group health plans. Even under the Department's guidance this question is ultimately decided by the individual facts and circumstances of each case. There is no statutory authority for CMS to create a special rule for HSAs and it would be both illegal and inappropriate to do so. Moreover, if HHS were to create a special exception from TrOOP only for those HSAs that were not employer plans would create an enforcement problem and an administrative nightmare. Who would determine whether the HSA in question was an ERISA plan? The Department of Labor? HHS? The plan sponsor? The individual who established the HSA himself or herself? The structure of the MMA and the proposed rule places a great deal of confidence in the plan sponsor to self-police compliance. Determining whether or not an arrangement constitutes an ERISA plan has always been the purview of the Department of Labor or, ultimately, the courts through actions brought under ERISA section 502. This would create a level of complexity and administrative burden that seems unjustified and unsupportable, given CMS' goals of

[2] Department of Labor Field Assistance Bulletin 2004-1 (April 7, 2004). This can be found at: http://www.dol.gov/ebsa/regs/fab_2004-1.html.

minimizing administrative burdens on employers, unions, plans and beneficiaries and minimizing costs to the government of providing retiree prescription drug coverage.

We believe that HSA amounts should be treated as other tax-favored forms of health coverage and excluded from incurred costs. They are not "essentially analogous to a beneficiary's bank account" because individuals who establish these accounts have been given extraordinarily generous tax preferences to use this form of tax-favored savings. Individuals can deduct amounts placed in HSAs when the contributions are made "above-the-line," contributions can be made by others on behalf of an individual and deducted by the individual, even though he or she didn't make the contribution, and withdrawals from HSAs for qualified medical expenses (including prescription drug costs) are tax free. In contrast, individuals who place money in a bank account are given no special tax preferences.

CMS' desire to give HSAs special treatment is simply another example of discrimination against retirees with employer-sponsored prescription drug coverage, since HSAs can be set up by individuals without any employer involvement, although employer contributions to HSAs on behalf of employees are permitted. HSAs should be treated as all other tax-favored savings mechanisms – whether individual or employer-sponsored (including FSAs, HRAs and MSAs). In other words, payments from all four of these vehicles should be excluded from incurred costs. To do otherwise would create a substantial windfall and an unjustified double taxpayer subsidy for individuals who establish HSAs. Not only would they receive a tax subsidy for establishing such an arrangement, they would be treated more favorably than individuals who pay prescription drug expenses through salary reduction programs that are employer-sponsored. To allow HSA amounts to count toward incurred costs while barring other forms of subsidized employer coverage from doing so is just another example of the bias against retiree drug coverage provided under employer-sponsored plans that is an integral part of the structure of the MMA, notwithstanding Congress' attempt to ameliorate that bias somewhat through the offering of an employer subsidy for continuing to provide coverage.

Waivers for Plan Sponsors to contract with or become Part D Prescription Drug Plans (PDPs) or Medicare Advantage (MA-PD) plans

Plan sponsors that do not choose to provide coverage that qualifies for the subsidy or provide coverage that supplements or wraps around the Part D benefit can instead contract with or become a PDP or Medicare Advantage (MA) plan. CMS indicates that an MA-PD plan or a PDP plan may request, in writing from CMS, a waiver or modification of the Medicare Advantage or Part D requirements that hinder the design of, the offering of, or the enrollment in Medicare Advantage plans by employees or former employees receiving benefits from plans sponsored by employers, labor organizations, or multiemployer plans. MA and PDP plans that receive a waiver may restrict the enrollment to participants and beneficiaries in an employer-sponsored plan. Waivers might include restricting enrollment to the plan sponsor's retirees and offer a benefit that resembles existing active coverage. A waiver might also include authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group.

A waiver process should be established for employers and other plan sponsors to contract with or otherwise create Medicare Part D PDPs and MA-PD plans that serve employment-based populations. Waivers should be published and made easily available online. Existing waivers that were made available to Medicare+Choice plans should be catalogued and placed online so that plan sponsors can determine what requirements have already been considered for waiver.

CMS recognizes that one option available to employers under the MMA is to provide retiree prescription coverage that supplements coverage offered under a PDP or MA-PD plan. For this option to work smoothly for plan sponsors, particularly those with retirees living across the PDP and MA-PD regions to be established, CMS should take appropriate steps to encourage the development of supplemental plans by PDP and MA-PD providers. If both the Part D plan and the supplemental plan are offered a single provider, it may be easier to coordinate benefits.

In addition, a number of multiemployer plans have joined together to establish purchasing coalitions to improve their purchasing leverage for prescription drugs with pharmacy benefit managers (PBMs). We strongly urge CMS to extend waiver authority to purchasing coalitions involved with employer-sponsored plans. It is quite likely that these purchasing coalitions may be potential PDP plan sponsors, so CMS should not preclude waivers for such entities.

Conclusion

Again we appreciate your willingness to seek input from the plan sponsor community and other stakeholders in the fight to preserve employer-sponsored retiree health programs. We are especially grateful for your willingness to consider the special administrative problems of multiemployer plans because of their structural differences from plans sponsored by individual employers. Please feel free to contact me for further information. We would be pleased to meet with you to discuss these comments and any other issues on which you are seeking input. We look forward to working with you in the future.

Yours truly,

Randy DeFrehn
Executive Director

VIA ELECTRONIC DELIVERY

October 4, 2004

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014
http://www.cms.hhs.gov/regulations/ecomments

Dear Sirs/Madams:

These comments are filed by the National Coordinating Committee for Multiemployer Plans (NCCMP) in response to the request for public comments by the Centers for Medicare and Medicaid Services (CMS) on the proposed rule to implement the new Medicare Prescription Drug Benefit authorized in section 101 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). This proposed rule was published in the Federal Register of August 3, 2004 (69 Fed. Reg. 46632).

The NCCMP is the only national organization devoted exclusively to protecting the interests of the approximately ten million workers, retirees, and their families who rely on multiemployer plans for retirement, health and other benefits. Our purpose is to assure an environment in which multiemployer plans can continue their vital role in providing benefits to working men and women. The NCCMP is a nonprofit organization, with members, plans and plan sponsors in every major segment of the multiemployer plan universe, including in the building and construction, retail food and service, and entertainment industries.

Most multiemployer plans today provide for retiree health benefits and many of those plans include some type of coverage for prescription drugs. As is well documented, the number of retirees covered by employer-sponsored health benefit plans today and in the future has continued to shrink, primarily because of the combination of accounting rule changes that force private sector employers to recognize the long-term liability of the retiree medical benefits and the rapidly escalating cost of providing that retiree health coverage.

Although facing the same marketplace cost pressures as other plan sponsors, employers and unions who have come together through collective bargaining to establish multiemployer plans have been less likely to drastically reduce or eliminate retiree coverage, in part because active workers in those industries where multiemployer plan coverage is prevalent have been willing to forgo some portion of their compensation to continue to subsidize the health benefits of their brothers and sisters who have retired. Even so, some multiemployer plans have been forced to alter the way benefits are financed in order to remain fiscally solvent. For some multiemployer plans, the rapidly escalating costs, the demographic trends, and the contraction of

the unionized workforce have required them to seriously rethink plan design and financing issues and to take steps to reduce or eliminate retiree benefits in ways that would have been unthinkable just a few years ago.

During the legislative process surrounding the passage of the MMA, the NCCMP urged Congress to consider carefully the structure of the new prescription drug program so as to avoid creating additional burdens on employer-sponsored plans and further incentives for them to reduce or drop prescription drug coverage for Medicare-eligible retirees. Although Congress incorporated an employer subsidy provision in the final legislation for plans that provided prescription drug benefits that were at least actuarially equivalent to the standard Part D drug benefit to encourage employers to continue providing retiree drug coverage, the overall structure of the new Medicare Part D benefit seriously disadvantages retirees with employer-sponsored coverage. This is particularly true with respect to the ability of retirees to meet the out-of-pocket limits that would trigger Medicare's catastrophic coverage. We recognize that CMS cannot through regulation remedy such a serious structural flaw in the statutory framework of the MMA, but we urge CMS to use its interpretive authority to ameliorate wherever possible the disadvantageous treatment of retirees with employer-sponsored coverage.

The statutory provisions of the MMA relating to employer-sponsored retiree prescription drug coverage are largely fashioned with a corporate health plan model in mind. Under this model, the plan sponsor is the employer who controls both plan design and financing decisions with little or no input from employees, unions or retirees. As you know, the world of multiemployer plans is quite different. Under applicable labor law, these collectively bargained plans are administered by a Board of Trustees consisting of equal numbers of representatives of labor and management. Under the Employee Retirement Income Security Act of 1974 (ERISA), the Board functions as both plan sponsor and the named fiduciary of the plan (and often the plan administrator as well) and therefore no individual employer can influence the operation or design of the plan because those decisions are reserved for the Board.

We appreciate the obvious effort that CMS has made in crafting its proposed rule to recognize that not all employer-sponsored plans are the same. We share your goals of maximizing the number of retirees retaining existing drug coverage, avoiding windfalls in which retirees receive a smaller subsidy from plan sponsors than Medicare would pay on their behalf, minimizing administrative burdens on beneficiaries, employers, unions, and plans, minimizing costs to the government of providing retiree drug subsidies and staying within the budget estimates. However, we believe that some of the rules that are being considered, particularly those directed at avoiding employer windfalls, may not be as relevant to multiemployer plans as they might be in a corporate plan setting, since it is the joint Board of Trustees that controls the design and financing of the retiree health plan, not any individual employer. This provides a degree of protection against potential manipulation that may be missing in other circumstances.

We have focused our comments on a handful of key issues raised in Subpart R of the proposed rule but we hope to open a dialogue with CMS staff on these and other issues of concern. Our detailed comments follow.

Comments Related to Subpart R – Payments to Sponsors of Retiree Prescription Drug Plans:

Section 423.882 Definitions

"Group health plan"

We support the use of the same definition of group health plan as found in section 607(1) of ERISA, 29 U.S.C. 1167(1). To further clarify the ability of multiemployer plans to qualify for the subsidy, we suggest also incorporating the definition of "multiemployer plan" found in section 3(37) of ERISA, 29 U.S.C. 1002(3)(37).

"Sponsor"

Although the proposed rule refers back to the definition of plan sponsor found in section 3(16)(B) of ERISA, we suggest that CMS confirm that in the case of a multiemployer plan (i.e., a plan established or maintained jointly by more than one employer and one or more employee associations), the plan sponsor is the board of trustees.

It would also be helpful for CMS to confirm how the employer subsidy provisions for prescription drug coverage operate in the context of a multiemployer health plan.

As we understand the statutory structure and legislative history of MMA regarding the employer subsidy for retiree prescription drug coverage, Congress intended for the Board of Trustees of the multiemployer plan to be the recipient of the employer subsidy since it is the plan that finances the retiree drug benefits (i.e., employer contributions and retiree contributions are placed in trust and those amounts, together with interest accumulated in the trust, are used to pay retiree prescription drug benefits). Therefore, as the entity claiming the subsidy, the multiemployer plan, not each contributing employer, will be responsible for meeting the procedural requirements to claim the subsidy, including providing the required disclosures to the Secretary and all eligible individuals (e.g., the notice of creditable coverage). The plan will apply for the subsidy (including furnishing the actuarial attestation and the list of qualified retirees covered under the multiemployer retiree prescription drug plan who are not enrolled in Medicare Part D). Once CMS has processed the application and verified the status of qualified retirees of all contributing employers, the subsidy would be paid to the multiemployer retiree prescription drug plan and these amounts would be credited toward future contributions to prescription drug coverage, by providing funds to cover costs that would otherwise have to be met through additional contributions. This approach eases burdens on CMS and individual contributing employers, while allowing the entity that pays the retiree prescription drug benefits (the multiemployer plan) to receive the subsidy and use it to cover retiree drug costs without incurring necessary administrative costs.

We would be happy to review with you the way that multiemployer plans operate and to furnish further detail why it is essential that the plan be treated as the plan sponsor for purposes of the subsidy, rather than individual contributing employers.

Section 423.884 Requirements for qualified retiree prescription drug plans

(a) Actuarial Attestation

Under the proposed rule, plan sponsors seeking to claim a subsidy for their prescription drug coverage must annually apply for the subsidy, no later than 90 days before the beginning of the calendar or plan year for which the subsidy is sought.

Although the proposed rule requires an actuarial attestation that the prescription drug benefits provided under the retiree prescription drug plan is at least actuarial equivalent to the standard Medicare Part D benefit, little guidance is given regarding the content of this attestation. CMS should consider developing a model form for this attestation, in which the plan's actuary could describe in simple terms how the determination of actuarial equivalency was made and what assumptions were used. A useful example of this type of standardized actuarial reporting for CMS to consider is the Schedule B to the Form 5500, the annual financial report that certain ERISA-covered pension plans must file with the U.S. Department of Labor. Of course, if CMS decides to promulgate a model form, its use should be considered a safe harbor for satisfaction of the attestation requirement and plan sponsors should be free to submit their own attestations in any other format as long as the required information has been included.

We think that CMS's proposal to require that an additional attestation must be filed with CMS no later than 90 days before a material change to the drug coverage that impacts the actuarial value of the coverage is generally reasonable, but we are concerned that the 90-day requirement may not be feasible in all situations.

The question of whether the 90-day deadline is feasible is interrelated with the issue of whether this deadline ought to be related to a calendar year or the plan year. CMS has indicated that it is leaning toward the use of a calendar year approach. Although most plan sponsors use a calendar year as the plan year, many do not. Clearly there are persuasive arguments favoring the use of a calendar year which can be made, however, we believe to reduce administrative burdens on plan sponsors, CMS should adopt a plan year approach.

Establishing actuarial equivalency

Under the MMA, the federal government will pay a cash subsidy to employers and other plan sponsors (including multiemployer plans) that provide retiree prescription drug coverage that is at least equal in value to the new Medicare Part D prescription drug coverage. The subsidy would be 28 percent of a retiree's total covered drug costs between $250 and $5,000 per year, which translates to a maximum subsidy payment to a plan sponsor of $1,330 per retiree. The subsidy would be payable for each retiree covered under the employer-sponsored plan who is not enrolled in Medicare Part D.

Although the cost of providing the new drug coverage under Medicare is partially financed by the Federal government, retirees enrolled in the new Medicare Part D benefit program will still be paying a substantial amount themselves for the coverage.

The standard Medicare Part D benefit design which will be offered through stand-alone prescription drug plans (PDPs) is as follows:

- Retirees will pay a monthly premium set by the PDP (estimated to be $35 per month in 2006 when the program begins, but expected to increase as costs increase);
- The PDP decides which prescription drugs to cover, as long as the PDP's formulary meets certain statutory requirements;
- Retirees must pay the first $250 in covered drug costs out of their own pocket (the standard deductible);
- Retirees pay 25% of covered drug costs between $250 and $2,250 during the year;
- Retirees pay 100% of covered drug costs between $2,225 and $5,100 during the year;
- Retirees pay no more than 5% of covered drug costs to the extent that those costs exceed $5,100. But to be eligible for this "catastrophic" coverage, an individual retiree must pay $3,600 (in 2006) in covered drug costs. Costs covered by a third-party, such as insurance or a group health plan, would not count toward this so-called "true out-of-pocket" amount (TrOOP).

To qualify for the 28% Federal subsidy, coverage provided by the employer-sponsored retiree medical plan does not have to be identical to the standard Part D drug benefit described above; it must be at least equal in value on an actuarial basis to the Part D coverage.

The MMA defines this measurement and comparison of the values of the two benefit design "actuarial equivalence." This test makes it possible to compare the value of different benefit designs. Actuarial equivalence looks at the expected cost of a benefit for a typical person, not how much it will actually cost for any given individual. This is important because a person who has greater health care needs obviously will cost more than one who is healthier.

The term "actuarial equivalence" is not defined in the proposed rule itself. CMS will have to create a standard for determining whether an employer retiree drug benefit is actuarially equivalent to the standard Part D benefit. However, in the preamble to the proposed rule, CMS has suggested a variety of differing approaches or tests to determine whether the employer-sponsored retiree drug plan is actuarially equivalent to the standard Medicare Part D prescription drug plan. CMS has asked for public comments on which, if any, of these standards is the right one and which may not be suitable. The standard CMS ultimately chooses will determine how generous a benefit employers have to offer retirees and how big a share of the benefit employers can require retirees to pay and still qualify for the federal subsidy.

Below is a brief description of each of the standards for which CMS seeks public comment:

- Single Prong Test: Under this test, also known as the "gross value test," an employer's benefit is good enough to qualify for a federal subsidy if, on average, the total value of

the benefit is at least equal to the total value of the standard Part D benefit. It does not matter what share of the benefit, if any, the employer pays. Under this test, the employer could contribute nothing and require the retiree to pay the full cost of the plan, yet the employer would still be paid the federal subsidy.

- Single Prong/No Windfall Test: As with the test above, an employer's benefit is good enough for a subsidy if on average the total value of the benefit is at least equal to the total value of the standard Part D benefit. However, the dollar amount of the subsidy paid to the employer cannot be greater than the dollar amount the employer pays toward the retiree coverage. The employer could design the plan so that it pays nothing towards retiree drug coverage after taking the federal subsidies into account.

- Two-Prong Test: This test begins with the single prong test but applies a second test (or "prong") in which the employer would also have to show it is paying for at least a specific minimum share of the total benefit. CMS offers several examples of the level at which it could set the minimum share or amount the employer must pay under the Two-Prong Test. These include:
    - The average per person amount Medicare would expect to pay as a subsidy to employers during the year, estimated by CMS to be $611 in 2006 when the program begins.
    - The expected amount of paid claims under the standard Part D prescription drug plan minus the monthly part D premiums paid by the retiree, estimated by the Congressional Budget Office to be approximately $1,200 in 2006.
    - The after-tax value of the average per person amount Medicare would expect to pay as a subsidy to employers during the year. For employers subject to the federal corporate income tax, this would be higher than the $611 estimated subsidy payment and will vary depending on the employer's tax rate.

One of Congress's policy goals under MMA is to ensure that the subsidy is used to preserve retiree benefits and not used simply to improve the employer's bottom line or for other non-health care uses. The preamble to the proposed regulation endorses the principle that the subsidy should be passed through to the retirees to pay for retiree prescription drug benefits. In particular, the proposed regulation states:

> "The intent of the MMA retiree prescription drug subsidy provisions is to slow the decline in employer-sponsored retiree insurance. By providing a special subsidy payment to sponsors of qualifying plans, the MMA provides employers with extra incentives and flexibility to maintain prescription drug coverage for their retirees. Our intention is to make these subsidy payments as reasonably available to plan sponsors as possible. We wish to take into account as much as possible the needs and concerns of plan sponsors, consistent with necessary assurances that Federal payments are accurate and in accordance with statutory requirements, that the interests of retiree-beneficiaries are protected, and that employers do not receive ''windfalls'' consisting of subsidy payments that are not passed on to beneficiaries."[1]

[1] 69 Fed. Reg. 46737 (August 3, 2004).

The structure of multiemployer plans assures that this policy goal is met.

After carefully considering each of the proposed standards, we have the following recommendations regarding the actuarial equivalence test that we believe are consistent with CMS's goals.

- CMS should adopt the Two-Prong Test for actuarial equivalence, which requires the portion of the prescription drug plan financed by the employer to be at least equal to the portion of the Part D benefit that is financed by Medicare. Only this test is consistent with the letter and intent of the MMA to provide for alternative drug coverage that is actuarially equivalent to the standard Part D benefit. In considering the portion of the plan that is financed by the employer, earnings on employer contributions held in trust as plan assets should be included. The comparison of the employer plan to the Part D benefit should be based on the benefits provided, not the cost.

- All of the other standards described by CMS in the preamble to the proposed rules could penalize retirees covered under a retiree drug plan and should be rejected. The Single Prong Test, the Single Prong/No Windfall Test, and the two versions of the Two-Prong Test that permit the employer to limit its contribution to the average subsidy amount it would expect to be paid from Medicare could all require a retiree to pay more for drug coverage than the retiree would if he or she were covered under a Medicare Part D prescription drug plan.

- Other tests being considered by CMS would allow for even greater windfalls to an employer. The Single Prong (or Gross Value) Test would allow for enormous windfalls to employers since it would permit an employer to pay nothing toward the drug benefit and still collect federal subsidies. This option has been roundly criticized in the press, is inconsistent with the intent of Congress, and would undermine the integrity of the Medicare drug program and therefore endanger the future of the program.

- In those cases in which a plan sponsor would be prohibited from claiming the largest possible retiree drug subsidy payable under the law due to the anti-windfall protections, CMS should provide a mechanism permitting the plan sponsor to claim the larger subsidy, so long as it passes through the value of the subsidy exceeding the windfall protections to the retirees. This is very important from a multiemployer perspective.

- Where a plan is fully insured, the regulations should require the insurance carrier to provide to the plan sponsor the information necessary to apply for the subsidy.

What is a "plan"?

As CMS acknowledges, many plan sponsors provide different levels and packages of benefits to different groups of retirees. In determining whether the coverage meets the actuarial equivalency test, one must first determine what the plan is that is being compared to the standard Medicare Part D prescription drug coverage. In its proposed rule, CMS indicates that it intends

to adopt a definition of "plan" that mirrors the current approach found in the Treasury regulations regarding the health insurance continuation requirements of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). Under those regulations, all health benefits provided by the plan sponsor are presumed to be under a single plan unless plan documents indicate otherwise.

As a result, actuarial equivalence would be determined by evaluating the plan as a whole, not on a benefit structure by benefit structure basis, and if, on average the actuarial value of the drug coverage equals or exceeds the value of the standard Part D coverage, the plan would satisfy the actuarial equivalency test.

We support the use of such an approach because it is one that is already familiar to plan sponsors and it provides flexibility without sacrificing retiree protections.

(b) Sponsor application for the subsidy payment

In general we support the approach taken by CMS that requires the plan sponsor to apply for the subsidy annually. As previously noted above, in the case of a multiemployer prescription drug plan, it is the plan itself, not each contributing employer that will file the application for the subsidy payment.

Under the proposed rule, plan sponsors must submit their subsidy applications no later than 90 days prior to the beginning of the calendar year for which the subsidy is requested. In order to receive the subsidy for 2006, applications with accompanying documentations must be submitted by September 30, 2005. For plans that begin coverage in the middle of a year, the plan sponsor must submit an actuarial attestation no later than 90 days prior to the date that coverage begins. For new plans that begin prescription drug coverage after September 30, 2005, the plan sponsor must submit an actuarial attestation no later than 150 days prior to the start of the program.

CMS also proposes to require that a plan sponsor submit a new actuarial attestation no later than 90 days before the implementation of a material change to the plan's drug coverage that impacts the actuarial value of the plan. A material change is defined as "any change that potentially causes the plan to no longer meet the actuarial equivalence test."

Although we generally support the proposed structure, we have concerns about the need to apply for a subsidy in the first year of the program by September 30, 2005. We are not sure whether the Boards of Trustees of multiemployer plans or other plan sponsors will be able to determine with certainty what alternatives there may be for retiree coverage other than simply continuing to provide benefits in the same way as in the past. For instance, some multiemployer plans may want to contract with qualified prescription drug plans (PDPs) to offer a coordinated or supplemental benefit. There is no guarantee that all the PDPs that might ultimately be offered in the region will be up and running by September 30, 2005. CMS should consider allowing plan sponsors who think they will be claiming the subsidy to file their application by September

30, 2005, but allow some flexibility in revising that application during a somewhat more extended period.

In addition, as previously noted in our comments on actuarial attestations generally, we think that CMS's proposal to require an additional attestation must be filed with CMS no later than 90 days before a material change to the drug coverage that impacts the actuarial value of the coverage is generally reasonable, but we are concerned that the 90-day requirement may not be feasible in all situations.

The question of whether the 90-day deadline is feasible is interrelated with the issue of whether this deadline ought to be related to a calendar year or the plan year. CMS has indicated that it is leaning toward the use of a calendar year approach. Although most plan sponsors use a calendar year as the plan year, many do not. Clearly there are persuasive arguments favoring the use of a calendar year which can be made, however, we believe to reduce administrative burdens on plan sponsors, CMS should adopt a plan year approach.

(c) Disclosure of creditable coverage

The proposed rule requires plan sponsors to disclose to retirees (and their Medicare-eligible spouses and dependents) whether the retiree prescription drug plan is actuarially equivalent to the standard Medicare Part D drug plan and therefore whether their coverage under the employer plan is creditable coverage. CMS has asked for input on a number of issues related to this requirement.

We encourage CMS to develop a model disclosure form that plan sponsors might use. We agree with CMS that it would be useful to consider as a model the approach taken by CMS, the Department of Labor and the Department of Treasury in their joint regulations regarding notices of creditable coverage under the Health Insurance Portability and Accountability Act of 1996, although the notice must be provided in a more timely fashion that would enable retirees to enroll in Part D if their plan is not actuarially equivalent.

CMS has also asked for comments regarding whether this disclosure could be incorporated into existing disclosures made to retirees in the normal course of plan operation or whether a separate notice should be required. In particular, CMS notes:

> We are soliciting comments regarding the types of materials that could provide an appropriate vehicle for this purpose, as well as ways to ensure that the notice is conspicuous and readily identified by recipients, particularly in those instances where the coverage is not creditable. 69 Fed. Reg. 46744.

Although we normally would oppose additional separate notices as unduly burdensome and would typically encourage CMS to allow plan sponsors to incorporate disclosure into existing types of dissemination, given the importance of the choice facing retirees, the need for timely disclosure of whether or not the plan's drug coverage is actuarially equivalent, and the

potential late enrollment penalties that retirees will face if they do not enroll in Part D when they are first eligible, we support requiring a separate notice regarding creditable coverage, unless the retiree prescription drug plan finds an alternative method of incorporating the notice with existing mailings or other forms of disclosure that assures that the notice will be conspicuous and readily identified by the recipients as important.

(d) HSAs, FSAs, HRAs, and MSAs

In the Preamble to the proposed rule, CMS requests input on whether the amounts used for prescription drug expenses under health savings accounts (HSAs) and other types of individual savings arrangements, including flexible spending accounts (FSAs), health reimbursement arrangements (HRAs) and medical savings accounts (MSAs) should be treated as group health payments for purposes of counting as incurred costs for purposes of meeting the Part D out-of-pocket threshold. 69 Fed. Reg. 46650. The general rule under Section 1860D-2(b)(4)(C)(ii) of the MMA is that any costs for which the individual is reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement do not count toward incurred costs.

CMS indicates that its "strong preference" is to treat HSA amounts differently so as to allow amounts reimbursed through an HSA to count towards incurred costs. Under this interpretation, a Medicare beneficiary could withdraw funds from his or her HSA, pay Part D drug expenses, and allow these expenses to count toward the beneficiary's out-of-pocket payments. Medicare catastrophic coverage would consequently begin sooner than if these payments were not counted toward TrOOP.

We strongly oppose creating a special exception for these payments. Although the Department of Labor has established a regulatory safe harbor for certain HSAs so that they may not be treated as group health plans under the Employee Retirement Income Security Act of 1974 (ERISA),[2] not all HSAs will fall into that safe harbor and some may, in fact, be group health plans. Even under the Department's guidance this question is ultimately decided by the individual facts and circumstances of each case. There is no statutory authority for CMS to create a special rule for HSAs and it would be both illegal and inappropriate to do so. Moreover, if HHS were to create a special exception from TrOOP only for those HSAs that were not employer plans would create an enforcement problem and an administrative nightmare. Who would determine whether the HSA in question was an ERISA plan? The Department of Labor? HHS? The plan sponsor? The individual who established the HSA himself or herself? The structure of the MMA and the proposed rule places a great deal of confidence in the plan sponsor to self-police compliance. Determining whether or not an arrangement constitutes an ERISA plan has always been the purview of the Department of Labor or, ultimately, the courts through actions brought under ERISA section 502. This would create a level of complexity and administrative burden that seems unjustified and unsupportable, given CMS' goals of

[2] Department of Labor Field Assistance Bulletin 2004-1 (April 7, 2004). This can be found at: http://www.dol.gov/ebsa/regs/fab_2004-1.html.

minimizing administrative burdens on employers, unions, plans and beneficiaries and minimizing costs to the government of providing retiree prescription drug coverage.

We believe that HSA amounts should be treated as other tax-favored forms of health coverage and excluded from incurred costs. They are not "essentially analogous to a beneficiary's bank account" because individuals who establish these accounts have been given extraordinarily generous tax preferences to use this form of tax-favored savings. Individuals can deduct amounts placed in HSAs when the contributions are made "above-the-line," contributions can be made by others on behalf of an individual and deducted by the individual, even though he or she didn't make the contribution, and withdrawals from HSAs for qualified medical expenses (including prescription drug costs) are tax free. In contrast, individuals who place money in a bank account are given no special tax preferences.

CMS' desire to give HSAs special treatment is simply another example of discrimination against retirees with employer-sponsored prescription drug coverage, since HSAs can be set up by individuals without any employer involvement, although employer contributions to HSAs on behalf of employees are permitted. HSAs should be treated as all other tax-favored savings mechanisms – whether individual or employer-sponsored (including FSAs, HRAs and MSAs). In other words, payments from all four of these vehicles should be excluded from incurred costs. To do otherwise would create a substantial windfall and an unjustified double taxpayer subsidy for individuals who establish HSAs. Not only would they receive a tax subsidy for establishing such an arrangement, they would be treated more favorably than individuals who pay prescription drug expenses through salary reduction programs that are employer-sponsored. To allow HSA amounts to count toward incurred costs while barring other forms of subsidized employer coverage from doing so is just another example of the bias against retiree drug coverage provided under employer-sponsored plans that is an integral part of the structure of the MMA, notwithstanding Congress' attempt to ameliorate that bias somewhat through the offering of an employer subsidy for continuing to provide coverage.

Waivers for Plan Sponsors to contract with or become Part D Prescription Drug Plans (PDPs) or Medicare Advantage (MA-PD) plans

Plan sponsors that do not choose to provide coverage that qualifies for the subsidy or provide coverage that supplements or wraps around the Part D benefit can instead contract with or become a PDP or Medicare Advantage (MA) plan. CMS indicates that an MA-PD plan or a PDP plan may request, in writing from CMS, a waiver or modification of the Medicare Advantage or Part D requirements that hinder the design of, the offering of, or the enrollment in Medicare Advantage plans by employees or former employees receiving benefits from plans sponsored by employers, labor organizations, or multiemployer plans. MA and PDP plans that receive a waiver may restrict the enrollment to participants and beneficiaries in an employer-sponsored plan. Waivers might include restricting enrollment to the plan sponsor's retirees and offer a benefit that resembles existing active coverage. A waiver might also include authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group.

A waiver process should be established for employers and other plan sponsors to contract with or otherwise create Medicare Part D PDPs and MA-PD plans that serve employment-based populations. Waivers should be published and made easily available online. Existing waivers that were made available to Medicare+Choice plans should be catalogued and placed online so that plan sponsors can determine what requirements have already been considered for waiver.

CMS recognizes that one option available to employers under the MMA is to provide retiree prescription coverage that supplements coverage offered under a PDP or MA-PD plan. For this option to work smoothly for plan sponsors, particularly those with retirees living across the PDP and MA-PD regions to be established, CMS should take appropriate steps to encourage the development of supplemental plans by PDP and MA-PD providers. If both the Part D plan and the supplemental plan are offered a single provider, it may be easier to coordinate benefits.

In addition, a number of multiemployer plans have joined together to establish purchasing coalitions to improve their purchasing leverage for prescription drugs with pharmacy benefit managers (PBMs). We strongly urge CMS to extend waiver authority to purchasing coalitions involved with employer-sponsored plans. It is quite likely that these purchasing coalitions may be potential PDP plan sponsors, so CMS should not preclude waivers for such entities.

Conclusion

Again we appreciate your willingness to seek input from the plan sponsor community and other stakeholders in the fight to preserve employer-sponsored retiree health programs. We are especially grateful for your willingness to consider the special administrative problems of multiemployer plans because of their structural differences from plans sponsored by individual employers. Please feel free to contact me for further information. We would be pleased to meet with you to discuss these comments and any other issues on which you are seeking input. We look forward to working with you in the future.

Yours truly,

Randy DeFrehn
Executive Director

CMS-4068-P-1239

Submitter : Mr. Carlos Ortiz **Date & Time:** 10/04/2004 08:10:02

Organization : CVS/pharmacy

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

Please accept these comments on behalf of CVS/pharmacy regarding the proposed rule addressing Medicare Program: Medicare Prescription Drug Benefit, CMS 4068-P, RON-0938-AN08.

CMS-4068-P-1239-Attach-1.doc

CARLOS R. ORTIZ, R.Ph.
Vice President of Government Affairs

September 30, 2004

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Subject: Medicare Program: Medicare Prescription Drug Benefit, CMS 4068-P, RIN-0938-AN08

To Whom It May Concern:

CVS/Pharmacy is providing comments with regard to the proposed rule published August 3, 2004. This rule would implement Title I of the Medicare Modernization Act of 2003 that establishes the voluntary Medicare Part D prescription drug benefit.

CVS operates over 5,300 pharmacies in 36 states and the District of Columbia. CVS is the largest provider of out-patient prescription drugs in the United States. As such, our expectation is that CVS will be a major provider of pharmacy services to Medicare recipients under the Part D program.

Section 423.30-423.50 – Issues Relating to Eligibility and Enrollment (Subpart A)

The confusion that has surrounded the Medicare discount card demonstrates the need for clear and understandable materials for Medicare recipients. CVS would also encourage CMS to recognize the role of the pharmacist in helping recipients to understand this benefit. Some of the components of these materials would include:

- The network status of a pharmacy and whether the pharmacy is a preferred or non-preferred pharmacy.
- The eligibility status of the recipient, whether they have met their front end deductible, and whether they have reached a gap in coverage (ie. the donut hole).
- This information must be provided to the pharmacist via an on-line real time basis.
- The experience with Medicare recipients, who were eligible for the $600 Transitional Assistance and failed to enroll, shows a definite need for special attention to be directed to the Medicare/Medicaid dual eligible. CVS would encourage CMS to allow for a transitional period for these dual eligible beneficiaries. We would also encourage an automatic enrollment process for these individuals.

Section 423.100 – Definition of Covered Part D Drugs

Options for Dispensing Fees – 69 Federal Register 46647-48

Most Medicare recipients will receive their Part D benefits from private insurers or prescription benefit managers (PBMs). CVS is concerned that these entities will attempt to utilize dispensing fees usually reserved for private insurers for this program. The complexity of providing services to this population, because of issues such as coordination of benefits, gaps in coverage, determination of front end deductibles, product and patient eligibility, etc. makes this program considerably more difficult. Recent studies, including the newly enacted California Medicaid dispensing fee, showing that the dispensing fee has to be in excess of $7 to adequately reimburse pharmacies for providing these services.

Section 423.104 – Requirements relating to Qualified Precription Drug Coverage

Access to negotiated prices

Subsection(h) of this section requires pharmacies to pass through negotiated prices during coverage gaps and for non-covered formulary drugs. This requirement amounts to nothing less than price controls on retail pharmacies. While this burden is extended to retail pharmacies, no such burdens are required of pharmaceutical manufacturers, or plan sponsors. Plan sponsors should not be able to keep any "pharmacy spreads" on prescriptions. Thus, they should not be able to reimburse pharmacies at a lower rate than they are charging the plan for filling the prescription.

Section 423.120 – Access to Covered Part D Drugs

Section 423.120(a)(1)-(5) – Issues relating to access to pharmacies

The legislative history demonstrates that it was the intent of Congress to require plans to comply, at a minimum, with the Department of Defense TriCare access standards. These standards require that 90% of Medicare beneficiaries must live within 2 miles of a participating pharmacy in an urban area, 90% of recipients in a suburban area must live within a 5 mile radius of a participating pharmacy, and 70% of recipients living in rural areas they must live within a 15 mile radius of a participating pharmacy. The proposed rule should also clearly define whether these distances are geographic or driving distances.

Averaging Access Standards

The proposed rules allow plans to meet these standards by averaging. CVS believes that each plan must meet these standards in each state and in region in which they operate. Allowing them to average the access standards could create areas where Medicare recipients lack adequate accessibility to a participating pharmacy. For

example, in Pennsylvania, averaging could result in a situation where Philadelphia is more than adequately served while Pittsburgh is not.

Creating "Preferred Pharmacy" Network

The proposed rule also allows plans to use this averaging methodology when creating networks of "preferred pharmacies" and "non-preferred pharmacies". By utilizing this method, the plan could create a higher cost non-preferred network that meets the TriCare access standards and at the same time create a lower cost preferred network that does not meet the standard. The proposed rule should be changed to require that all networks meet the TriCare access standard.

Section 423.120(a)(4) – Contracting Terms with Pharmacies and Prohibition of Transferring Insurance Risk

This section and Congress clearly prohibited plans from requiring pharmacies to accept insurance risk as a condition of participation. The proposed rule defines insurance risk as "risk that is commonly assumed by insured licensed by a state". It further states that it should not include payment variations due to performance based measures. Although these performance based incentives are common in the market place, they are usually in addition to the basic reimbursement. They represent additional payments for meeting certain objectives and there are no deductions from the basic payment, if these objectives are not met.

The final rule should prohibit plans from utilizing a variation of the system detailed above to require pharmacies to accept any contractual terms that would require them to accept lower payment rates if a plan experiences cost over runs. The plans should also cleanly identify to the pharmacy the pricing source that they will use for payment.

Section 423.120(a)(6) – Level playing field between mail order and network pharmacies

The Legislative Record shows that it was the intent of Congress to allow community pharmacies to provide a 90-day supply with no artificial cost sharing that would "coerce" recipients to obtain their maintenance medication from a mail order entity. Thus, the only additional cost to the recipient should be the difference in the negotiated price for the covered drug at the network pharmacy and the mail order pharmacy. With this in mind, the definition of "negotiated price" should reflect the price to the plan net any rebates, discounts or other price concessions paid to the plan for a similar drug quantity obtained from either the retail pharmacy or the mail order pharmacy. These price concessions should be applied directly to reducing the cost of the prescription. The plan should not be allowed to use the price concessions to artificially lower the cost of mail order prescriptions.

Section 423.153(b)) – Quality Assurance Programs

The preamble of the proposed rule contains extensive discussion of quality assurance programs the plans should incorporate. CVS fully supports the incorporation of quality assurance programs. However, rather than requiring the prescription drug plans to establish their own quality assurance programs, the role of the plans should be to develop a system that ensures that the provider has established a quality assurance program and measures the value of such programs. The preamble also states that future reporting of error rates may be required to allow recipients to compare the quality of service in choosing a plan. All studies involved in accessing quality assurance plans have shown that the most effective quality assurance programs allow for an anonymous and confidential reporting structure with legal protection from discovery.

Section 423.851-.875 – Subpart Q – Guaranteeing Access to Choice of Coverage (fall back plans)

These sections contain the requirements that the government establish a fall back plan in the event there is a region where there are not two choices of either a risk bearing PDP or MA-PD. The final rule should make clear that these fall back plans must comply with all the access and quality standards that PDP and MA-PD must adhere to. Additionally, the fall back plan should also be required to adequately reimburse pharmacies with regard to a dispensing fee and an appropriate product cost reimbursement.

In conclusion, CVS appreciates this opportunity to comment with regard to the proposed regulations regarding the Medicare Part D portion of the Medicare Modernization Act. We would urge CMS to use its discretionary power to amend the proposed rule to address our concerns with regard to adequate reimbursement for pharmacies, access standards, quality assurance issues, and education of recipients and pharmacies.

Sincerely,

Carlos R. Ortiz, R.Ph
Vice President of Government Affairs

CO:bab

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CMS-4068-P-1240

Submitter : Mr. Robert McKay **Date & Time:** 10/04/2004 08:10:14

Organization : PharmaCare

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

This is PharmaCare's response to Medicare Drug Benefit; Comments to
The Proposed Rule.

CMS-4068-P-1240-Attach-1.rtf

Medicare Drug Benefit; Comments to The Proposed Rule

Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)

Contents

Background, Intent and Acknowledgement

Founded in 1994, PharmaCare is a wholly owned subsidiary of CVS Corporation, the nations largest operator of retail pharmacies with annual sales in excess of $33 billion. PharmaCare has more than 3,000 employees and is the most diversified pharmaceutical care management company in the country. PharmaCare holds leading positions in pharmacy benefit management services, mail-service pharmacy, specialty drug pharmacy and clinic pharmacy services. PharmaCare is also a Medicare approved national drug discount card sponsor. By the conclusion of 2004, over 140,000 Medicare beneficiaries will have enrolled in ***myPharmaCare***.

Through this document PharmaCare offers comment to the proposed rule (42 CFR Parts 403, 411, 417 and 423; Medicare program; Medicare Drug Benefit). The creation of Prescription Drug Plans (PDP's), Limited Risk Plans and Fallback Plans through the Act are of potential interest to PharmaCare. However, some aspects of the proposed rule, which we address herein, raise concerns that should be addressed by CMS. These concerns are not unique to PharmaCare as they are, in many respects, shared by our competitors. We are sure that should CMS publish a final rule that satisfactorily addresses these issues that all Medicare beneficiaries will be better served.

Finally, PharmaCare appreciates the opportunity to make comment to this proposed rule. Today PBM's are providing millions of Medicare beneficiaries drug benefits through employer sponsored plans and Medicare Choice contractor plans. Consultation between PBM's and CMS is the right course of action. Accordingly, PharmaCare offers our services freely to CMS now, and throughout the process ahead that will conclude with the successful implementation of Medicare Part-D in 2006.

The Proposed PDP Regions

Introduction. PharmaCare attended the open forum held in Chicago, IL (Rosemont) regarding the formation of regions for MA-PD and PDP's. The presentations made indicated that serious study and analysis had been given to each option under consideration. In the broader context the issue of fewer versus many regions clearly dominates the debate at hand.

Discussion. PharmaCare offers the following comments.

Comments About Fewer Regions. Of the two options being considered (10 regions or 11) we believe that the option for 11 regions has greater merit. It is our view that this option represents a better distribution of markets, or concentrations of beneficiaries, over the 10-region option. However, while fewer regions create larger pools of beneficiaries for PDP's to market to, they also offer unique barriers that also inhibit the scale value of such large multi-state regions. State insurance regulations are the most noteworthy barrier. State licensure and oversight would will prove burdensome for PDP's. As the proposed rule offers PDP's no safe-harbor in this regard, PDP's will not freely enjoy the scale inherent in multi-state regions, but will instead be forced to operate as multiple state based entities within a region. This will increase cost and hamper the ability of PDP's to effectively capitalize on the larger pools of beneficiaries offered through multi-state regions.

Comments About Many Regions. Of the four regions being considered (32, 34, 37 and 50) we believe that the option of 50 regions is most appealing and the option for 37 regions has merit as well. In summary the 50-region option simplifies many regulatory and operational considerations by equating region with state. Of the remaining regional considerations, we believe the option for 37 regions does the better job of joining several states to form the few multi-state regions. In these cases the 37 region option does the best job of preserving the

integrity of traditional regional markets; e.g. Northern New England, Pacific Northwest, etc. While not by any means uniform, insurance considerations should vary less among the states joined to form these few multi-state regions.

Recommendation. For the reasons discussed above, PharmaCare recommends many regions versus few, with 50 regions being recommended above all other considerations. We appreciate the goals and intent of CMS through the concept of larger multi-state regions. However, given the pace of this program, the challenges posed by such an approach would be too numerous and prove a barrier to program implementation. The issue of multi-state regions is always a consideration CMS could revisit in the future.

Issues Related to TROOP

Introduction. PharmaCare has studied the proposed rule regarding TROOP (True Out Of Pocket) and has participated in CMS special open door forums regarding TROOP as well. Of all of the topics worthy of comment, TROOP represents a topic in need of serious comment by industry and re-consideration by CMS.

Discussion. At the heart of the issue with TROOP is the requirement to coordinate benefits with the beneficiary's Other Health Insurance (OHI) on a real time basis. While there are several issues that make TROOP coordination problematic, it is the issue of real time coordination that is most serious.

Under the proposed rule PDP's would be required to assure TROOP through coordination with OHI as self-identified by the beneficiary upon their application. While the intent of TROOP can easily be appreciated, the practicality of coordinating OHI on a real time basis for pharmacy benefits is very problematic. In summary, with respect to pharmacy claims, the activity of claims adjudication corresponds to the actual time of service; a process that takes less than 5 seconds. This differs significantly from the process used for medical billing. Under medical claims management, claims adjudication is not associated real time with the performance of service, but instead occurs days, weeks even months later, and this lag time makes OHI coordination possible under a medical claims approach. The rule, as written, approaches TROOP coordination in the context of a medical claims management model, not the existing pharmacy model. And, it assumes this model is transferable to pharmacy, when it is not. The approach to TROOP in the proposed rule is inconsistent with pharmacy claims management standards and practice, and should be changed in the final rule. We offer amplification below to support this recommendation.

Are pharmacies the answer? Pharmacies are not the solution to accomplish TROOP. Pharmacies do not and cannot split claims. The point of sale (POS) systems used universally by pharmacies direct each claim to a designated single payor; not multiple payors. The transaction is processed in 2 to 3 seconds with a response as either paid or denied, but only from the one payor. With respect to the relationship between the patient and the pharmacy, the pharmacy is only a provider. It has no way of knowing what the beneficiary disclosed regarding OHI when the beneficiary made their application to the PDP. The pharmacy will only know to submit a beneficiaries claim to a PDP when beneficiary presents a prescription and their PDP program card.

Are PBM's the answer? Given that pharmacies are not the solution for TROOP, the question is rightfully directed to PBM systems for consideration. As the PBM system receives claims from pharmacy systems, is it possible that that the PBM system can coordinate TROOP on a real time basis? The answer is, no. The adjudication process is bi-directional only: e.g. between the pharmacy, where the claim is originated, and the PBM. PBM systems do not systematically redirect claims to other health insurance providers in real time before responding to the claims originator, the pharmacy. Coordination of benefits is most often accomplished by PBM systems by denying claims for plan members where the plan sponsor has indicated the existence of other health insurance through the eligibility file. Under these conditions a beneficiary would be denied until the plan sponsor indicated they were satisfied that the member's OHI had been exhausted. Such a determination would occur directly between the beneficiary and the plan sponsor, and outside of the claims adjudication process.

The PBM's role in coordinating TROOP is further complicated by other considerations. Today, PBM's contract almost entirely with group payers (e.g. self-insured employer plans, managed care plans, etc.), and not individuals. Should a group payer have just one source of OHI, it ***may*** be possible for the PBM to coordinate with that singular source in real-time under unique conditions;

(e.g. the PBM already had a contractual relationship with the other health insurance payer). However, as Part-D is not a group product, enrolling beneficiaries may have OHI from any number of sources (e.g. an employer wrap-plan; a Med-Sup plan; a drug manufacturer plan; etc.). As written, the proposed rule would require that TROOP be coordinated real-time with each and every OHI source identified by the beneficiary. This would require the PBM to establish contracts and real-time electronic claims processing procedures with an open-ended number of OHI sources. This is unrealistic. First, as discussed previously, PBM systems are not configured to redirect claims to OHI providers in real-time. Second, assuming the first problem could be overcome, it is unrealistic to assume that a PBM could successfully conclude contract terms and on-line claims transaction coordination with every source of OHI. Many of these sources would not even be capable of on-line claims transactions. In conclusion, PBM's and their systems are not the solution for assuring accurate coordination of TROOP.

Recommendation. PharmaCare recommends that CMS confer with the National Council for Prescription Drug Programs (NCPDP). NCPDP serves an important role for all industries associated with pharmacy programs. Most importantly they establish the electronic claims standards necessary to accomplish prescription drug program management. Together, NCPDP and CMS can coordinate a workable solution for TROOP.

Also, CMS should give serious consideration to allowing PDP's to simply deny acceptance for any applicant who indicates they have OHI. The approach to TROOP under the proposed rule is a source of unacceptable risk to potential PDP's in terms of investment and accountability. As PDP's are risk based providers they should be asked to only assume risk for beneficiaries where accurate risk accountability can be assured. Beneficiaries with OHI are perfectly suited for Limited Risk Plans or Fallback Plans, and we recommend that PDP's should not be required to enroll such beneficiaries.

The Proposed Data Set

Introduction. PharmaCare participated in a CMS sponsored Open Door Forum (ODF) on September 9, 2004 regarding the Bidders' Data Set for Prescription Drug Plans. The forum's intent was for the American Academy of Actuaries Working Group to identify the high-priority data needs for bidders, to summarize their discussions with CMS on developing a bidders data set, and to present a plan for making essential data available in a timely manner. A summary of the ODF went on to describe the need for a data set as follows: *A data set including detailed information on drug utilization is an essential element in facilitating bids by insurers to provide prescription drug coverage.*

Discussion. PharmaCare concurs that an accurate and comprehensive data set is an essential element to facilitate bidding. The ODF, however, pointed to significant problems with the approaches being pursued by the Academy's Working Group.

The data sources available to the Working Group are of little value as they are incomplete and dated. The Medicare Current Beneficiary Survey (MCBS) has significant limitations and shortcomings as an instrument for producing the necessary drug utilization information needed by potential PDP bidders. The 2001 FEP retirees' data does not reflect the many new drugs that have come to market since that time nor the changes in drug prices. In summary, these sources are inadequate and incomplete.

Recommendation. To gain the confidence of PDP's, CMS should endeavor to secure credible sources of data for the Academy's Working Group to analyze. Such sources are readily available. Three excellent sources are discussed below.

1. TRICARE. The TRICARE pharmacy benefit program includes a program unique to over 1.5 million retirees. CMS should coordinate the transfer of both a historical drug utilization file from the Department of Defense's TRICARE Management Activity (TMA) and update files as necessary. The TRICARE TMA subscribes to the standards established by NCPDP. The creation of file reflecting the data fields and layout standards of NCPDP is a task that can be easily accomplished by TMA or its contractor. PharmaCare recommends CMS act quickly as this approach to securing valuable and relevant data represents a low or no cost activity that can be accomplished in days.

2. Pharmacy Benefits Managers. Today PBM's administer pharmacy benefit programs for millions of Medicare beneficiaries through employer sponsored plans and Medicare Choice contractor plans. No better source of data is available than that which can be provided by PBM's. PharmaCare recommends that CMS ask PBM's to voluntarily offer the Working Group data files reflecting the utilization of Medicare age beneficiaries. The process would result in the largest, most robust data set possible and provide the Working Group the information they need to produce quality results.

3. Chain Drug Stores. The National Association of Chain Drug Stores (NACDS) is an excellent source of data. Pharmacies are stakeholders in this endeavor and desire a well-developed program. Their membership, if approached, would freely cooperate with CMS by sharing data.

Issues Related to PDP's and Risk

Introduction. It will be the PBM industry that makes administration of the Medicare Drug Benefit possible. However, their role as PDP's or in association with PDP's is questionable unless the proposed rule is modified. Since the enactment of MMA in December 2003, some in the PBM industry have made public comment to the issues of PDP's being treated as insurers and of the requirement to assume risk. These requirements are in inconsistent with commercial practices where PBM's are not insurers and do not assume risk. Consequently, we recommend that CMS appreciate that unless the final rule satisfactorily addresses these issues PBM's may not view Medicare as such an important new market opportunity, which in turn could place the implementation of the Medicare Drug Benefit in jeopardy.

Discussion. Risk posses many new considerations for PBM's. Several of these considerations are discussed below, and illustrate why some PBM's have indicated they may be required to forgo the opportunities presented by MMA unless the final rule is modified.

In the context of an insurer risk is defined as "the danger or probability of loss". Auto insurers, for example, know that not every policyholder will file a claim, making the probability of loss low among most policyholders and high only among a few at one time. It is the excess premium secured from non-claimant policyholders that pay for the excess costs of the few claimant policyholders. With respect to prescription drugs, however, the opposite is true. The probability of loss in never low because it can be assumed that most policyholders will be claimants and few will not. Even worse, in the case of the elderly it can be assumed that substantially ALL elderly beneficiaries will be claimants. And, as drug therapy is the primary form of treatment today for almost all chronic medical conditions that afflict the elderly, the possibility of radically curtailing drug use is unrealistic, especially given the overwhelming efficacy offered by most drug

therapies today. In summary the elderly are a very bad risk because there is almost certainty of loss.

The issue of adverse selection is also very problematic for PBM's. As the Medicare Drug Benefit will be voluntary, only the sickest beneficiaries can be expected migrate to the new Part-D leaving the premium payments for lower utilizing healthier beneficiaries unavailable to supplement the excess costs of the adverse membership. This is not conjecture, but reality. Medicare Choice contractors struggled under the weight of adverse selection for years resulting in withdrawal from numerous counties across the country. Adverse selection is assured for a PDP under the Medicare Drug Benefit.

And finally, PBM's are not insurers. Requiring PDP's to be insurance companies creates a significant new burden for PBM's and creates unintended business risk. In the precious little time available to prepare for this program a PBM faces many costly hurdles associated with state licensures. This is unknown territory for PBM's and States alike. One concern PBM's have that licensing actions may in fact trigger an unintended response from states whereby they attempt to bring substantially all PBM operations under state insurance authority. This would be a costly struggle to defend against. And, should the states succeed, it would prove very problematic to the PBM industry as it would add significant cost and seriously hamper the evolution of business practices, benefit design and even quality management programs.

Recommendation. PharmaCare recommends CMS publish a final rule that lowers the barriers posed by insurance and risk. The final rule should set out a safe harbor for PDP's with respect to state insurance regulations. And, in order to lower the adverse risk associated with Medicare aged beneficiaries, the government should consider adopting a final rule that limits the risk faced by PDP's. One example includes creating risk-free sources of revenue for PDP's such as separate program management fees rather than all-inclusive premiums.

In another example CMS could offer to cap the PDP's risk to a maximum loss. Changes such as these are important as they will serve to attract prospective PDP's. A final rule that does not mitigate the implications of insurance and risk may not attract PBM's to this program as PDP's.

Risk and The Issue of Any Willing Provider

Introduction. The issue of Any Willing Provider (AWP) is problematic for PDP's as risk bearing entities. Also, the proposed rule offers guidance that is impracticable to potential PDP's. PharmaCare believes the proposed rule should be modified to reposition the intended role of AWP to what we believe was intended by the authors of MMA.

Discussion. The MMA and the proposed rule make reference to both Any Willing Provider and pharmacy network access standards. In the context of commercial practices, the two are in some ways redundant. Prescription plan sponsors seeking pharmacy network services from a PBM, for example, specify access standards to ensure a PBM contracts with sufficient providers, but not all providers. In the process of assembling a network a PBM uses the leverage offered by the access standards to negotiate price knowing that more aggressive prices can be secured if there is no requirement to allow the participation of any willing provider. Under a requirement to assemble a network where any willing provider may participate, no such leverage exists and no access standard may be assured as providers participate at will.

It is the opinion of PharmaCare that the authors of the Act included access standards as a means for prospective PDP's to establish network contracting leverage while protecting the interests of beneficiaries. This is fundamentally consistent with any entity bearing risk and assures the government of the best possible basis of cost. And, the Federal Government also shares this opinion. The Federal Trade Commission has concluded that Any Willing Provider requirements are fundamentally in conflict with the ability of any network assembler to secure best price. Please refer to the FTC's web site at http://www.ftc.gov/opa/2004/04/ribills.htm for an example of a recent example of the Commission's position on AWP.

PharmaCare also believes the issue of Any Willing Provider has also been misinterpreted as presented in the proposed rule. The proposed rule infers that Any Willing Provider is a requirement of a PDP, which we believe incorrectly interprets the intent of the Act. PharmaCare believes the Act discusses Any Willing Provider in the context of a right of the beneficiary, not a requirement of a plan sponsor or PDP. It is common for States to extend the privilege of pharmacy Freedom of Choice (FOC) to the membership of health insurance carriers; the terms Freedom of Choice and Any Willing Provider are often used interchangeably in the context of a member or beneficiary. But this privilege offered by States to members does not necessarily flow by extesnion to health insurers as a requirement. In summary, such laws are intended to reinforce and support the freedom of individuals to secure service from providers of their choice, but not by extension require health insurers to contract with them.

Recommendation. PharmaCare recommends that the final rule clarify the intent of the Act by specifying that the law protects the right of each beneficiary to choose their own provider, but does not require the PDP to include any willing provider in their network. And, it is not sufficient enough for CMS to allow PDP's to designate such providers as "non-preferred" or "out of network" if it still requires they contract with them. In-network providers will not negotiate best price if they know other providers can participate through circuitous means. The rule should clearly state that while beneficiaries may use providers of their choice, benefits will not be payable unless they use a contracted in-network provider of the PDP. The final rule should also clarify that the access standards set out in the Act are the principle methodology for assuring adequate access and drop any reference to AWP with respect to the establishment of networks.

Medication Therapy Management (MTM)

Introduction. The final rule should make clarification with respect to Medication Therapy Management (MTM) and the role of PDP's and providers. The proposed rule raises concerns that PDP's may be required to fund MTM by themselves.

Discussion. Considerable attention has been paid to the topic of MTM. However, the proposed rule should make clarifications in several regards. First, the proposed rule leaves questions unanswered as to the source of funding for MTM services. One could interpret the proposed rule as inferring that MTM services will be paid for by PDP's. This raises concerns. Assume a provider (e.g. a pharmacy) performs an MTM service. If the obligation to pay for that service falls on the PDP then where will those funds come from? If the answer is, from the fixed premium's paid by the beneficiary and Medicare, then this poses significant risk to PDP's. Such services would represent an open checkbook to providers who could perform them at will and make payment demands on a PDP, who in turn must pay from a fixed pool of premium revenue. Even worse the MTM activity could actually cause increased drug use, which is in conflict with a fixed price risk-based program.

The proposed rule should also clarify the MTM is an activity that can be performed by the PDP itself and is not the exclusive domain of others like pharmacists, nurses and physicians. PDP's will be in the best position to perform MTM themselves as they will have all available utilization data available. The final rule should clarify that MTM is a service that may be performed by providers as exclusively determined by the PDP. Otherwise the PDP will lose control of where and how these services are performed.

And, finally, the final rule should make it clear that MTM is not an exercise or activity that is exclusively performed in person between a health care provider

and the beneficiary, but may also be performed remotely by phone, internet and by paper. These recommended approaches are very cost effective and can reach more beneficiaries than in-person approaches. And, many quality programs already exist that employ these approaches.

Recommendation. The final rule must clarify the issue of MTM. MTM cannot be an at will activity of any willing provider. PDP's must hold the authority to establish who may provide MTM to their program membership. The final rule must also clarify from what source of funds the services of MTM will be paid. PharmaCare recommends that CMS pay for MTM separately and not include MTM funding as part of an inclusive premium calculation. MTM payments should also not be subject to risk as the activity of MTM will, in many cases, cause increases in drug use (e.g. under-utilization, therapy initiation, etc.).

Beneficiary Late Enrollment Penalty

Introduction. The formula for imposing beneficiary late enrollment fees, as discussed in the proposed rule, is not aggressive enough to promote rapid beneficiary enrollment in PDP's.

Discussion. Underlying the intent of the MMA is the belief that the government's best interest is served when industry participates on a risk basis to share the financial management challenge posed by Medicare beneficiaries. To attract the most qualified entities to serve as PDP's CMS should make every effort to ensure fast and rapid adoption of Medicare Part-D through PDP's. To this end, the proposed late enrollment fee is insufficient. PharmaCare does not believe $0.36 per month is enough of a fee to motivate beneficiaries to rapidly adopt Medicare Part-D.

Recommendation. PharmaCare recommends that CMS consider a black-out period where enrollment is not authorized rather than a late penalty. For example, offering beneficiaries the right to enroll only in November and December of each year for proceeding calendar year, with January through October being closed to enrollment (e.g. the black-out). Such an approach would create a sense of urgency among beneficiaries. The late enrollment penalty, as proposed, will only promote a "wait and see" attitude. If CMS is to attract prospective PDP's, then the final rule should include an approach that creates a sense of urgency for beneficiaries to enroll in Medicare Part-D through a PDP.

Conclusive Comments & Contact Information

PharmaCare again extends our thanks to CMS for the opportunity to make comment to this proposed rule. The Medicare Drug Benefit can only be viewed as a sea change event. As such PharmaCare very much desires to take part in this exciting program. We recognize that CMS has precious little time to implement this program, however, if prospective PDP's are to value the opportunity created by the Act then CMS should give serious consideration to our recommended modifications of the proposed rule. The modifications recommended by PharmaCare are, in our opinion, modest yet essential to assuring a workable program. PharmaCare offers our service freely to CMS for the purpose of concluding a final rule.

Should CMS desire to contact PharmaCare regarding these topics, all inquiries may be made to the following individual:

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CMS-4068-P-1241

Submitter : James Finley **Date & Time:** 10/04/2004 08:10:09

Organization : National Association of Social Workers

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

See attached comments

CMS-4068-P-1241-Attach-2.doc

CMS-4068-P-1241-Attach-1.doc

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

The National Association of Social Workers (NASW) welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. NASW is the largest professional social work organization with more than 153,000 members nationwide. NASW promotes, develops, and protects the practice of social work and social workers, while enhancing the well being of individuals, families, and communities through its work, service, and advocacy. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

Coverage of Dual Eligibles (§ 423.34)

Of grave concern is the impact of the new Medicare drug benefit on those beneficiaries who currently have drug coverage through their state Medicaid programs, i.e. the dual eligibles. CMS must ensure that these very vulnerable beneficiaries receive coverage for the medications they need under the new drug benefit and are not harmed or made worse off when their drug coverage is switched from Medicaid to Medicare.

Based on social workers experience with this group of beneficiaries, we are gravely concerned that the proposed regulations would cause harmful disruption in care and inadequate drug coverage for dual eligibles. In particular, the proposed regulations do not address how access to needed medications by dual eligibles will be maintained when their drug coverage is switched from Medicaid to Medicare.

We urge CMS to take account of the unique circumstances and needs of this population, and delay transfer of drug coverage from Medicaid to Medicare for the dual eligibles for at least six months to allow adequate time to educate and enroll these vulnerable and often hard-to-reach individuals and to ensure they receive the drug coverage to which they are entitled.

CMS must also address the real threat of adverse health outcomes facing dual eligibles. Under the proposed rule, dual eligibles would effectively be forced to enroll in the lowest cost plans in their areas because the low-income subsidy they will receive will only cover the premium for these plans (and automatic enrollment would require placement in a low-cost plan). While it is critical that the transfer from Medicaid to Medicare drug coverage maintain continuity of care, the proposed regulations provide no such protection. To the contrary, the formularies for these low-cost drug plans will not be as comprehensive as the drug coverage these individuals currently have through Medicaid. Without access to the coverage they need, dual eligibles would have no real choice but to switch medications. Yet changing medications is for those with complex conditions is both very difficult and potentially dangerous. For example, abrupt changes in psychiatric medications bring the risk of serious adverse drug reactions and interactions and the potential for a severe loss of functioning.

With respect to beneficiaries with mental illness, these regulations must give meaningful effect to the concern Congress itself voiced, stating in the conference report on the Act that: "[i]f a plan chooses not to offer or restrict access to a particular medication to treat the mentally ill, the disabled will have the freedom to choose a plan that has appropriate access to the medicine needed. The Conferees believe this is critical as the severely mentally ill are a unique population with unique prescription drug needs as individual responses to mental health medications are different." [Report No. 108-391, pp. 769-770] Unfortunately, the proposed rule does not adequately provide the protection for people with mental illness that Congress called for. We urge that the regulations be revised to provide for "grandfathering" coverage of psychiatric medications for dual eligibles into the new Part D benefit, as a number of states have done in implementing preferred drug lists for their Medicaid programs.

Lastly, for the dual eligibles in particular, CMS must fund collaborative partnerships with organizations representing people with disabilities and other vulnerable populations. Such partnerships will be critical to an effective outreach and enrollment process. Targeted and hands-on outreach to vulnerable Medicare beneficiaries, especially those with low-incomes, is vitally important in the enrollment process. We strongly urge CMS to develop a specific plan for facilitating enrollment of beneficiaries with disabilities and complex medical conditions in each region that incorporates collaborative partnerships with the state and local agencies and advocacy organizations that serve them.

Alternative, Flexible Formularies for Beneficiaries for Vulnerable Populations (§ 423.120(b))

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing deteriorating health, unnecessary hospitalizations and even death, on the other. Often, people with disabilities and complex medical conditions need access to the newest medications, because they have fewer side effects and may represent a better treatment option than older less expensive drugs. Many individuals have multiple disabilities and health conditions making drug

interactions a common problem. Frequently, extended release versions of medications are needed to effectively manage these conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects making it more important for the doctor to be able to prescribe the best medication for the individual. Often that pharmacological process takes time since many people with significant disabilities must try multiple medications and only after much experimentation find the medication that is most effective for their circumstance. The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury or debilitating side effects, even hospitalization or other types of costly medical interventions.

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs, and the enormous potential for serious harm (including death) if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations who:

- are dually eligible for Medicare and Medicaid;
- live in nursing homes, ICF-MRs and other residential facilities;
- have life threatening conditions; or
- have pharmacologically complex condition such as mental illness, Alzheimer's disease, multiple sclerosis, HIV/AIDS, and epilepsy.

Furthermore, new limits on cost management tools must be imposed for these vulnerable populations. We urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications that are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

Involuntary Disenrollment for Disruptive Behavior (§ 423.44)

The proposed regulation raises grave concerns in allowing Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" (§ 423.44(d)(2)). These provisions create enormous

opportunities for discrimination against individuals with mental illness and cognitive impairments. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and as a result they could also be subject to a late enrollment penalty increasing their premiums for the rest of their lives. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage.

As a matter of principle, for a critical safety net program such as Medicare prescription drugs for dual eligibles, NASW cannot support automatic disenrollment of this population under any circumstances. We are therefore alarmed that CMS has proposed an expedited disenrollment process that would undermine the minimal standards and protections included in the proposed rule. This expedited process proposal must not be included in the final rule. In addition, CMS must provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and must waive the late enrollment penalty for these individuals as well. The final rule must include the following protections:

- drug plans must be prohibited from disenrolling a beneficiary because he/she exercises the option to make treatment decisions with which the plan disagrees, including the option of no treatment and/or no diagnostic testing;
- drug plans may not disenroll a beneficiary because he/she chooses not to comply with any treatment regimen developed by the plan or any health care professionals associated with the plan;
- documentation provided to CMS arguing for approval of a plan's proposal to involuntarily disenroll an individual must include:
  - documentation of the plan's effort to provide reasonable accommodations for individuals with disabilities in accordance with the Americans with Disabilities Act; and
  - documentation that the plan provided the beneficiary with appropriate written notice of the consequences of continued disruptive behavior or written notice of its intent to request involuntary disenrollment; and
- drug plans must provide beneficiaries subject to involuntary disenrollment with the following notices:
  - advance notice to inform the individual that the consequences of continued disruptive behavior will be disenrollment;
  - notice of intent to request CMS' permission to disenroll the individual; and
  - A planned action notice advising that CMS has approved the plan's request for approval of involuntary disenrollment.

Appeals Procedures (§§ 423.562-423.604)

The appeals processes outlined in the proposed regulations are overly complex, drawn-out, and inaccessible to beneficiaries. Under these proposed rules, there are too many levels of internal appeal that a beneficiary must request from the drug plan before receiving a truly independent review by an administrative law judge (ALJ) and the

timeframes for plan decisions are unreasonably long. In order to qualify for a hearing by an ALJ, beneficiaries must first request a coverage determination or exception from a tiered cost-sharing scheme or formulary which can take between 14 and 30 days, unless a plan honors a beneficiary's request that the determination or exception be expedited in which case it could still take up to 14 days. To appeal adverse determinations or exception decisions, beneficiaries must request plans to review their decision again and make a redetermination within 30 days unless the beneficiary paid out-of-pocket for the medication at issue, in which case the plan has 60 days to decide. Even if a plan honors a request to expedite a redetermination, the deadline for plans to make a decision could be as long as 14 days. Following a redetermination, beneficiaries may appeal to a so-called independent review entity for a reconsideration of their case, but these entities will not be authorized to review or question the criteria plans use to evaluate exceptions requests. The proposed rules do not even set deadlines for reconsideration decisions. After receiving a reconsideration decision, beneficiaries are only allowed to appeal to an administrative law judge if the amount in controversy meets a threshold level of $100 and it is unclear how CMS will calculate whether a beneficiary has met this threshold.

In addition to imposing unreasonable delays and burdens on beneficiaries, these appeal processes are far from transparent. Drug plans would be authorized to establish their own criteria for reviewing determination, exceptions, and redetermination requests and these criteria will vary from plan to plan. Plans would also be authorized to establish varying degrees of paperwork requirements for beneficiaries and their prescribing physicians who wish to request exceptions from tiered cost-sharing schemes or formularies. Far from ensuring that beneficiaries' rights are protected, which should be their primary function, these procedures would actually impede the right of beneficiaries to a fair hearing.

Beneficiaries with disabilities and complex health needs often have an extremely limited capacity to navigate grievance and appeals procedures. To accommodate the special needs of these beneficiaries and others who are vulnerable or with low income, CMS must establish a simpler process that puts a priority on ensuring ease of access and rapid results for beneficiaries and their doctors and includes a truly expedited exceptions process for individuals with immediate needs, including individuals facing health care crises, which should be modeled after the federal Medicaid requirement that states respond to prior authorization requests within 24 hours.

We also urge CMS to require plans to dispense a temporary supply of drugs in emergencies. The proposed system does not ensure that beneficiaries' rights are protected and does not guarantee beneficiaries have access to needed medications. For many individuals with disabilities such as epilepsy, mental illness or HIV, treatment interruptions can lead to serious short-term and long-term consequences. For this reasons the final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

Outreach and Enrollment (§ 423.34)

The proposed regulations do not adequately address the need for collaboration with state and local agencies and community-based organizations on outreach and enrollment of beneficiaries with disabilities and complex health conditions. In the conference report for the Medicare Modernization Act, Congress directed that "the Administrator of the Center for Medicare Choices [sic] shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriated [sic] access to pharmaceutical treatments for mental illness" (Report No. 108-391, pp. 769-770).

To respond to Congress's concern with ensuring enrollment and comprehensive coverage for beneficiaries, CMS must partner with community-based organizations focused on addressing the needs of vulnerable beneficiaries and the state and local agencies that coordinate benefits for them. Beneficiaries with special needs will most likely turn to organizations that they know and trust with questions and concerns regarding the new Part D drug benefit. Making information and educational materials available at these sites will help inform beneficiaries with mental illness about the new benefit, but providing community-based organizations with pamphlets and brochures alone is not adequate. To answer the many difficult, detailed, and time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be needed. Social workers and community-based organizations can provide the kind of detailed help needed, but they will need additional resources.

CMS must develop a specific plan for facilitating enrollment of beneficiaries with special needs, in each region that incorporates collaborative partnerships with and additional funding for state and local public and nonprofit agencies and organizations focused on these needs. In addition, in their bids, drug plans should include specific plans for encouraging enrollment of often hard-to-reach populations.

NASW strongly urges that the concerns discussed above be addressed in order to ensure access to psychiatric medications under the Part D drug benefit for the many Medicare beneficiaries who need them.

Thank you for your consideration of our comments.

Sincerely,

Toby Weismiller, ASCW
Director, Professional Development and Advocacy

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

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To respond to Congress's concern with ensuring enrollment and comprehensive coverage for beneficiaries, CMS must partner with community-based organizations focused on addressing the needs of vulnerable beneficiaries and the state and local agencies that coordinate benefits for them. Beneficiaries with special needs will most likely turn to organizations that they know and trust with questions and concerns regarding the new Part D drug benefit. Making information and educational materials available at these sites will help inform beneficiaries with mental illness about the new benefit, but providing community-based organizations with pamphlets and brochures alone is not adequate. To answer the many difficult, detailed, and time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be needed. Social workers and community-based organizations can provide the kind of detailed help needed, but they will need additional resources.

CMS must develop a specific plan for facilitating enrollment of beneficiaries with special needs, in each region that incorporates collaborative partnerships with and additional funding for state and local public and nonprofit agencies and organizations focused on these needs. In addition, in their bids, drug plans should include specific plans for encouraging enrollment of often hard-to-reach populations.

NASW strongly urges that the concerns discussed above be addressed in order to ensure access to psychiatric medications under the Part D drug benefit for the many Medicare beneficiaries who need them.

Thank you for your consideration of our comments.

Sincerely,

Toby Weismiller, ASCW
Director, Professional Development and Advocacy

CMS-4068-P-1242

Submitter : Ms. Marcie Roth **Date & Time:** 10/04/2004 08:10:08

Organization : The National Spinal Cord Injury Association

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

see attached document

CMS-4068-P-1242-Attach-1.doc

National Spinal Cord Injury Association

6701 Democracy Boulevard • Suite 300-9 • Bethesda, Maryland • 20817

Telephone: (301) 588-6959 • Fax: (301) 588-9414 • Email: info@spinalcord.org • Web: www.spinalcord.org

September 30, 2004

Department of Health and Human Services
Centers for Medicare and Medicaid Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

To Whom It May Concern:

The National Spinal Cord Injury Association is pleased to submit comments on the proposed rule "Medicare Program;
Medicare Prescription Drug Benefit," 69 FR 46632. The National Spinal Cord Injury Association (NSCIA), founded in 1948, is the nation's oldest and largest civilian organization dedicated to improving the quality of life for hundreds of thousands of Americans living with the results of spinal cord injury and disease (SCI/D) and their families. This number grows by thirty newly-injured people each day.

Tens of thousands of individuals with spinal cord injury or disease (sci/d) are Medicare beneficiaries. NSCIA has grave concerns because the proposed rule does not provide critical protections for people with sci/d and almost 13 million other Medicare beneficiaries with disabilities and chronic health conditions. We offer the following essential recommendations:

DESIGNATE SPECIAL POPULATIONS WHO WILL RECEIVE AFFORDABLE ACCESS TO AN ALTERNATIVE, FLEXIBLE FORMULARY:

Individuals who have sci/d or other with serious and complex health issues must have access to the right medications. Such medications are critical to leading healthy, functioning, productive lives in the community as opposed to being institutionalized in nursing homes. Not having access to the correct medications can cause expensive hospital stays and life threatening events. People with sci/d and other disabilities may need the latest medications because they have fewer side effects.
Denying the suitable medication for an individual with a disability or chronic health condition can cause serious side effects, create unnecessary health problems, and lead to costly medical interventions. We strongly support the suggestion in the proposed rule that people with disabilities and other chronic conditions require special treatment due to unique medical needs, and the enormous potential for serious harm or death if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program.

We recommend the following groups be among those included in these exempt populations:

- people who are dually eligible for Medicare and Medicaid
- people with sci/
- people who live in nursing homes and other residential facilities
- people who have life threatening conditions
- people who have pharmacologically complex conditions

POSTPONE THE IMPLEMENTATION OF THE PART D PROGRAM FOR DUAL ELIGIBLES:

Dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. Among these are many with sci/d. They rely extensively on prescription drug coverage to sustain their basic health. Because of low income, they are the most vulnerable beneficiaries. NSCIA believes there is not enough time allowed to address how drug coverage for these health and fiscally exposed beneficiaries will be transferred to Medicare on Jan. 1, 2006.

CMS and the private Part D plans giving drug coverage do not have enough time to implement a prescription drug benefit staring on January 1, 2006. These time constraints may well lead to plans that jeopardize the lives of people with sci/d and

other disabilities who fall into the dual eligible population. It is highly improbable that 6.4 million dual-eligibles could be identified, educated, and enrolled in six weeks (from November 15th the beginning of the enrollment period to January 1, 2006),

Therefore, **NSCIA urges that transfer of drug coverage from Medicaid to Medicare be delayed a minimum of six months even if legislative mandate is required.**
We further urge CMS to actively support such legislation in the current session of Congress.

FUND COLLABORATIVE PARTNERSHIPS WITH ORGANIZATIONS REPRESENTING PEOPLE WITH DISABILITIES THAT ARE CRITICAL TO AN EFFECTIVE OUTREACH AND ENROLLMENT PROCESS:

Organizations representing people with disabilities and other targeted populations of Medicare beneficiaries should be funded to collaborate with CMS in the outreach and enrollment process. These advocacy and service groups are one of the most effective inroads to disseminate outreach and enrollment information. **NSCIA strongly recommends that CMS develop national and regional partnerships with disability service and advocacy groups and local and state agencies.**

COST MANAGEMENT LIMITS AND CONSUMER PROTECTION:

NSCIA recommends that CMS make major enhancement to its provisions for consumer protection. One key example is not allowing any plan to require 100% cost sharing for any medication. These and other proposed cost burdens on the consumer could threaten and adversely effect people with sci/d and other disabilities. In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We oppose any regulations that allow cost containment practices that would limit a physician from prescribing the best medication for an individual. This elimination of said cost containment practices is especially critical for the lives of people with sci/d and other disabilities.

ENHANCE AND STRENGTHEN INADEQUATE EXCEPTIONS AND APPEALS PROCESSES:

NSCIA believes the appeals processes in the proposed rule are not accessible, too complex and will have a major adverse and deleterious impact on beneficiaries with disabilities. We
urge that CMS develop an understandable process that allows simplicity of access and fast results for beneficiaries and their doctors. NSCIA also urges an expedited appeals process. Along with many other disability organizations, NSCIA believes that the proposed rule **fails to meet Constitutional due process requirements and fails to satisfy the requirements of the statute**. The proposed rule has so many levels of cumbersome internal appeals to the drug plan that it makes unbiased appeal nearly impossible. The appeals process itself could preclude critical medications over a duration of time so as to be life threatening to people with disabilities.

The parts of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) that call for design and implementation of an exception process are vital consumer protections that must include regulations that are enforced. Such procedures could assure that individuals with sci/d and other disabilities would receive timely coverage determination for on and off formulary medications in a manner unique to their complex needs.

NSCIA joins other disability organizations in asking that CMS revamp the exceptions process to: establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

REQUIRE PLANS TO DISPENSE A TEMPORARY SUPPLY OF DRUGS IN EMERGENCIES:

Persons with sci/d, other disabilities, and chronic health conditions must have access to prescribed medications at all times. The proposed system does not ensure beneficiary
access to needed medications. Said drugs are vital to the continued, productive functioning of persons with sci/d and other disabilities. Interruption of medication regimes can cause serious health complications and may even be life threatening. Consequently, the final rule must ensure that an emergency supply of drugs be made available for dispensing while pending the resolution of an exception request or an appeal.

NSCIA appreciates your consideration of these public comments.

CMS-4068-P-1243

Submitter : Dr. John C. Lewin **Date & Time:** 10/04/2004 08:10:29

Organization : California Medical Association

Category : Physician

Issue Areas/Comments

Issues 1-10

BACKGROUND

Comments Attached.

CMS-4068-P-1243-Attach-1.doc

CMS-4068-P-1243-Attach-2.doc

California Medical Association
Physicians dedicated to the health of Californians

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014
E-mail: http://www.cms.gov/regulations/ecomments

Re: CMS-4068-P Comments on Part D, Medicare, Proposed Outpatient Drug Program Rules

Dear Dr. McClellan:

On behalf of the California Medical Association, we wish to join the American Medical Association in seeking further clarification regarding a range of patient safeguards that should be more explicitly addressed in your proposed rules. We believe it is imperative that these regulations clearly prohibit manipulations of a physician's prescribing authority that could subsequently result in disruptions in both the quality and continuity of medical care.

We strongly agree with your comments recently in the Wall Street Journal that "the choice of drugs should reflect current medical practice." In that spirit, we respectfully urge that CMS consider the following:

Benefit Design: As noted in AMA's testimony, we are concerned by 'serious deficiencies' in the USP's proposed model classification system. We find numerous circumstances whereby entire classes of vital drugs could be excluded by an HMO, PBM or other plan administrator. While some may believe this could help produce short term savings in the drug benefit program, it is inevitable that such limitations on coverage will shift the ensuing costs resulting from therapeutic failure to other parts of the Medicare program.

P&T Committee Coverage Decisions: We join the AMA in expressing our concern that absent further clarification, P&T Committees may be allowed to meet in secret, limit clinical and public input, and be stacked to favor the plan administrator's drug class preferences. It is not clear that the scope of the P&T Committees would include other coverage restriction strategies, such as prior authorization procedures or tiered/step formularies, nor if the committee's decisions would be binding on the PDP. We feel very strongly that the rule should be modified to make it clear that P&T committees must be responsible for the development of all coverage policies, and that their decisions should be made and explained openly through a transparent process that allows for public input.

Patient Protections: We are also very concerned that the plans could change formularies with only 30 days notice. You are aware that the Medicare population in general, and the dual eligible population in particular, commonly have multiple chronic conditions that require multiple ongoing drug therapies. In a majority of these patients their conditions are medically fragile and the dosages and drug products have been carefully titrated. Other than adding drug products, we believe formularies should only be modified, with adequate notice and P&T Committee approval, between plan years/contracts.

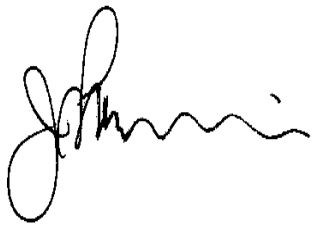
Drug Switching, Federal Preemption of State Pharmacy and Patient Protection Laws. While the preamble states that drug switching should require explicit approval by the treating physician, the rules themselves fail to expressly preserve this vital principle. Similarly, nowhere in the rule is the likely effect of the MMA on state pharmacy laws – which currently regulate the practice of therapeutic interchange – or drug switching – discussed. Switching prescriptions without the consent of the treating physician is the practice of medicine by non-physicians. Health plan or PBM employees who have virtually no history or contact with affected patients should not be permitted to override the treating physician's expert judgment. Again, Medicare is essentially a closed system—short-term savings which result in higher costs overall do not serve Medicare patients or the public well. To ensure that the final rules are not interpreted as permitting drug switching without the explicit consent of the treating physician, we urge you make it clear in the text of the regulations that state laws regulating therapeutic interchange must continue to be respected.

Office-Based Injectible Drugs for Oncology and Other Specialties: The MMA will drastically reduce the payment amount for drugs and drug administration services compared to the 2004 amounts. In addition, it appears likely that the payment methodology for drugs (106% of the manufacturer's average sales price) will result in payment amounts for many drugs that are lower than the prices at which physicians can purchase them, yet there is no mechanism in the MMA for adjustments in such circumstances. These changes have the potential to create substantial impairment of patient access to cancer and other essential treatments. Therefore, Congress should create exceptions under which CMS would be required to ensure that the payment amounts for in 2005 and later years are sufficient to cover the cost that physicians incur in purchasing the drugs. In addition, Congress should revise the MMA's transitional adjustment payment for drug administration services to an amount that will maintain the net revenue available to physicians from drugs and drug administration services in 2005 and 2006 at the same level as in 2004.

We readily acknowledge the daunting, complex nature of this new and promising program. And we applaud your efforts to implement it in a fair and responsible fashion. As you work to refine the implementing rules, we ask that the agency anticipate the consequences of arbitrarily limiting access to medically necessary drug products and work diligently to ensure that the standards and requirements that you ultimately set out for the program first and foremost do no harm.

Thank you for your consideration of these important medical principles and our mutual support of the patients we all serve.

Sincerely,



John C. Lewin, M.D.
Chief Executive Officer
California Medical Association

California Medical Association
Physicians dedicated to the health of Californians

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014
E-mail: http://www.cms.gov/regulations/ecomments

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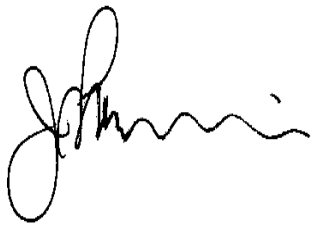
Sincerely,



John C. Lewin, M.D.
Chief Executive Officer
California Medical Association

Submitter : Daniel Hilferty **Date & Time:** 10/04/2004 08:10:59

Organization : AmeriHealth Mercy Health Plan

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Comments from AmeriHealth Mercy Health Plan

CMS-4068-P-1244-Attach-1.doc

October 4, 2004

Mark B. McClelland, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Dr. McClellan:

AmeriHealth Mercy Health Plan is pleased to have the opportunity to submit comments in response to the notice of proposed rulemaking by the Centers for Medicare & Medicaid Services (CMS) to establish the program for the Medicare Prescription Drug Benefit under Part D. AmeriHealth Mercy Health Plan is submitting separate comments to the Medicare Advantage (MA) regulations that relate to some of the same issues discussed here.

Background

AmeriHealth Mercy Health Plan is a subsidiary jointly owned by Independence Blue Cross and Mercy Health System. AmeriHealth Mercy Health Plan is a leading provider of Medicaid managed care programs and services. Together with its affiliate Keystone Mercy Health Plan and *PerformRx*, its pharmacy benefits management division, AmeriHealth Mercy Health Plan touches the lives of more than one million Medicaid members in seven states. AmeriHealth Mercy Health Plan and its affiliates (collectively, AmeriHealth Mercy Health Plan) are very interested in the opportunities provided by the Medicare Modernization Act (MMA) to participate both in the MA program through the offering of specialized MA plans for dual eligibles and in the offering of pharmacy benefit services on behalf of specialized MA plans serving dual eligibles.

The need to effectively manage prescription drug benefits for our large mandatory enrollment Medicaid populations led AmeriHealth Mercy Health Plan to develop *Perform Rx,* a Medicaid pharmacy care management program that meets financial objectives while improving the quality of health care for members. *PerformRx* manages drug benefits and services for almost 900,000 Medicaid beneficiaries in six states.

As further background, AmeriHealth Mercy has significant experience in serving dual eligible populations. AmeriHealth Mercy Health Plan furnishes services to about 50,000 full benefit dual eligibles in the following three health plans:

- Keystone Mercy Health Plan, Southeastern Pennsylvania's largest Medicaid managed care health plan serving more than 280,000 Medical Assistance recipients, including 31,000 dual eligibles, in Bucks, Chester, Delaware, Montgomery and Philadelphia counties**.** Keystone Mercy Health Plan operates this plan under a license held by Vista Health Plan, a subsidiary of Independence Blue Cross.
- AmeriHealth Mercy Health Plan serves about 76,000 Medical Assistance recipients, including about 6, 000 dual eligibles, in fifteen counties in Central and Northeastern Pennsylvania. AmeriHealth Mercy Health Plan operates this plan under a license held by Vista Health Plan, a subsidiary of Independence Blue Cross.
- Passport Health Plan[1] is a Medicaid managed care plan that serves over 130,000 members in Louisville and 15 surrounding counties in Kentucky. Its membership includes 12,000 dual eligibles. Passport was formed in 1997 by a group of safety net Medicaid providers. AmeriHealth Mercy provides complete health plan management and administrative support services under the governance of the Passport Health Plan board. Passport Health Plan is currently in the process of completing an application to participate in the Medicare Advantage program as a specialized MA plan for dual eligibles.

Discussion

1. Introduction

As an overall comment, AmeriHealth Mercy's experience in managing comprehensive prescription drug benefits for high risk Medicaid populations is that the management of the prescription drug benefit and medical benefits (hospital, physician, ancillary, etc.) are inherently interrelated because the quality outcomes and total costs are interdependent. Good disease management programs incorporate prescription drug data and management as integral components to clinical quality improvement and utilization/cost management efforts. Successful disease and case management programs serving high risk, low income populations focus on removing barriers to services. While total medical costs can be stabilized/reduced, an individual's prescription drug utilization may actually increase with appropriate use and adherence to medication plans. Thus, from the perspective of an MA-PD plan that is managing medical and pharmaceutical services, the sponsoring MA organization has strong motivation to ensure that the Part D drug benefit is designed and administered in a manner that serves the best interests of its enrollees. Over the years, health plans have developed effective programs to appropriately manage their drug benefits. AmeriHealth Mercy Health Plan urges CMS to develop the Part D regulations in a manner that gives health plans the discretion to continue these programs.

2. Subpart B – Eligibility and Enrollment

[1] Passport Health Plan is the trade name for University Health Care, a section 501(c)(3) tax exempt organization.

In this section of our letter, we provide our rationale for requesting that CMS adopt a policy that would allow the auto-assignment of full benefit dual eligibles into an MA-PD that is offered by a health plan in which the full benefit dual eligibles are enrolled or a health plan under common ownership and control of the health plan in which the full benefit dual eligibles are enrolled. Because of the importance of these comments, AmeriHealth Mercy Health Plan has repeated these recommendations in its comments to the MA proposed rule.

The MMA establishes a mechanism for full benefit dual eligibles who will be losing their outpatient drug coverage under Medicaid to select enrollment in an MA-PD plan or a PDP. The statute allows for default enrollment into a PDP in the event that a full benefit dual eligible fails to select a PDP or an MA-PDP Plan. Based on information provided at an open door forum, our understanding is that CMS intends to have this default enrollment occur effective January 1, 2006.

In the preamble to the PDP proposed rule (page 46638), CMS explains that there are conflicting statutory provisions related to default enrollments. To address these conflicts, CMS is proposing to default full benefit dual eligibles into an MA-PD if the full benefit dual eligible was enrolled in the MA organization previously. In the preamble, CMS articulates its policy justification for this decision as follows:

> To the extent that the MA-only portion of the MA-PD plan parallels the coverage under a full benefit dual eligible individual's MA plan, enrolling the individual in the MA-PD plan would be similar to permitting the individual to remain enrolled in the MA plan while simultaneously enrolling the individual in a PDP. In other words, enrolling the individual in a MA-PD plan offered by the same MA organization is, in effect, simply adding qualified prescription drug coverage to the individual's MA benefits. For this reason, we believe the reference to ``prescription drug plans'' in section 1860D-1(b)(1)(C) of the Act should be interpreted as requiring enrollment of a full benefit dual-eligible into a plan that will provide the individual with Part D drug benefits in addition to any other benefits the individual receives under Medicare, whether through Medicare Part A and/or Part B, or through enrollment in the Medicare Advantage program under Part C. We believe this interpretation promotes the policies underlying sections 1860D-1(b)(1)(C) and 1860D-1(a)(1)(B)(ii) of the Act, giving full effect to both statutory provisions.

AmeriHealth Mercy Health Plan fully supports CMS proposed policy, but requests that CMS expand this policy to allow for default enrollments in two additional, related circumstances illustrated below. First, Passport Health Plan currently enrolls 12,000 dual eligibles and is in the process of applying for an MA-SNP to serve dual eligibles. AmeriHealth Mercy Health Plan is recommending that CMS expand its policy to allow for the current full benefit dual eligible enrollees of Passport Health Plan's Medicaid MCO who do not otherwise select an MA-PD or PDP to default into Passport Health Plan's MA-PD. Because virtually all Medicare services are covered under Medicaid, allowing such a default enrollment would permit these full benefit enrollees to continue to receive the full range of A/B services and drug benefits from the same

health plan. Moreover, AmeriHealth Mercy Health Plan believes that allowing dual eligibles to retain their prescription drug providers and the existing pharmacy management structure is fully consistent with the objectives stated above.

AmeriHealth Mercy Health Plan believes there is legal precedence to support our interpretation that would permit members of another health plan offered by the same organization to be viewed as members of the Medicare managed care organization. Section 1851(a)(3)(B) includes the provision that prohibits beneficiaries with end-stage renal disease (ESRD) to enroll in an MA plan. This paragraph includes an exception that permits the enrollment of "an individual who develops end-stage renal disease while enrolled in an MA plan may continue to be enrolled in that plan." As part of the BBA regulations, CMS was confronted with the issue of whether a Medicare beneficiary who was enrolled in a non-Medicare+Choice plan and who developed ESRD could enroll in a Medicare+Choice plan offered by the same organization. In answering this question, CMS appropriately asserted its authority to depart from the literal reading of the statute and took the following position:

> For purposes of this provision only we are considering individuals who are enrolled in a private health plan offered by the M+C organization to have been enrollees of the M+C plan when they developed ESRD. (63 FR 34976, June 26, 1998)

While this ESRD enrollment issue is in a different context from the default enrollment issue under the MMA, it illustrates the clear willingness of CMS to depart from the literal reading of the statute to reach an important and desirable policy result. In this case, that departure entailed treating a non-MA enrollee of an organization as an MA enrollee of that same organization for purposes of enrollment into an MA plan. Consistent with CMS' willingness to extend a reference to M+C organizations to a non-Medicare health plan offered by the same entity, we believe that CMS has the corresponding legal authority to make an analogous legal interpretation. AmeriHealth Mercy Health Plan believes that strong policy reasons also support this result because this interpretation would allow a single organization to coordinate the services and be responsible for the full range of Medicare and Medicaid benefits for the full benefit dual eligibles. In making this recommendation, we emphasize that these full benefit dual eligibles would have the right to disenroll from the MA-SNP, if they want.

We also believe our recommendation has policy support under the statutory provision in Section 1851(c)(3)(a)(II), which address seamless continuation of coverage. Under that provision, CMS has the authority to establish procedures under which an individual who is enrolled in a health plan (other than an MA plan) offered by an MA organization at the time of the initial election period and who fails to elect to receive coverage other than through the organization is deemed to have elected the MA plan offered by the organization. While this provision applies to initial election period when a person is first eligible for Medicare coverage, the provision demonstrates Congressional support for arrangements that facilitate enrollment into an MA plan of an enrollee covered by a non-MA plan sponsored by the same organization. In addition, this provision offers clear authority for CMS to provide for this default enrollment in the future when an

enrollee of a Medicaid MCO first becomes eligible for Medicare and the same entity also offers an MA plan.

Our second policy recommendation related to how CMS interprets the default enrollment provision is an extension of our initial request and relates to the two Pennsylvania Medicaid managed care plans: Keystone Mercy Health Plan in Southeastern Pennsylvania, and AmeriHealth Mercy Health Plan in Central and Northeastern Pennsylvania. As noted above, AmeriHealth Mercy Health Plan and its affiliate, Keystone Mercy Health Plan, are owned by Independence Blue Cross and Mercy Health System. Both of these Medicaid plans are operated under an HMO license held by Vista Health Plan, a wholly owned subsidiary of Independence Blue Cross.

Independence Blue Cross itself and through its subsidiaries has three separate MA contracts. One contract is a PPO sponsored by Independence Blue Cross itself. The second contract is held by a wholly owned subsidiary of Independence Blue Cross, Keystone Health Plan East, Inc., and is offered in Southeastern Pennsylvania. The third contract is held by AmeriHealth HMO, Inc. AmeriHealth Mercy Health Plan is requesting that CMS adopt a policy that would allow the full benefit dual eligible enrollees of AmeriHealth Mercy Health Plan and Keystone Mercy Health Plan and who do not otherwise select another MA-PD or PDP to default on January 1, 2006, into the MA-SNP sponsored by AmeriHealth HMO, Inc, and Keystone Health Plan East, Inc., respectively. In making this request, we want to be clear that substantial efforts will be made in advance of the default date to have these Medicaid enrollees either select a MA-PD plan or a drug plan. Keystone Health Plan East and AmeriHealth HMO, Inc. will be actively marketing the dual eligibles enrolled in their affiliated Medicaid managed care organizations in a manner consistent with CMS rules. However, as CMS is aware from its experience in the drug discount card program and the challenges associated with enrolling dual eligibles in the Medicare savings programs, many dual eligibles will take no action prior to January 1, 2006. AmeriHealth Mercy Health Plan strongly believes it is in the best interests of their enrollees and the Medicare program to default these enrollees into Keystone Health Plan East's MA-SNP.

AmeriHealth Mercy Health Plan also believes there is a legal precedent for allowing affiliates of organizations to avail themselves of statutory rights under the Medicare or Medicaid program. Prior to enactment of the BBA, Medicaid MCOs were prohibited from having more than 75 percent of their enrollment comprised of persons eligible for Medicare and Medicaid. Certain community health centers, migrant health centers, and Appalachian health centers were exempt from this requirement. When CMS implemented this statutory provision, CMS departed from the literal reading of the statute and extended this exemption to HMOs owned by these health centers. CMS discussed this issue in the following manner:

> As noted in the previous section, we are proposing to amend the regulations to recognize the statutory exemption from the composition of enrollment standard for certain Community, Migrant, and Appalachian Health Centers. It has come to our attention that some of these exempt centers have joined to form larger organization in order to operate an HMO of adequate size. Under simple arrangements, several community health centers have established an HMO that

> enrolls members who are then provided primary care services through the same community health centers. The HMO serves simply as the corporate vehicle allowing the centers to combine their efforts. In this circumstance, we believe that, consistent with Congressional intent, the HMO formed by centers that are exempt from the composition of enrollment standard should itself be exempt from the standard. (53 FR 746, January 12, 1988)

This discussion illustrates CMS willingness to extend statutory rights from an organization to an affiliate of that organization in appropriate circumstances. In the context of the issues being raised to CMS here, it is important to note that the complexity arising from these different organizational structures derives both from the limitations that Independence Blue Cross has to use the Blue Cross mark outside of its designated area and Medicaid managed care program requirements. Notwithstanding this complexity, it is clear that all of the entities that hold the MA contracts and Medicaid contracts with the Pennsylvania Department of Public Welfare are wholly owned subsidiaries of Independence Blue Cross. Therefore, for purposes of developing public policy interpreting the default enrollment provisions, we believe it is reasonable and appropriate for CMS to treat these affiliated companies as a single entity.

AmeriHealth Mercy Health Plan recognizes that CMS' consideration of AmeriHealth Mercy Health Plan's requests needs to be considered in the context of a broader policy that is consistent with the objectives of the MMA and serves the best interests of full benefit dual eligibles. To achieve this end, AmeriHealth Mercy Health Plan recommends that CMS adopt the following policy:

> That CMS approve default enrollment of a full benefit dual eligible who has not otherwise selected an MA-PD or PDP into an MA-PD that is administered by an MA organization (1) that operates the Medicaid MCO in which the dual eligible is enrolled or (2) that is affiliated by common ownership or control with an organization that operates the Medicaid MCO in which the dual eligible is enrolled. As a condition of CMS approving this policy, the MA organization would be obligated to meet the following conditions:
>
> 1. The MA organization would have to assure that the full benefit dual eligibles are given notice of the default enrollment and their opportunity to select other options in advance of the default enrollment as well as their continued ability to disenroll from the specialized MA-PD plan following their enrollment.
>
> 2. The bid for A/B benefits would not include beneficiary premiums or cost sharing that would be paid by the full benefit dual eligible enrollees. If the Part D premium is determined to be in excess of the low income premium subsidy, the MA-PD plan would reallocate rebate dollars to the amount of the low income premium subsidy (if permitted by CMS).
>
> 3. The MA organization must represent that substantially all of the Medicaid providers currently furnishing services to the full benefit dual eligibles are either

part of the MA-SNP's delivery system or would have the opportunity to participate in that delivery system provided that the MA organization's credentialing requirements could be met.

4. The same pharmacy benefits manager that will administer the Part D benefit on behalf of the MA-SNP must also have previously managed the pharmacy benefit for the dual eligible enrollees of the Medicaid MCO.

AmeriHealth Mercy Health Plan would welcome the opportunity to discuss with CMS its proposal. As implicitly reflected in the above conditions, AmeriHealth Mercy Health Plan is recommending that CMS allow default enrollments into an MA-PD even if the Part D premium exceeds the low income premium subsidy. We believe the enrollees' best interests will be met by enrolling them in the MA plan under the above conditions rather than forcing them into a PDP.

3. Subpart C – Benefits and Beneficiary Protections

a. USP Classification structure

AmeriHealth Mercy Health Plan supports the proposed USP classification structure. We believe that the skeletal structure does exactly what it was primarily intended to do -- prevent enrollee discrimination through non-inclusion of certain medication types and categories. This skeletal structure provides a good basis from which to create a workable formulary that will ultimately be reviewed by CMS for appropriateness. AmeriHealth Mercy Health Plan reiterates its earlier point that it is very important for CMS to give MA organizations the flexibility to administer their drug benefit in a manner that serves the best interest of their beneficiaries. AmeriHealth Mercy Health Plan has substantial experience developing and managing formularies under Medicaid programs in a number of states. These formularies make available to enrollees in a cost effective manner the pharmaceuticals they need. AmeriHealth Mercy Health Plan urges CMS not to develop requirements that impair the ability of health plans like AmeriHealth Mercy Health Plan to continue the effective pharmaceutical programs that they currently offer to their enrollees.

b. Formulary development

AmeriHealth Mercy Health Plan supports the formulary development requirements and believes that the statutory and proposed regulatory requirements are generally consistent with industry practices in the development of formularies. Under the proposed rule, the majority of members comprising the P&T committee would be required to be practicing physicians and/or practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician member would have to be an expert in the care of elderly and disabled individuals and free of conflict with respect to the PDP sponsor and PDP or MA organization and MA-PD. AmeriHealth Mercy Health Plan believes this standard, in general, is reasonable and consistent with standard industry practice. However, AmeriHealth Mercy Health Plan has one concern with regard to how CMS is

interpreting "independent." In the preamble discussion, it appears that CMS would preclude a pharmacist from being viewed as "independent" if the pharmacist was part of the pharmacy network of the MA-PD plan. AmeriHealth Mercy Health Plan believes that many health plans attempt to create their P & T Committees composed of the "best and brightest" physicians within their geographic area. They also have this same goal for their provider networks. As a result, we have concerns that it may not be possible to obtain a physician or pharmacist who meets the requisite qualifications but is not part of the health plan's network. The health plan would be forced to find a pharmacist or physician who is located outside their service area to participate on their P & T Committee. Consequently, the selected P & T Committee member would lack a good understanding of local health care issues and concerns.

c. Use of rebates to reduce cost sharing

Under §423.100 in the definition of "required prescription drug coverage" an MA-PD plan may offer enhanced alternative coverage if there is no supplementary beneficiary premium as a result of the use of rebate dollars from A/B savings. In the preamble, CMS notes that an MA-SNP may use rebate dollars to reduce the nominal copayments that apply to low-income subsidy individuals who have incomes below 135 percent of FPL. We are seeking CMS confirmation on an issue related to this position. These dual eligibles may have copayments of $1/$3 or $2/$5. Our understanding is that an MA organization offering an MA-SNP for dual eligibles may use rebate dollars to remove both levels of copayments. AmeriHealth Mercy Health Plan is requesting that CMS confirm this interpretation in the preamble to the final regulation.

d. Drugs covered under Part B and Part D

CMS sets forth a lengthy discussion in the preamble concerning issues arising from drugs that may be provided under Part B and Part D. Based on our experience in the Medicaid program, AmeriHealth Mercy Health Plan has found that enormous issues can arise regarding the appropriate classification of drugs when the classifications dictate different financial obligations. AmeriHealth Mercy Health Plan urges CMS to the fullest extent possible to provide clear guidance regarding which drugs fall under Part B and those that fall under Part D. This guidance should also explain the rules determining treatment of newly approved drugs. This guidance should also delineate clearly the circumstances in which a drug may fall under either Part B or Part D depending on the manner in which it is administered.

4. Subpart D – Cost Control and Quality Improvement

As proposed under §423.153(b), CMS is requiring MA-PD plans and PDPs to have a cost-effective drug utilization management program. This program must:

(1) Include incentives to reduce costs when medically appropriate; and
(2) Maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications.

AmeriHealth Mercy Health Plan believes an effective drug utilization program is integral to the success of the Part D program. To this end, AmeriHealth Mercy Health Plan urges CMS to convey in the preamble its support for current practices that are commonly used by health plans and pharmacy benefit managers to manage utilization and control costs.

While unfortunate, the reality in today's health care environment is that a significant amount of beneficiary fraud and abuse occurs. This type of activity occurs in spite of significant efforts on the part of both pharmacists and the majority of practicing physicians to prevent this type of behavior. AmeriHealth Mercy Health Plan asks CMS to consider providing options, policies and processes that would allow health care payers/providers to investigate potential beneficiary fraud and misuse, and when verifiable, to attempt to control the activity in question. A large number of States already have beneficiary fraud and misuse programs in place for their Medicaid programs, and, in our opinion, these programs can be extremely successful in reducing the unwanted behavior.

AmeriHealth Mercy Health Plan, through its working relationship with the Commonwealth of Pennsylvania, has designed, developed, and implemented a program that attempts to eliminate/reduce fraud and misuse of drug products within our specific member population. Our particular program is referred to as "Recipient Restriction."

The pharmacy services department for the health plan constantly monitors drug claim data, looking for potential fraud and misuse. There are a number of algorithms that exist or could be developed by CMS to give guidance on what would, or would not, be considered fraud and/or misuse. The focus of these programs is typically on drugs and drug products that have "street" or "abuse" potential, with the primary products being the therapeutic class – opiate/narcotic pain medications. A number of other products have been included and are monitored as research and practice dictate.

The current process requires that once the health plan identifies a member misusing either products or services, a request to "restrict" that member is submitted to the Commonwealth's Department of Public Welfare "Recipient Restriction" oversight committee for a review and final determination. If the committee feels that there is enough data/information to support the restriction, based on the restriction criteria that has been approved and is in place, the member is restricted to using a single provider or group of providers and/or a single retail pharmacy vendor for a period of five years. What is also important is that this restriction attaches to the recipient and follows that recipient as they move from health plan to health plan. This is an extremely important component of the program as it precludes the recipient from re-initiating the unwanted behavior simply by changing health plans.

There appears to be little comment given in the MMA to programs/processes geared toward beneficiary fraud and misuse, the ability of MA-PD plans PDPs to initiate these types of programs, or CMS's willingness/ability to support this type of program.

AmeriHealth Mercy Health Plan's experience with this type of restriction program has been very positive. Once identified and "restricted," our research shows a significant decrease in the detrimental practices and behavior of the restricted recipients.

AmeriHealth Mercy Health Plan would encourage CMS to address and clarify the types of programs and support for these programs that might be forthcoming. The ability of a health plan to take limited action against a recipient that is misusing the system, with only the slightest impact of that recipient's access to the health care system, is an extremely valuable tool to improve appropriate utilization of medications and reduce unnecessary financial expenditures. While it may not be possible to establish a program under Medicare that parallels exactly the Medicaid programs, AmeriHealth Mercy Health Plan urges CMS to consider these issues and convey in the preamble to the final rule or the rule itself the manner in which these programs may be administered as well as alternative practices that may be followed by PDPs and MA-PD plans to accomplish the same objectives.

AmeriHealth Mercy Health Plan is also seeking confirmation from CMS with regard to the ability of MA-PDs and PDPs to require that certain drugs receive prior approval before a prescription is filled. Prior approval is a common practice and CMS repeats a number of times in the preamble the ability of health plans to continue their existing programs to manage costs. We also note that the Federal Medicaid law expressly provides:

> A State may subject to prior authorization *any* covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5)." § 1396r- 8(d)(1)(A) (emphasis added).

Paragraph (5), entitled "Requirements of prior authorization programs," reads as follows:

> A State plan under this subchapter may require, *as a condition of coverage or payment* for a covered outpatient drug for which Federal financial participation is available in accordance with this section, ... the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval-
> (A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
> (B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

42 U.S.C. § 1396r-8(d)(5) (emphasis added)

AmeriHealth Mercy Health Plan believes the process we currently use, follows the federal Medicaid guidelines. This guideline has worked well for years in the Medicaid environment, and AmeriHealth Mercy Health Plan recommends that CMS approve a comparable policy for the Part D program.

5. Subpart F Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

In the preamble discussion, CMS is clear that it expects PDP sponsors and MA organizations to identify the additional costs that may arise as a result of supplemental benefits. CMS states that a portion of these costs will be associated with increased utilization of the Part D basic benefit. CMS expects that the costs associated with this increased utilization will be included in the component of the bid attributable to the supplemental benefits, not the basic benefits.

This position raises a number of very significant and troubling issues for AmeriHealth Mercy Health Plan. If AmeriHealth Mercy Health Plan were to offer a MA-SNP for dual eligibles, its enrollees would have substantial "supplemental" coverage through the payment by CMS of the low-income subsidies. Our actuaries estimate that the utilization associated with an MA-SNP is well above that associated with the basic plan -- potentially 20 percent higher. This increased utilization is for the same population; it does not reflect populations choosing the plan or the value of the cost sharing itself. It is in addition to any risk adjustment needed due to diagnosis or medical conditions of a given population. Of the total allowed costs due to the increased utilization, a portion is reimbursed through increased cost sharing subsidies or increased reinsurance subsidies. The remaining portion is not reimbursed through any of the Part D direct subsidy, the reinsurance subsidy, the low-income premium subsidy, or the low-income cost sharing subsidy. Most importantly, the additional costs associated with this additional utilization cannot be reallocated outside of the basic drug benefit because AmeriHealth Mercy Health Plan will not be offering supplemental benefits.

As a result, AmeriHealth Mercy Health Plan and other MA-SNPs will be placed at a significant competitive disadvantage to MA-PDs and PDPs that will not have these additional costs included in their basic bid. More importantly, this inequity increases the likelihood that the premium of an MA-SNP will be greater than the low-income premium subsidy in its region. If this should occur, full benefit dual eligibles, who might otherwise have no premium, will be forced to pay a premium to the MA-SNP. This occurrence could create an incentive for the full benefit dual eligibles of the MA-SNP to disenroll and enroll in another plan that may be less expensive, but may not offer the special services needed by the dual eligible population.

For this reason, AmeriHealth Mercy Health Plan opposes CMS' proposed decision to require the costs associated with increased Part D basic services that arise when supplemental benefits are provided to be removed from the basic bid.

6. Subpart G Payments to PDP Sponsors and MA Organizations Offering MA-PD plans for all Medicare Beneficiaries for Qualified Prescription Drug Coverage

On page 46688 of the preamble, CMS included the following discussion conveying its concerns that plans serving large portions of low-income subsidy beneficiaries may not be paid adequately under the new Part D risk adjustment system:

> Any risk adjustment methodology we adopt should adequately account for low-income subsidy (LIS) individuals (and whether such individuals incur higher or lower-than average drug costs). Our risk adjustment methodology should provide neither an incentive nor a disincentive to enrolling LIS individuals, and we request comments on this concern and suggestions on how we might address this issue.
>
> Our particular concern is that a risk adjustment methodology, coupled with the statutory limitation restricting low-income subsidy (LIS) payments for premiums to amounts at or below the average, could systematically underpay plans with many LIS enrollees (assuming LIS enrollees have higher costs than average enrollees). If the risk-adjustor fails to fully compensate for the higher costs associated with LIS recipients, an efficient plan that attracts a disproportionate share of LIS eligible individuals would experience higher costs to the extent the actual costs of the LIS beneficiaries are greater than the risk-adjustment compensation. Failing to discourage enrollment by LIS beneficiaries in 2006, the plan would experience higher than expected costs in that year and presumably be driven to reflect these higher costs (due to adverse selection, not efficiency) in its bid for 2007. In this hypothetical, plans would have a disincentive to attracting a disproportionate share of LIS beneficiaries. One possible solution would be to assure that the initial risk-adjustment system, which will be budget neutral across all Part D enrollees, does not undercompensate plans for enrolling LIS beneficiaries. In fact, to the extent that an initial risk-adjustor might at the margin tend to overcompensate for LIS beneficiaries, plans would have a strong incentive to disproportionately attract such beneficiaries. Plans could attract LIS beneficiaries both by designing features that would be attractive to such beneficiaries but also by bidding low. We would appreciate comments on this concern and suggestions on how we might address this potential problem.

AmeriHealth Mercy Health Plan shares the concern that the risk adjustment methodology could systematically underpay plans with many low-income subsidy enrollees. As noted above, of the total allowed costs due to the increased utilization, a portion is reimbursed though increased cost sharing subsidies or increased reinsurance subsidies. The remaining portion is not reimbursed through any of the Part D direct subsidy, the reinsurance subsidy, the low-income premium subsidy, or the low income cost sharing subsidy. Because these costs are not reimbursed, MA-SNPs will need to build them into member premium. As a result, MA-SNPs like AmeriHealth Mercy Health Plan will be less competitive than plans without such low-income eligibles.

To address this issue, CMS could include in the risk adjuster a component that reflects both the extra utilization the dually eligible Medicare/Medicaid population reflects due to its inherent risk (if it bought the basic Part D plan) and the extra utilization because it will effectively receive a much richer $1/$3 copay plan. AmeriHealth Mercy Health Plan believes that this incremental adjustment would be beyond that reflected in the standard (to be determined) diagnosis-based risk adjuster. We believe that this solution would protect both MA-SNPs and other PDP or MA-PD plans that happen to enroll low-income members.

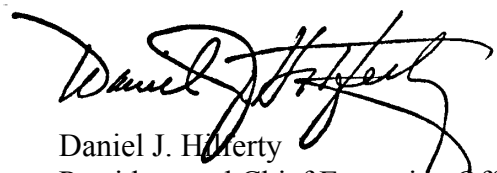
In addition to the increased costs associated with the greater utilization of services, we believe that the additional administrative expense involved in the increased utilization and the administration of the cost sharing subsidy is also unlikely to be included in:

- Standard PDP bids
- Reinsurance subsidies
- Low income premium subsidy
- Cost sharing subsidy

If so, it again would be in the member premium and put plans with LIS enrollees at a competitive disadvantage. This cost could be either a) added to a Medicaid/low income risk adjustment (as above), or b) added as a load onto the actual cost sharing reimbursement.

AmeriHealth Mercy Health Plan appreciates the opportunity to comment on these regulations. If you would like to discuss any of our comments, feel free to call me at (215) 937-8200.

Sincerely,



Daniel J. Hilferty
President and Chief Executive Officer

CMS-4068-P-1245

Submitter : Mrs. Stephanie Belling **Date & Time:** 10/04/2004 08:10:12

Organization : The Medicine Shoppe of LaCrosse, Wisconsin

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I am writing today in regards to the proposed Medicare Part D rules. As a pharmacist of the Medicine Shoppe Pharmacy located in LaCrosse, WI, I am greatly concerned about these proposed rules and the impact they will have on pharmacy services for our patients.

Please know that myself and all pharmacists want to see this Medicare Part D benefit work for all those involved. Unfortunately as past history will show, the private sector health plans have and continue to target pharmacies and pharmacy reimbursement in cost containment measures rather than teaming with pharmacy providers to enhance the quality and accessability to important health care services. We cannot continue to follow this path.

As a community pharmacist, I am concerned with three aspects of the Medicare Part D proposed rule and recommend that Centers for Medicare and Medicaid Services enable the following three policies:

1) Medicare recipients must be able to choose their own pharmacies.
It is critical that plan sponsors make every effort to include as many pharmacy providers as possible in the Part D benefit. Accessibility should be applied at a level no broader than a county to ensure all patients have ready access to the pharmacies in their community. Furthermore, plan sponsors must be required to provide pharmacy payment such that it at a minimum covers the average costs associated with dispensing prescription drugs. Private health plans often use their market force to drive down pharmacy reimbursement rates below a pharmacy's operational costs, thereby forcing pharmacy providers to shift costs to other business sectors. Medicare must now allow plan sponsors to continue this practice.

2) Implement measures to prohibit incentives designed to coerce recipients into choosing plans that exclude pharmacies.
Medicare patients should not be economically coerced into using one pharmacy over another unless the plan sponsor can justify quality reasons for a preferential pharmacy. Plan sponsors should be prohibited from providing economic incentives to recipients for using mail order pharmacies. Plan sponsors should also be prohibited from promoting pharmacies in which they have ownership interest.

3) Plan sponsors should be required to establish specified Medication Therapy Management services.
The Center for Medicare and Medicaid Services should require all plan sponsors to provide at least a specified set of medication therapy management services. Plan sponsors could provide additional MTM services, beyond the minimum required, but each must meet the CMS miminum requirements. Likewise, all plan sponsors should be directed to allow any pharmacist who receives an order for an MTM service to be able to provide that service.

All medicare eligible prescribers shoud be allowed to refer their patients in need of MTM services to a provider of such. At a minimum, each plan should be required to pay for MTM services ordered by such prescribers.

Plan sponsors should also have a plan in place to direct specifed patients, such as those with multiple chronic diseases and/or drug therapies, to MTM service providers. In turn, MTM service payment must be adequate to warrant provision of the necessary services provided by a pharmacist. As well, all pharmacists practicing within a region should be afforded the opportunity to provide MTM services.

In closing, I would like to express my appreciation for this opportunity to offer CMS my opinion of the rules being proposed for Medicare Part D benefit. I hope that my concerns and the concerns expressed by pharmacists locally and nationally are being considered.

Thank you for your time and consideration.

Sincerely,

Stephanie Belling, RPH
Wis Lic 12172
1585 Crestwood Ave
West Salem, WI 54669

CMS-4068-P-1246

Submitter : **Date & Time:** **10/04/2004 08:10:57**

Organization : **Option Care of East and Central Iowa**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

Please see comments in attached Word document.

CMS-4068-P-1246-Attach-1.doc

Option Care of East and Central Iowa is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Option Care of East and Central Iowa is a member of the national network of the Option Care home infusion companies and is located in Cedar Rapids, Iowa. We are an employee-owned company that has been specializing in this type of home care services for over 20 years. We are a member of the largest network of home infusion companies in the country. We are accredited by the Joint Commission and have earned a rather large market share in this state through clinical excellence and the resulting high patient satisfaction. We serve several hundred infusion patients on an on-going basis and have relationships with all government payers and most managed care organizations.

Option Care of East and Central Iowa appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

* Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm <http://www.nhianet.org/perdiemfinal.htm> .

* CMS should establish specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require specific standards for home infusion pharmacies under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the X12N 837 P billing format for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should mandate that prescription drug plans maintain open formularies for infusion drugs to ensure that this population of vulnerable

patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Shari Mailander, RN
Chief Operating Officer

Bryce Jackman, RPh
Director of Pharmacy

Option Care of East and Central Iowa
402 10th Street Ste 100
Cedar Rapdis, Iowa 52403

CMS-4068-P-1247

Submitter : **Date & Time:** **10/04/2004 08:10:41**

Organization : **Center on Budget and Policy Priorities**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

Please find attached our comments to the Medicare Prescription Drug Benefit proposed regulations (CMS-4068-P).

Sincerely,

Center on Budget and Policy Priorities
820 First Street, N.E., Suite 510
Washington, D.C. 20002
(202) 408-1080

CMS-4068-P-1247-Attach-1.doc

CENTER ON BUDGET AND POLICY PRIORITIES

820 First Street, NE, Suite 510, Washington, DC 20002
Tel: 202-408-1080 Fax: 202-408-1056 center@cbpp.org www.cbpp.org

October 4, 2004

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Subject: Comments on Medicare Prescription Drug Benefit Proposed Rule
(*69 Fed. Reg. 46632-46863,* August 3, 2004)

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulations that implement the new Medicare Prescription Drug Benefit enacted in last year's Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Center on Budget and Policy Priorities is a non-profit policy organization that works at the federal and state levels on fiscal policy and public programs that affect low- and moderate-income families and individuals. Our comments here focus on the new Part D benefit as it will apply to low-income Medicare beneficiaries including those who are dually eligible for both Medicare and Medicaid.

One key issue that we believe has not received appropriate attention in the proposed regulations is the historic opportunity the new drug benefit offers in improving enrollment in various public programs such as food stamps for which many low-income elderly and disabled beneficiaries are eligible. We believe that it is important that the regulation ensures that eligible beneficiaries are connected to other benefits for which they are likely to be eligible. We recognize that one agency, the Centers for Medicare & Medicaid Services (CMS) is promulgating this regulation and that the regulation relates to programs under its purview. But, in addition to Medicare, full Medicaid, and the Medicare Savings Programs for which CMS is responsible, other programs like food stamps, SSI and Social Security are the linchpins of federal support for the members of our society who are aging or experience a disability. This low-income Medicare population cannot be expected to navigate overly complicated enrollment procedures. To the extent that the government as a whole fails to coordinate these benefits, it is failing a very vulnerable population.

In addition, as noted by numerous other groups concerned with the dual eligibles and low-income Medicare beneficiaries, we find that the regulation falls short in many other areas especially in transitioning the dual eligibles from Medicaid drug coverage to the new Medicare drug benefit, ensuring that dual eligibles have access to the drugs they need, and in the processes that are envisioned for enrolling low-income beneficiaries in the low-income subsidies.

Please find below our general comments to the proposed regulations on these issues. Please note that we have also submitted more comprehensive comments along with other groups. These comments were submitted by Families USA.

Sincerely,

Robert Greenstein Executive Director	Edwin Park Senior Health Policy Analyst	Dorothy Rosenbaum Senior Policy Analyst

cc: Eric M. Bost, Under Secretary for Food, Nutrition, and Consumer Services, U.S. Department of Agriculture

Jo Anne B. Barnhart, Commissioner, Social Security Administration

I. General Comments on Improved Coordination with Other Programs Like Food Stamps

A. Background

Many Medicare beneficiaries who are eligible for a low-income subsidy under the Medicare Part D benefit will also be eligible for food stamps. The MMA and the proposed rule provide that applications for the Part D low-income subsidy may be filed with either a State's Medicaid program or with the Social Security Administration (SSA). The proposed rule has very little detail, however, about how the application process is likely to work. Because so many people who are eligible for but not participating in food stamps are likely to apply for the Part D subsidy, this application process presents an historic opportunity to connect eligible seniors and people with disabilities to the Food Stamp Program.

Many Medicare Beneficiaries Who Are Eligible for Part D Subsidies Also Are Eligible for Food Stamps

Many of the low-income Medicare beneficiaries who will be eligible for — and apply for — the new low-income drug subsidies that the prescription drug law provides are eligible for food stamps but not enrolled. A Medicare beneficiary will be eligible for some additional subsidy under Part D if his or her income, together with the income of any spouse who is present, is below 135 percent of the federal poverty level. The asset limit for the Part D low-income subsidy will be $6,000 for single beneficiaries and $9,000 for married couples. (Those with incomes below 150 percent of the poverty line with assets below $10,000 for individuals and $20,000 for couples receive a smaller low-income subsidy).

Food stamp eligibility rules are very similar — the universe of food stamp-eligible Medicare beneficiaries is a subset of the Part D-eligible population. Specifically, to be eligible for food stamps a household must have *net* income, after all available deductions are taken into account, below the federal poverty level and assets, not including a primary residence, personal items, and an automobile in most states, must be below $3,000.

Deductions play an important role in food stamp eligibility and benefit levels by taking into account certain household expenses in determining the amount of income that is available to purchase food. In practice, this means that a Medicare beneficiary could have gross income somewhat above the poverty level and still be eligible for food stamps. For the elderly and people with disabilities, the most important deductions are: a *medical expense deduction* for out-of-pocket medical expenses greater than $35 a month; a *dependent care deduction*, for expenses of up to $175 a month for adults who need care; and a *shelter deduction*, for households that have high shelter costs (including mortgage, rent, taxes, insurance, and utility expenses) in relation to their income.

The primary difference between the Part D subsidy eligibility and food stamp eligibility is the definition of who is considered in the family unit. For the Part D subsidy, only the Medicare beneficiary and his or her spouse, if present, will be considered unless there are related dependents who rely on the individual or his or her spouse for at least one-half of their financial support. For food stamps a household consists of individuals who live together and who purchase and prepare meals together. So in some instances where Medicare beneficiaries live

with others, the food stamp unit will include more people than the Part D family unit. USDA finds, however, that about half of elderly people who are eligible for food stamps but do not participate live alone, so in many cases there will be no difference.

Seniors and People With Disabilities Have Low Food Stamp Participation Rates, Despite Being Eligible for Sizable Benefits

Very low-income elderly and individuals with disabilities — those with annual incomes below about 75 percent of the poverty line (which is $6,788 for an individual and $8,554 for a couple) — are fairly well connected to the safety net; they are generally eligible for cash assistance under the Supplemental Security Income (SSI) Program and health coverage under Medicaid. The majority of these very low-income individuals do participate in food stamps.

But low-income elderly and individuals with disabilities with incomes above this level — including many such people who live below the poverty line — generally do not qualify for SSI or Medicaid, and although they are eligible for food stamps, they often are not enrolled. Overall, the program serves only about a quarter of eligible elderly people and just under half of the population of eligible adults with disabilities. In total, USDA estimates that there are over 6 million seniors and adults with disabilities who are eligible for food stamps but do not receive them.[1] Of course, Medicare beneficiaries who are not receiving SSI or Medicaid are the people who will be applying for the Part D benefit through SSA or state or local offices.

For many low-income Medicare beneficiaries, Social Security benefits bring them close to or modestly above the poverty line. For such households who do not have high expenses — for example, because they live in public housing and have no out-of-pocket medical costs — the food stamp benefit for which they qualify can be relatively low, perhaps only $10 a month. If, however, such a household has high shelter expenses, out-of-pocket medical expenses, or dependent care expenses, its monthly food stamp benefit will be significantly higher. The average Social Security recipient who has medical expenses and receives food stamps qualifies for about $50 a month in benefits. A typical household with members who are elderly or disabled and very high deductions can receive close to $90 a month or more in food stamps. Outreach messages that SSA or states use may be more useful if they explain that households with high expenses will qualify for more food stamps.

Current Responsibilities of SSA and States Make Them Appropriate to Play a Role in Enrolling Medicare Beneficiaries in Food Stamps

The states and SSA each currently have responsibilities related to the Food Stamp Program. Although food stamp benefits are 100 percent federally-funded and many of the program's eligibility and benefit rules are set by federal rules, the states have primary responsibility for virtually all aspects of the administration of the program (as they do with Medicaid), including outreach, certification and enrollment, issuance, and on-going case management. States receive a 50 percent federal match for administrative costs related to food

[1] For the Food Stamp Program an individual is considered to be elderly upon turning 60. So this figure somewhat overstates the number who would also be Medicare beneficiaries.

stamps. With only a handful of exceptions, the same local agency or local office that processes Medicaid applications also determines food stamp eligibility.

The Food Stamp Act envisions that SSA will play an important role in informing seniors and people with disabilities about food stamps. Under section 11(j)(1) of the Food Stamp Act, Social Security and SSI applicants and recipients are to be "informed of the availability of a simple application to participate in [the food stamp] program at the social security office." Section 11(j)(2) of the Food Stamp Act further requires SSA to "forward immediately" to state agencies food stamp applications from households where all members are applicants for or receive SSI. Finally, section 11(j)(2)(C) provides that the Secretary of Agriculture will reimburse the Commissioner of Social Security for any costs associated with these activities. To be clear, this means that food stamps, an entitlement with open-ended funding, can fully reimburse SSA for these food stamp-related activities without Congress needing to appropriate additional funds. (See 7 U.S.C. § 2020(j) — attached.)

Unfortunately, to our knowledge, SSA and USDA are largely out of compliance with Section 11(j)(2) of the Food Stamp Act. There is no uniform simple application currently available at social security offices for applicants or recipients to use to apply for food stamps. Not many social security offices make much effort to inform Social Security or SSI applicants about the availability of food stamps. Nationwide, the total amount that SSA received from USDA for these activities was less than $10 million in fiscal year 2003.

One promising exception is the "Combined Application Projects," or CAPs, that have been implemented in four states (Mississippi, New York, South Carolina, and Washington) in the past decade. In the CAP states, for SSI applicants who live alone, SSA provides a shortened food stamp application form with just a couple of additional questions to what the SSI application gathers. Data from the SSA application and interview are transferred to the food stamp agency, and food stamp benefits are determined without the applicant having to take any further action. (See http://www.fns.usda.gov/fsp/government/caps.pdf.) SSA has agreed to allow three additional states (Florida, Massachusetts, and Pennsylvania) to adopt this model but has declined to make the option available nationwide.

B. Comments on Subpart P Section 423.774 and Subpart S Section 423.904

The Part D enrollment process offers an historic opportunity to connect Medicare beneficiaries to food stamps and other assistance programs that might help them make ends meet. We urge you in the final regulation, and through other implementation decisions, to set up an eligibility process for the Part D low-income subsidy that allows low-income Medicare beneficiaries to be enrolled as seamlessly as possible in food stamps, as well as other state- or SSA-administered benefits for which they may qualify. This will require CMS to work collaboratively with SSA, USDA, and state agencies. Below are some specific opportunities that we see.

- **Provide information about food stamps and other major benefits for which applicants may be eligible in any outreach materials that CMS, SSA, and state Medicaid programs design and distribute.** CMS and SSA are planning

large-scale information and outreach efforts in the lead-up to the Medicare drug benefit going into effect. Mailings, on-line resources, and other materials that are made available to low-income Medicare beneficiaries and to groups that work with such beneficiaries could easily include information about the availability of food stamps and how to apply. USDA has developed an on-line prescreening tool at http://209.48.219.49/fns/.

- **Design procedures that allow applications that are filed and other information that applicants provide to be shared between SSA, state agencies, and CMS so that it is available to all agencies.** Such data sharing would allow states to target follow-up outreach to applicants who appear to be eligible for other programs, such as food stamps. For example, states could use the information that applicants provide to them or SSA for the drug benefit to automatically fill out significant sections of a food stamp application. The state could then mail the application to the elderly individual asking him or her simply to fill in the remaining questions and mail the application back, without having to come to the food stamp office.

- **Collaborate with other federal agencies, primarily USDA and SSA, on ways to enroll eligible applicants in all benefit programs.** The three agencies should seek to simplify federal program rules so that low-income Medicare beneficiaries can readily access all programs for which they qualify. A model may be the SSA Combined Application Projects that now operate in a handful of states, where SSI applicants are asked only a couple of additional questions and are certified automatically for food stamps based on their SSI applications. The standardized federal rules under these projects have allowed SSI applicants who live alone to apply for food stamps with significantly less burden than would otherwise be required.

- **Develop coordinated redetermination processes that are as simple as possible for Medicare beneficiaries.** Under the regulation, CMS seems to envision that once the Part D benefit is underway, Medicare beneficiaries will have their eligibility redetermined annually. It appears that a beneficiary who receives a Part D subsidy, is a QMB, and also receives food stamps would have to reapply separately for these three benefits at different times and would potentially have to provide virtually all of the same information to three different entities. This is an unreasonable burden for a poor senior or individual with a disability who may find it difficult and confusing to navigate three separate processes. In addition, this population tends to have relatively stable income and other circumstances. One option would be for SSA and state agencies to renew Part D eligibility based on information the beneficiary has provided for other programs, such as food stamps, if it is current. Many states have successfully used this type of “passive renewal” procedure in their Medicaid and State Children’s Health Insurance Programs (SCHIP).

- **USDA can reimburse SSA for the food stamp program's share of any costs associated with efforts to inform Social Security recipients of the availability of food stamps and other programs.** This could include, for example, outreach mailings to Medicare beneficiaries or costs associated with making computerized information available to states.

II. General Comments on Other Proposed Regulations

A. Comments on Subpart B — Eligibility and Enrollment

Enrollment of Dual Eligibles in Medicare Part D Plans

The proposed regulations fail to address adequately how responsibility for providing drug coverage for the 6.4 million Medicare beneficiaries with full Medicaid coverage (i.e., the full dual eligibles) will be appropriately transferred from Medicaid to Medicare on January 1, 2006. There are issues both of timing and of the mechanics of instituting the enrollment process. The proposed regulations do not adequately address these issues in a way that would ensure that these 6.4 million dually eligible beneficiaries avoid a potential loss of drug benefits or a gap in drug coverage, either of which could have unfortunate health consequences for these individuals.

According to the preamble, automatic enrollment of dual eligibles as required under section 423.34(d) will not begin until the end of the initial enrollment period on May 15, 2006. However, the Medicaid drug benefit for dual eligibles will no longer be available on January 1, 2006. (Federal Medicaid matching funds will no longer be available for providing outpatient drug coverage to the dual eligibles after January 1, 2006.) Given the difficulty of appropriately educating this population about Part D plan choices, it is a near certainty that a substantial number of dual eligibles will face a several month gap in coverage between the end of Medicaid's drug benefit and the scheduled automatic enrollment. This likely scenario would directly contravene Members of Congress' and the Administration's commitment that dual eligibles will be better off under Medicare Part D (or at least not be made worse off). The most appropriate solution would be to delay the cut-off of federal Medicaid matching funds to allow more adequate time to ensure an effective transition of the dual eligibles from Medicaid to the new Medicare Part D benefit. However, that would likely require statutory changes to the MMA. At the very least, CMS needs to encourage large-scale education efforts targeted to the dual eligibles by states and other organizations and allow for an earlier auto-enrollment deadline prior to January 1, 2006 to avoid gaps in coverage for the dual eligibles.

In the preamble, CMS requests comments on whether CMS or the states should perform automatic enrollment of dual eligibles. State officials are familiar with the needs of their dual eligible populations and have more data readily available on the dual eligibles in their state. They also will already be involved in the enrollment process because they are required to perform low-income subsidy enrollment; therefore, we recommend that states have the option of performing automatic enrollment. (We are concerned that under section 1860D-1(b)(1)(C) of the MMA and section 423.34(d)((2) of the proposed regulations, the auto enrollment must be conducted on a random basis, which may limit the ability of states that are conducting this auto

enrollment from moving dual eligibles to the plan that provides the greatest access to drugs. This too may require further statutory changes)

We are also extremely concerned with ensuring continuity of care for dual eligibles who have substantial drug needs. As discussed below in our comments on the need for special open formularies for the dual eligible population, for example, a disproportionate number of dual eligibles struggle with mental illness and need access to a wide variety of medications.

As outlined in the proposed regulations, dual eligibles would be forced to enroll (or be automatically enrolled) in the "benchmark" or average cost plans in their areas because, under the low-income subsidy, they will receive only a premium subsidy up to the cost of the premium for these plans. They will not receive additional premium subsidies for plans with premiums higher than the premium cost of a benchmark plan. The formularies for these plans, however, may not be as comprehensive as the drug coverage that these individuals currently have through Medicaid.

Without access to the coverage they need, dual eligibles may be forced to switch medications. In the treatment of HIV/AIDS, for example, such switches can be highly problematic and potentially deadly. We believe the same is true for a number of other illnesses and categories. Not ensuring continuity of care for prescription drugs for the dual eligibles could increase the costs of their care; dual eligibles with restricted access to drugs could end up requiring expensive services like hospitalization.

The regulations do provide a special enrollment period for full dual eligibles to use "at any time" (section 423.36). However, this provision of the regulations does not adequately address the needs of dual eligibles. There may not be adequate choice of low-cost drug plans in each region, particularly in rural areas which have not had much luck attracting Medicare managed care plans in the past. In addition, the dual eligibles are unlikely to have income or resources to pay the additional premiums (in addition to the low-income subsidy) necessary to enroll in higher cost plans that may have more comprehensive drug coverage and greater access to drugs. Moreover, the special enrollment provisions under section 423.36 do not specify that dual eligibles would not be subject to a late enrollment fee if this complex process of disenrollment and reenrollment results in a gap in coverage of more than 63 days.

In addition, full benefit dual eligibles (and their personal representatives) should receive a notice explaining their right to a special enrollment period both when they enroll in a plan and each time the prescription drug plan changes its coverage in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

In the preamble to the proposed regulations, CMS points to the exceptions process as a means of securing coverage of off-formulary medications. But the process proposed is extremely complex and will likely be impossible to navigate for people having a psychiatric crisis, facing cognitive impairments, or in the midst of aggressive chemotherapy, to list just a few examples. Moreover, the timelines established are drawn out; an expedited determination could

take as long as two weeks. Drug plans are not required to provide an emergency supply of medications until at least two weeks following a request.

Congress and the Administration have promised that dual eligible beneficiaries would be better off with this new Part D drug benefit (or at least no worse off) than they were receiving drug coverage through Medicaid. To honor this commitment, coverage of medications currently available to dual eligibles and other special populations under Medicaid must be grandfathered into the new Part D benefit just as a number of states (such as Wisconsin, Oregon, Kentucky, Texas and California) have done in implementing preferred drug lists under their Medicaid programs. For dual eligibles (and for others with life-threatening diseases such as HIV/AIDS, mental illness, cancers, and other extreme conditions), Part D plans should be required to cover their existing medications. At a minimum, this protection should be given to dual eligibles, because it is likely to be impossible for dual eligibles to enroll in more generous drug plans by paying supplemental premiums or paying for off-formulary drugs on an out-of-pocket basis.

B. Comments on Subpart C —Benefits and Beneficiary Protections

Special Formulary Protections for Dual Eligibles

Section 423.120(b) outlines the requirements on Part D prescription drug plans and on Medicare Advantage plans for their drug formularies. We strongly support the suggestion in the preamble to the proposed rule that certain populations require special treatment due to their unique medical needs. Such populations include full dual eligibles as well as institutionalized populations, persons with life-threatening conditions, and persons with pharmacologically complex conditions. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and must be protected from tiered cost-sharing that could create insurmountable access barriers. We recommend that the final rule provide for alternative, flexible formularies for special populations that include coverage for all FDA-approved covered Part D drugs with a valid prescription. Furthermore, because of the clinical importance of providing access to the specific drugs prescribed, drugs prescribed to these defined populations ought to be made available at the preferred level of cost-sharing for each drug.

In enacting the MMA, Members of Congress and the Administration committed to the principle that dual eligibles (persons eligible both for Medicare and Medicaid) would be better off (or at least not be made worse off) when their coverage for prescription drugs shifted from Medicaid to the new Medicare Part D coverage. Historically, the Medicaid prescription drug benefit has been closely tailored to the poor and generally sicker population it serves, providing beneficiaries with a range of drugs that they need with little or no co-payment. Under section 1927 of the Social Security Act, states that elect to provide prescription drug coverage under their Medicaid programs must cover all FDA-approved drugs from every manufacturer that has entered into an agreement with the Secretary of Health and Human Services to pay rebates to states for the products that the states cover. All drug manufacturers currently participate in the Medicaid rebate program.

Dual eligibles are the most vulnerable Medicare beneficiaries. Dual eligibles are people with disabilities and other serious conditions who tend to need a wide variety of prescription drugs. They are more than twice as likely to be in fair or poor health as other Medicare beneficiaries; they are three times more likely to have problems with Activities of Daily Living (ADLs) as other beneficiaries; and they are ten times more likely to be in a long-term care facility than other beneficiaries. In serving dual eligibles, Medicare prescription drug plans must be able to respond to a range of disabilities and conditions, such as physical impairments and limitations like blindness and spinal cord injury, debilitating psychiatric conditions, and other serious and disabling conditions such as Parkinson's disease and HIV/AIDS. If dual eligibles are not to be worse off when Part D prescription drug coverage begins, then they must have continued access to an alternative and flexible formulary that permits treating physicians to prescribe the full range of FDA-approved medications.

This will particularly be the case for many of the dual eligibles who reside in nursing facilities and other residential facilities. Such institutionalized beneficiaries require access to flexible formularies on the basis of their complex and multiple prescription drug needs.

Moreover, although we recommend that any alternative formulary include access to all FDA-approved medications, if the final rule permits a more restrictive alternative formulary, it should ensure that all drugs included on the formulary of participating Long-Term Care (LTC) pharmacies are included in the plan's formulary, and drugs that are preferred by the LTC pharmacies' formularies should be treated by the plan as a preferred drug. Institutionalized individuals also have little or no capacity to pay cost-sharing for non-preferred drugs or to purchase drugs for which coverage has been denied. It is imperative that any alternative formulary provide strong protections that prevent such individuals from being charged cost-sharing. For dual eligibles who reside in institutions, a condition of eligibility requires them to pledge all but a nominal personal needs allowance, usually $30 per month, to the cost of the institutional care. (We note that individuals who require an institutional level of care but live in the community under home- and community-based Medicaid waivers should have the same special protections as institutionalized beneficiaries because of their similar substantial need for prescription drugs. Otherwise, providing greater access to drugs for institutionalized individuals than to those living in the community would have the adverse effect of reversing the continued progress states have made in moving people from nursing homes to the community setting.)

C. Comments on Subpart P — Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Automatic Eligibility and Enrollment of Dual Eligibles for Low-Income Subsidy

Section 423.773 of the proposed regulations states that both full benefit dual eligibles (as well as Medicare Savings Program beneficiaries, as discussed below) are *eligible* for the additional low income subsidies, but it does not explicitly state that these beneficiaries are to be automatically *enrolled* in the subsidy program. The regulations should clarify that an individual treated as a full subsidy individual (such as a dual eligible or a MSP beneficiary) does not have to take any further action with respect to the subsidy (i.e., to make application or in any other to way verify their status), except to the extent that they need to enroll in a Part D plan. This will

help smooth the transition from Medicaid drug coverage for dual eligibles and should improve participation for others.

Treatment of Resources

Under section 423.772, we support the proposed regulation's limitation of countable resources to liquid assets only. However, the definitions of liquid assets and what it means for an asset to be able to be converted into cash in 20 days need to be clarified. The final rule should enumerate the list of countable resources that constitute liquid assets to promote clarity for states and beneficiaries. The scope of countable liquid assets should be construed narrowly, as experience under the MSP programs shows that assets tests tend to discourage enrollment and raise administrative costs for states. Experience among the states with MSPs has shown that when states waive the assets test or make it more reasonable by excluding, for example, burial plots, burial funds and life insurance from the list of countable assets, enrollment in MSP increases, with the additional costs of enrollment at least partly offset by administrative savings.

Moreover, it is harsh and inappropriate to deny an applicant the low-income drug benefit because the applicant will not liquidate a life insurance policy or burial fund. We are especially troubled by an SSA draft of the application for the low-income subsidy that asks whether an applicant has life insurance with a face value of $1,500 or more. Such a policy should not be acceptable; low-income elderly people and people with disabilities should not be disqualified from the low-income drug benefit because they have a modest life insurance policy that is intended to cover their funeral and burial costs when they die. The Food Stamp Program, for example, entirely excludes the value of a life insurance policy from its asset test. At most, the only part of a life insurance policy that should be considered is the cash surrender value to the extent that the value exceeds some much more reasonable amount, such as $20,000.

In addition, retirement accounts such as a 401(k) plan or IRA should either be fully exempt for all beneficiaries, or fully exempt for disabled Medicare beneficiaries up to age 65, with an assumed annuity value, based on the account, considered as income for all beneficiaries aged 65 and over. If calculating an annuity value would be too complicated, a simplified approach could be used, under which a fixed percentage of such an account is treated as income each year, based on Census (or other official) life expectancy tables. In other words, if a person aged 65 is assumed to live 20 years based on the life expectancy tables, five percent of the amount in the individual's 401 (k) or IRA would be counted as income each year. These accounts would *not* be counted as assets.

This is a much fairer and more rational approach. To count such accounts as assets and disqualify people with modest account balances would undercut efforts to encourage low- and moderate-income people to build some savings that can ease their poverty throughout their old age. Counting these accounts as assets for disabled beneficiaries who are below retirement age also may reduce work incentives. If such accounts are counted as assets, such individuals may be forced to liquidate modest retirement accounts. It would be far better to preserve such accounts so that the prospect of enlarging them if an individual with a disability can return to work may operate as a work incentive.

Counting the amounts in such accounts as assets is inappropriate. Such accounts are supposed to help support these people throughout their old age. Counting such accounts as assets implies that the accounts should be emptied out now to help pay for prescriptions, with the individual then left deeper in poverty for the rest of his or her life.

(Finally, we would note that the draft SSA application contains a problematic and confusing treatment of "annuities," which the application says should be treated as an asset rather than as income. The term "annuity" is popularly used for a range of financial instruments, including "life-time annuities." And an individual with a life-time annuity *no longer owns the underlying assets*. Such an individual has essentially sold the assets to the annuity company in return for a stream of income in the form of a guaranteed monthly payment for the rest of the individual's life. In these cases, it is wholly inappropriate to count the value of the underlying assets against the asset test; the individual no longer owns the assets and has no legal access to them. Furthermore, in these cases, the monthly payments that such an individual receives from the annuity company clearly ought to be counted as income. The draft SSA application is likely to lead to confusion and erroneous determinations in this area.)

Treatment of MSP Beneficiaries by SSA

We strongly support the decision reflected in section 423.773(c) to deem Medicare Savings Program ("MSP") beneficiaries automatically eligible for the low-income subsidy. This would greatly ease the administrative burden on states and SSA while also ensuring that many more MSP beneficiaries enroll in the low-income subsidy.

We are concerned, however, that MSP beneficiaries are likely to be treated differently depending on whether they apply for the low-income subsidy through Medicaid or through a SSA office. Inequities and confusion among beneficiaries may result because SSA would apply its standard for assets which may be less generous than the asset eligibility rules for MSPs in place in some states. For example, Alabama, Arizona, Delaware, and Mississippi have eliminated the assets test under the MSP programs. Eligibility requirements for the low-income subsidy should be as generous at the SSA office for subsidy-eligible individuals as at a Medicaid office, regardless of where and how people apply within the same state. Under the proposed rules, in states that have adopted less restrictive asset methodologies, people whose assets are slightly above the limits set in section 423.773 would likely be enrolled in a less generous subsidy, or have their application rejected entirely, if they apply directly through SSA, because SSA will apply the national guidelines proposed in section 423.773. However, the same people would have their application accepted if they applied through their states' Medicaid offices, were screened and then enrolled in an MSP, and were then automatically eligible for the low-income subsidy.

To resolve this problem, we propose that SSA should apply state-specific asset eligibility rules in determining eligibility for the low-income subsidy when they are more generous than under the national standard, an option discussed, though rejected, in the preamble at page 46,727. This means that for applicants from states that have eliminated the asset test or have more generous disregards under section 1902(r)(2) of the Social Security Act for MSP eligibility, SSA should apply the state's more generous rules to determine eligibility if applicable. This option is

permitted under Section 1860D-14(a)(3)(E)(iv) of the statute. (We note that the statute should be amended to allow SSA to also apply state-specific income eligibility rules when they are more generous as well.)

The regulations should also provide that subsidy applicants who appear to have excess assets *or* incomes either be screened by SSA for eligibility in an MSP program or have their applications forwarded to the state Medicaid agency to be screened for MSP eligibility. States would be precluded from requiring beneficiaries to resubmit information, such as income and asset levels, that they have already provided to SSA. Applicants would be enrolled in the appropriate MSP program, be deemed automatically eligible for the low-income subsidy under section 423.773(c) and then be enrolled in the appropriate low-income subsidy. Adopting this policy, which is not precluded by the statute, will ensure that all subsidy applicants are treated equitably and in a manner most favorable to the applicants, as well as increase participation in MSPs.

As part of this policy, the low-income subsidy application should allow an applicant to opt out of screening and enrollment for an MSP, as it is possible that a few applicants may not wish to participate in an MSP. Under Section 1860D-14(a)(3)(v)(II) of the statute, beneficiaries who are determined eligible for MSPs may be enrolled in the low-income subsidy. There is no requirement that beneficiaries actually enroll in an MSP. Therefore, applicants who meet the eligibility requirements for an MSP but who decline to enroll in the program should still be made automatically eligible for the low-income subsidy.

Because enrollment in an MSP can affect the amount of assistance a beneficiary may receive through other public assistance program, such as Section 8 housing vouchers or food stamps, there will be a profound need for beneficiary counseling during the enrollment process. We recommend that CMS plan for this need by making funds available to local agencies, including state health insurance assistance programs (SHIPs) and other community-based organizations.

In addition, we suggest that states not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective but can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP. We include the same suggestion in our comments to section 423.904(c) discussed below.

D. Comments on Subpart S — Special Rules for States — Eligibility Determinations for Subsidies and General Payment Provisions

State Medicaid Screening for Medicare Savings Programs

We believe that section 423.904(c) of the proposed regulations regarding states' obligations to screen subsidy applicants and offer them enrollment in MSPs is inadequate. In particular, proposed section 423.904(c)(2) should specify what "offer enrollment" means. We believe an applicant must be offered the opportunity to enroll during the same visit or contact (in office, by phone, or by mail), without providing further documentation or completing additional

forms. Only if enrollment is easy and convenient would Congress's intent of increasing participation in MSPs be accomplished. Furthermore, because enrollment in an MSP may be the only entry into the subsidy for some low-income beneficiaries, a simple and easy application for MSP programs is essential.

As written, section 423.904(c) would permit states to say they have "offered enrollment" if they tell applicants that they might be eligible for an MSP and can return another time to complete another application form if they wish to apply. Such an outcome would defeat the purpose of the screen-and-enroll provision included in the new Section 1935(a)(3) of the Social Security Act that was established in Section 103(a) of the statute. The low-income subsidy application should include an "opt-out" provision, under which qualified applicants would be enrolled in an MSP unless they affirmatively decline to do so. This provision would make enrollment in an MSP another way to qualify for the low-income subsidy.

Moreover, it is critical that state Medicaid offices provide good quality counseling to applicants, including their potential eligibility for other benefits such as MSPs. In addition, to ensure that enrollment requirements between MSPs and the low-income subsidy are aligned, states should not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective and can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP.

In the interest of further aligning eligibility rules for MSPs and the low-income subsidy and easing administrative burdens, we suggest that CMS should direct states to apply the definitions of resources used in Subpart P, section 423.772, if they are more generous than the MSP standards used in the individual state, in making their resource determinations for MSP applicants.

In addition, should CMS adopt a policy, as has been discussed publicly, under which most subsidy applications to state Medicaid agencies would simply be forwarded to SSA for the actual eligibility determination for the low-income subsidy, the regulations should be clear that screening for MSP eligibility must take place prior to the transmittal of the applications to SSA. Potential beneficiaries should not have to wait to be screened and offered enrollment in MSPs until after SSA processes their low-income subsidy application and provides such information back to the state Medicaid offices (if SSA in fact does so). Furthermore, an individual cannot be told by either SSA or the state that she or he is ineligible for the low-income subsidy until MSP eligibility has been determined (if the individual wishes). It would be highly problematic for an individual to receive a notice from SSA that he or she is ineligible for the low-income subsidy, have her MSP eligibility determined by the state, and then receive a notice from the state that she is eligible for both MSP and the subsidy. Alternatively, the individual may be found ineligible for the low-income subsidy by SSA and subsequently enrolled in a MSP but never redetermined for eligibility for the low-income subsidy. Whatever the mechanics, the individual must be told that MSPs are a route to subsidy eligibility.

Finally, SSA should also screen subsidy applicants for eligibility in MSPs and develop a system with states to enroll eligible beneficiaries. SSA should use the income and resource

disregards used by the state for MSPs, if they are more generous than under the uniform national definition. Applicants should not miss out on the opportunity to enroll in MSPs simply because they apply through SSA rather than state Medicaid offices. The same concerns about beneficiary education and estate recovery discussed above would apply to enrollment through SSA.

State Medicaid Screening and Enrollment for Full Medicaid

We believe that the regulations should also ensure that beneficiaries are screened not only for MSPs but also for eligibility for full Medicaid and offered enrollment if they qualify, consistent with 42 C.F.R. § 435.404. Ideally, all subsidy applicants would be screened for full Medicaid and offered enrollment if they qualify (similar to current screen-and-enroll procedures under the State Children's Health Insurance Program described in 42 C.F.R. § 457.350, and in particular for states that use separate SCHIP applications as described in 42 C.F.R. § 457.350(f)(3)). Because the importance of maintaining a simple application process for the low-income subsidy is paramount, CMS may wish to consider using a simple screening process based on information obtained through the subsidy application. This screening would trigger a follow-up with applicants who appear to be eligible for full Medicaid.

ATTACHMENT
Food Stamp Act [7 U.S.C. § 2020(j)] on SSA's responsibilities

Section 11(j) of the Food Stamp Act:

(1) Any individual who is an applicant for or recipient of supplemental security income or social security benefits (under regulations prescribed by the Secretary in conjunction with the Commissioner of Social Security) shall be informed of the availability of benefits under the food stamp program and informed of the availability of a simple application to participate in such program at the social security office.
(2) The Secretary and the Commissioner of Social Security shall revise the memorandum of understanding in effect on the date of enactment of the Food Security Act of 1985, regarding services to be provided in social security offices under this subsection and subsection (i), in a manner to ensure that—
(A) applicants for and recipients of social security benefits are adequately notified in social security offices that assistance may be available to them under this Act;
(B) applications for assistance under this Act from households in which all members are applicants for or recipients of supplemental security income will be forwarded immediately to the State agency in an efficient and timely manner; and
(C) the Commissioner of Social Security receives from the Secretary reimbursement for costs incurred to provide such services.

CMS-4068-P-1248

Submitter : Mr. Steve Roling **Date & Time:** 10/04/2004 08:10:43

Organization : Missouri Department of Social Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the Medicare Part D proposed rules. The Medicare Drug Program is a very complex program with significant ramifications for a large number of vulnerable Missourians. The Missouri Department of Social Services (DSS) urges the Centers for Medicare and Medicaid Services (CMS) issue the next version of these regulations in a format that will allow one more round of comment, even if it is a shortened comment period. We are concerned that failure to provide for additional public input when the regulation is more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

CMS-4068-P-1248-Attach-1.doc

MISSOURI
DEPARTMENT OF SOCIAL SERVICES

BOB HOLDEN
GOVERNOR

Steve Roling
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October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244–8014

Attention: CMS–4068–P

Thank you for the opportunity to comment on the Medicare Part D proposed rules. The Medicare Drug Program is a very complex program with significant ramifications for a large number of vulnerable Missourians. The Missouri Department of Social Services (DSS) urges the Centers for Medicare and Medicaid Services (CMS) issue the next version of these regulations in a format that will allow one more round of comment, even if it is a shortened comment period. We are concerned that failure to provide for additional public input when the regulation is more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

Enrollment Process

General

Missouri is concerned that the under the proposed Medicare Part D rule automatic enrollment of full benefit dual eligibles might not occur until May 15, 2006. This would cause dual eligibles active on January 1, 2006 who do not voluntarily enroll in Medicare Part D to go as long as five and a half months without prescription drug coverage. Many of the individuals who have been long time Medicaid recipients may be confused by the voluntary enrollment process and fail to enroll by January 1, 2006. Medicare's experience with the drug discount card has demonstrated that vulnerable populations often will not enroll on their own initiative in a program such as the Part D benefit, despite the advantages of the benefit being offered. Leaving dual eligibles with no coverage seems in conflict with the purpose of the Medicare Modernization Act (MMA). Automatically enrolling the full benefit dual eligibles prior to January 1, 2006 would not allow much opportunity to select a plan; however, this is preferable to having no coverage. Intermittent eligibility in Medicaid programs may further

complicate the transition to Part D and disrupt access to prescription drugs. Unique Medicaid "spenddown" or "medically needy" programs operate in 39 states. These programs allow people with high medical costs, including nursing home residents, to qualify for Medicaid by spending their income and resources down to a state-defined medical assistance eligibility level. In many cases, an individual may begin a month with a pension check or other source of income that makes them ineligible for Medicaid for the first part of the month, but once that income is put toward the cost of their care (that is, spent down), they become eligible for the remainder of the month. Depending on the spenddown period designed by the state, individuals can cycle on and off of Medicaid eligibility on as often as a monthly basis. This intermittent eligibility will significantly complicate the initial education and enrollment process and must be factored into continuing administrative and policy decisions for states, the federal government, and providers of prescription drug benefits.

Accordingly, Missouri seeks amendment to both §423.34(b) and §423.42(a) in order to clarify that a state may assist an individual with completion of the individual's Private Prescription Drug Plan (PDP) application, including executing the application on the individual's behalf, or may otherwise assist an individual in the Part D enrollment process as long as the individual is provided an opportunity to decline this assistance or "opt out" of any available PDP. Another option CMS should consider is allowing full benefit dual eligibles not enrolled in Part D to continue to receive prescription drug coverage under Medicaid with Federal Financial Participation (FFP) until the automatic enrollment date.

B. Eligibility and Enrollment (Federal Register page 46637)

2. Part D Enrollment Process (§423.34) (Federal Register page 46639)

CMS: *In implementing the automatic enrollment process for full benefit dual eligible individuals, we are considering which entity is best suited to perform the automatic and random enrollment function. We invite comment on the most appropriate method of performing automatic assignment of dual eligibles and the appropriate entity to do so.*

DSS Comments: The Missouri Department of Social Services believes automatic enrollment of full benefit dual eligibles can be handled most efficiently by the states if CMS is able to provide up-to-date information on persons currently enrolled in Medicare Part D. Having the states be responsible for performing the automatic enrollment would allow for the shortest period of time between the Medicaid approval and enrollment in Part D. DSS is concerned that the administrative cost of requiring the states to do the automatic enrollment would be an unfunded mandate. The preamble mentions compensating the states through FFP for administrative expenses or through contractual or other arrangements. Since the cost to develop a

system for automatic enrollment may be extensive, DSS feels states should receive more than the current administrative match for assuming this burden to meet this "new national workload of indeterminate size."

4. Effective Dates of Coverage and Change of Coverage (§423.38)

c. Special Enrollment Period (Federal Register page 46641)

CMS: *The rule states that for special enrollment periods, the effective date of the enrollment will be determined by CMS.*

DSS Comments: CMS should make the effective date of enrollment in Part D retroactive to the date the person's Medicaid was effective and they became a full benefit dual eligible. If the enrollment in Part D is not retroactive to the date Medicaid eligibility began, full benefit dual eligibles will have no prescription drug benefit during the prior quarter coverage. Longstanding Missouri statute requires that medical assistance (Medicaid) is only paid during such times as grants-in-aid (FFP) is provided or made available to the state.

Subpart P: Premiums and Cost-Sharing Subsidies for Low-Income Individuals (Federal Register page 46725)

2. Eligibility Determinations, Redeterminations and Applications (§423.774) (Federal Register pages 46727-46728)

CMS: *We invite comments on state Medicaid agency procedures how to best implement the determination, redetermination, and appeal process.*

DSS Comments: Section 1860D-14(a)(3)(B)(i) of the Act and the proposed 423.774 both say that determinations of eligibility for the subsidies are made by the state Medicaid agency or Social Security Administration (SSA). Our initial interpretation of this was that both agencies were required to make determinations and the Medicare recipient was free to choose which to apply with. However, it has come to our attention that SSA is proposing that the states can comply by taking applications and submitting them to SSA for the eligibility determination. This appears to conflict with Section 1935 of the Act and the proposed 423.904 that require the state Medicaid agency to make determinations of eligibility for the subsidies. If CMS believes that a state Medicaid agency can meet the requirements of both Sections 1860D-14(a)(3)(B)(i) and 1935 by taking applications and submitting them to SSA, that should be clarified in the regulations. The regulation should be clear on what obligation a state choosing this option has for keeping track of what applications were submitted and what happened to them.

The regulations do not specify the time standards within which an eligibility determination must be completed. Would the state Medicaid agency be required to complete determinations within 45 days as is required for most Medicaid eligibility determinations under 42 CFR 435.911? The regulations should specify a time standard that would apply to determinations made either by the state or SSA.

Subpart S: Special Rules for States – Eligibility Determinations for Low-Income Subsidies and General Payment Provisions (Federal Register page 46861)

CMS: *Each of the 50 states and the District of Columbia is required to provide for payment to the Secretary a phased-down contribution to defray a portion of the Medicare drug expenditures for individuals whose projected Medicaid drug coverage is assumed by Medicare Part D.*

DSS Comments: The regulations in Subpart S provide an overview of the clawback (phased-down state contribution) calculation, but it lacks the specifics for the states to estimate the clawback. The comments provided are based somewhat on information provided in conference calls attended by CMS.

The clawback is based on expenditures in calendar year 2003. The base year expenditures are trended based on National Health Expenditure (NHE) trends. The NHE trends are significantly higher than the actual increase experienced by the state. Therefore, the state will be paying a higher clawback and is further impacted since the state will continue to pay this "higher rate" for the life of the Medicare Modernization Act. Based on the last couple of years, it is also highly likely that the NHE trend will be higher than the trend experienced in Missouri Medicaid. This difference will also result in a higher clawback payment from the state.

The rebate adjustment factor is based on the pharmacy expenditures and rebates collected for the same period of time through the CMS-64 reports. When reporting these quarterly, the rebates will lag six months behind the expenditures due to the rebate process. The rebate adjustment factor artificially reduces the actual percent of rebate that is collected, which, in turn, results in a higher clawback that the state will be paying monthly to eternity. A more appropriate rebate adjustment factor would be the expenditures for calendar year 2003 and rebates collected for July 2003 – June 2004.

The clawback calculation apparently does not allow for adjustments. Missouri is a "Pay and Chase" state for pharmacy claims. Since there are no provisions for these collections in the clawback calculation, the gross per capita spent is artificially high, resulting in a higher clawback payment for Missouri. The clawback calculation also does not take into account that Medicaid recipients in calendar year 2003 were the beneficiaries of a drug

formulary that contained more drugs than they may have access to under a PDP. The clawback calculation does not allow adjustment for the more restrictive drug formulary.

Involuntary Disenrollment of Beneficiary by the PDPs (§423.44) Federal Register page 46641

CMS: *The proposed rule provides that PDPs may disenroll individuals whose behavior is disruptive.*

DSS Comments: The Department of Social Services has concerns regarding provisions in the proposed regulations to allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening." These provisions create enormous opportunities for discrimination against individuals with mental illnesses, Alzheimer's, and other cognitive conditions. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and as a result, they could also be subject to a late enrollment penalty, increasing their premiums for the rest of their lives. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage.

Under the MMA, section 1860D-1(b) directs the Secretary to establish a disenrollment process for PDPs using rules similar to a specific list of rules for the MA program. This list does not include reference to section 1851(g)(3)(B) of the Social Security Act which authorizes MA plans to disenroll beneficiaries for disruptive behavior.

Therefore, this provision regarding disenrollment of individuals by the PDP for disruptive behavior should be eliminated entirely or there should be a heightened standard for involuntary disenrollment of dual eligibles with mental health issues. There should also be expansion of the "special enrollment exceptions" for individuals disenrolled by a PDP (such as, for disruptive behavior) so that the individual will have an opportunity to join another PDP and continue with necessary medications. These "special enrollment exceptions" are necessary given the high risk of discrimination presented by the provisions for involuntary disenrollment. CMS should provide a special enrollment period for beneficiaries involuntarily disenrolled. It should include a reasonable time period for plan selection and be exempt from late enrollment penalties. Dual eligible beneficiaries who are involuntary disenrolled will face significant hardship because the Missouri Medicaid program will no longer be able to cover prescription drugs if there is no FFP.

Access to Covered Part D Drugs (§423.120) (Federal Register page 46655)

b. Formulary Requirements (Federal Register page 46659)

CMS: *To the extent that a PDP sponsored or MA organization uses a formulary to provide qualified prescription drug coverage to Part D enrollees, it would be required to meet the requirements of §423.120(b)(1) and section 1860D–4(b)(3)(A) of the Act to use a pharmaceutical and therapeutic (P&T) committee to develop and review that formulary. As a note of clarification, we interpret the requirement at section 1860D–4(b)(3)(A) of the Act that a formulary be ''developed and reviewed'' by a P&T committee as requiring that a P&T committee's decisions regarding the plan's formulary be binding on the plan. However, we request comments on this interpretation. In addition, it is our expectation that P&T committees will be involved in designing formulary tiers and any clinical programs implemented to encourage the use of preferred drugs (e.g., prior authorization, step therapy, generics programs).*

DSS Comments: Continuity of pharmaceutical treatment is of great importance to effective disease management and appropriate healthcare. As the proposed regulations themselves seem to acknowledge, PDP formularies must be developed with appropriate consideration of the point that – especially for older individuals – it is often therapeutically counter-productive, or even dangerous, to abruptly change medications. Accordingly, we believe that coordination of formulary development between State Pharmaceutical Assistance Programs (SPAP) and PDPs is especially important and should be expressly encouraged by the Part D rules.

As we understand the CMS proposal, CMS expects that the model categories and classes developed by United States Pharmacopeia (USP) will be defined so that each includes at least one drug that is approved by the Food and Drug Administration (FDA) for the indication(s) in the category or class. That is, no category or class would be created for which there is no FDA approved drug and which would therefore have to include a drug based on its "off label" indication. While DSS generally approves of the process being utilized by USP we point out an inherent flaw in the decision that, in some cases, only one drug approved in a given therapeutic class will be included in the formulary. In the case of many drugs that require lengthy periods to determine "stable" doses, abruptly changing a beneficiary's medicines in order to ensure reimbursement as a covered Part D drug could have serious consequences to that individual's health and welfare. Such negative outcomes are especially likely in the case of psychotropic compounds.

Moreover, we believe that any established formulary exceptions criteria must be flexible enough to take into account the actual circumstances of a particular beneficiary. The Secretary should provide a guideline to Medicare Advantage Prescription Drug (MA-PD) plans, as well as stand-alone

prescription drug plans, that requires such flexibility. In addition, anything less than a comprehensive formulary should be considered when calculating the state's "phase down/clawback" payment since Missouri had a non-scaled down formulary Missouri does not believe it should pay clawback/phase down for a more restricted drug formulary.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections (Federal Register page 46646)

1. Overview and Definitions (§423.100) (Federal Register page 46646)

c. Long-Term Care Facility (Federal Register page 46648)

CMS: *We request comments regarding our definition of the term long-term care facility in §423.100, which we have interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act, or a nursing facility, as defined in section 1919(a) of the Act. We are particularly interested in whether intermediate care facilities for the mentally retarded (ICF/MRs) or related conditions, described in §440.150, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. It is our understanding that there may be individuals residing in these facilities who are dually eligible for Medicaid and Medicare. Given that payment for covered Part D drugs formerly covered by Medicaid will shift to Part D of Medicare, individuals at these facilities will need to be assured access to covered Part D drugs. Our proposed definition limits our definition to skilled nursing and nursing facilities because it is our understanding that only those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies. However, to the extent that ICF/MRs and other types of facilities exclusively contract with long-term care pharmacies in a manner similar to skilled nursing and nursing facilities, we would consider modifying this definition.*

DSS Comments: As a result of the Olmstead decision, states have been moving seniors and persons with SSI benefits from institutions into less restrictive placements. These placements include ICF/MR facilities for the disabled, community care, and assisted living facilities for the aged. In addition to these less restrictive institutional settings, states have implemented waiver programs for home and community based care as an alternative to placement in a nursing home. Medicare beneficiaries spend down their assets until they are forced into nursing homes. These alternatives provide Medicare eligible beneficiaries with a choice of placement. Exclusive contracts with a long term care pharmacy should not be the deciding factor on whether or not to extend the definition of long term care facility to other forms of housing other than traditional nursing homes; the beneficiaries' qualification for Medicare and their placement should be the deciding factor. States can identify Medicare eligible individuals who were

institutionalized, and can also identify those individuals that, if it were not for the Olmstead decision or an 1115 waiver, would be institutionalized. These individuals are low income Medicare beneficiaries; having a Medicare prescription benefit at no cost will allow their income to be used for daily living expenses and not on prescriptions.

Therefore, we recommend that the final rule include a definition of "long-term care facility" that explicitly includes intermediate care facilities for persons with mental retardation and related conditions and assisted living facilities. We believe that many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

3. Establishment of Prescription Drug Plan Service Areas (§423.112) (Federal Register page 46655)

CMS: *We intend to initially designate both PDP and MA regions by January 1, 2005. In accordance with section 1858(a)(2)(C)(i) of the Act, there will be between 10 and 50 PDP regions within the 50 States and the District of Columbia and at least one PDP region covering the United States territories. The PDP regions, like the MA regions, will become operational in January 2006.*

DSS Comments: The State of Missouri believes that the establishment of PDP regions consistent with MA regions (as described in proposed §422.55) is of far less importance than establishing PDP regions that are defined by individual state boundaries. It is critical to a number of operational aspects of Part D benefits administration that each state should be a separate PDP region. As the proposed rule seems to acknowledge, existing SPAPs will play a critical role in coordinating benefits with the PDPs for the most vulnerable populations to be served under the Part D program, as well as in providing "wrap-around" coverage for beneficiaries within these populations. The administrative complexities and burden of effectuating these goals will be enormously – and unnecessarily – increased to the extent that the boundaries of PDP regions are not consistent with the state boundaries defining the relevant SPAP service areas.

6. Coordination of Benefits with Other Providers of Prescription Drug Coverage (Federal Register page 46700)

a. Coordination with SPAPs (State Pharmaceutical Assistance Programs) (Federal Register page 46701)

CMS: Our goal is to make the coordination of benefits process as functional for the beneficiary, pharmacy, and states as possible.

DSS Comments: SPAPs are prohibited from encouraging enrollees to join a particular PDP, and the law and regulatory language prohibits SPAPs

from discriminating based on the PDP in which the beneficiary is enrolled. The federal law does not prohibit a state from providing consumer advice to its citizens as to which plan might work best with a SPAP, which plan offers the best value, etc. Given the intense need for consumer assistance, we urge that the regulation either be silent on the issue or that the regulation actually encourage the states to help their citizens with the many difficult choices and questions they will be facing.

The proposed regulation portrays a much broader and very different non-discrimination rule than is contained in the statute, and is inconsistent with the express statutory language establishing limitations on that rule Under the statute's express language, a qualifying SPAP would quite plainly be permitted to encourage beneficiaries to enroll in a "preferred" PDP by any otherwise legal means that does not constitute disparate treatment of individuals in respect to determinations of eligibility for, or the amount of, assistance. In other words, while a Part D qualifying SPAP would be required to provide the same amount of "wrap-around" coverage to an individual in an alternative plan as would be provided to the individual if enrolled in a "preferred" PDP designated by the SPAP, this would not prevent the SPAP from implementing a preference for a given PDP through other means. CMS, in its proposed regulations, has rewritten this statutory rule so as apparently to prohibit *any* kind of SPAP activity that might grant preference to a given PDP or steer beneficiaries to a particular PDP; the law does not permit this substitution of agency policy for clearly expressed legislative intent.

The final regulations should include a revision of Section 423.464(e)(1)(ii) so that the rule conforms to the express language and intent of Congress in prohibiting qualifying Part D SPAPs from employing determinations of beneficiaries' eligibility or amount of benefits to favor one PDP over another; but the CMS regulations may not validly expand this statutory rule to preclude any preferential treatment of a PDP by an SPAP.

Subpart J: Coordination Under Part D Plans With Other Prescription Drug Coverage (Federal Register page 46696)

6b. Coordination With Other Prescription Drug Coverage (Federal Register page 46702)

CMS: *Comments requested regarding situations that might involve coordination between states and PDPs.*

DSS Comments: Case management services for our elderly and disabled full benefit dual eligible require the identification of prescription drugs being used by the client. We cannot rely on the patient's information, as they might not be capable of recalling all drugs they are currently using. To be effective in providing the best care to these individuals, their adjudicated drug claims data would be vital. We would expect to see these claims "crossover" to the state from CMS just as fee for service Medicare

claims do presently. The state would not want to set up data exchanges with every PDP versus one with CMS.

6c. Coordination of Benefits (Federal Register pages 46702-46703)

1.a. Covered Part D Drug (Federal Register page 46646-46647)

CMS: *Comments requested concerning gaps that may exist in the combined Medicare Part B and D coverage package.*

DSS Comments: Many of Missouri's full benefit dual eligibles do not have Part B coverage. Missouri is a 209b state and has different eligibility guidelines. These individuals would obtain their Part B covered drugs from Medicaid under the current system. Under the MMA, these drugs would not be covered under the Part D program as they are covered under the Part B. However, since the client does not have Part B but does have Part D (dual eligible), these drugs could not be covered by Medicaid. Interpretation of the law in this manner will limit the access to care these individuals should have available to them.

On page 46703 of the Federal Register it states, "We interpret the definition of covered Part D drug to exclude coverage under Part D for drugs otherwise covered and available under Parts A or B for individuals who choose not to enroll in either program. We interpret the words payment is available to mean that payment would be available to any individual who could sign up for A or B, regardless of whether they are actually enrolled." Thus, for all Part D individuals, Part A drugs and Part B drugs are "available" if they choose to pay the appropriate premiums. Consequently, Part D would not be required to pay for drugs covered under Parts A and B on the basis of a Part D eligible individual's status regardless whether the beneficiary is receiving Part A or B." For Medicaid recipients who are not eligible for Part A but could be enrolled in Part B if they choose to do so through the state buy-in program but do not take advantage of this offer, can their prescription drugs be covered by Medicaid with FFP? If not, dual eligibles will be receiving a lesser pharmacy benefit than they do currently. Our full benefit dual eligible population is accustomed to accessing drugs that are necessary to their health. Medicare's criteria for coverage of Part B drugs is much more restrictive than other insurance entities and/or Medicaid. Who would be responsible for payment if a dual eligible obtains a Part B covered drug as part of a recognized treatment plan by sources other than Medicare, the drug is rejected as non-covered by Medicare Part B using Medicare criteria, and it does not become a Part D drug? Will the beneficiary have to assume liability for their drugs? Would this become a non-covered Medicare drug payable by Medicaid at the normal federal match based on Medicaid coverage criteria? How would such a determination be made and relayed to the state and the provider? Could a process in which "exceptions" are processed for these drugs be implemented? An appeals process could be dangerous to the health of an individual who has relied on these drugs for successful treatments.

Those involved in such scenarios may be very physically or mentally ill and may not have the ability or resources to pursue the appeal process.

6.d. Collection of Data on Third Party Coverage (Federal Register page 46704)

CMS: *Comments on collection of third-party data.*

DSS Comments: The status of third party payer can change many times. Pharmacies will contact health insurance companies and Medicaid agencies now if they have discrepancies with eligibility data at the point of sale. To have them contact the disputed coverage entity should be no greater demand on their resources than they have now. This data would then be fed back to the PDPs through the coordination of benefits process who would send it to CMS for updated records.

The original collection of such data should be incorporated into the application process just as it is with the Medicaid eligibility determination process. This would require mandatory release of information by the beneficiary.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections

b. Dispensing Fees (Federal Register page 46647)

CMS: *We invite comments on three different options for the term dispensing fee.*

DSS Comments: The Department of Social Services believes that option 1 is the best interpretation of dispensing fee. Any supplies and equipment needed for the administration of the medication and any cognitive services should be reimbursed separately.

Subpart M: Grievances, Coverage Determinations, Reconsiderations and Appeals (Federal Register, page 46717)

Coverage Determination (§423.566 through §423.576)

CMS: *The PDP sponsor must make its expedited determination and notify the enrollee and the prescribing physician as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.*

DSS Comments: Currently Medicaid recipients whose prescription requests are not being honored receive a 72-hour supply of medications pending the initial coverage request. They are entitled to notice, face-to-face

hearings, and aid paid pending an appeal if their request is denied and they file their appeal within a specified time frame. All state Medicaid appeals processes are completed more expeditiously than Medicare appeals. The appeals process as described in Subpart M does not accord dual eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity to a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes.

The Missouri Department of Social Services appreciates the opportunity to submit comments on the Proposed Rule for the Medicare Prescription Drug Benefit. We welcome questions you may have or comments you may wish to discuss. Please contact Christine Rackers, Director, Division of Medical Services, at 573/751-6922.

Sincerely,

Steve Roling
Director

SR:kl

CMS-4068-P-1249

Submitter : Mr. David Zentner **Date & Time:** 10/04/2004 09:10:07

Organization : North Dakota Department of Human Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4068-P-1250

Submitter : Ms. Denise Feldman **Date & Time:** 10/04/2004 08:10:27

Organization : California Healthcare Consulting, Inc.

Category : Individual

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

please see attached comments

CMS-4068-P-1250-Attach-1.pdf

CMS-4068-P-1251

Submitter : Barbara Edwards **Date & Time:** 10/04/2004 08:10:41

Organization : Ohio Department of Job and Family Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments from the Ohio Department of Job and Family Services Office of Ohio Health Plans regarding the proposed regulations for the Medicare Part D prescription drug benefit.

CMS-4068-P-1251-Attach-1.doc

Bob Taft
Governor

Tom Hayes
Director

OHIO Job & Family SERVICES

30 East Broad Street • Columbus, Ohio 43215

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October 4, 2004

Mark McClellan, PhD, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Comments on the Proposed Rule Concerning the Medicare Prescription Drug Benefit

Dear Dr. McClellan,

Thank you for the opportunity to comment on the proposed rules regarding the Medicare Prescription Drug benefit. Within the Ohio Department of Job and Family Services, the Office of Ohio Health Plans administers Ohio Medicaid, the Medicare Premium Assistance Program, and the Ohio Disability Medical Assistance Program. Collectively, these programs cover 1.7 million Ohioans, including more than 200,000 Medicare beneficiaries.

Preserving access to prescription drugs for dual Medicare-Medicaid eligible beneficiaries ("dual eligibles") should be a priority for CMS. In Ohio, as in many states, dual eligibles have access to an open formulary, including many of the "Medicaid-optional" drugs that may not be covered by Medicare Part D (over-the-counter drugs, barbiturates, benzodiazepines, and vitamins). In addition, Ohio Medicaid consumers receive their prescriptions with zero out-of-pocket cost, except when drugs require prior authorization. For our most fragile residents, the benefit proposed in the Medicare Modernization Act (MMA) will replace a comprehensive, zero out-of-pocket plan with a more limited plan which will require out-of-pocket costs that may prohibit indigent Medicare beneficiaries from getting their prescriptions.

Access to prescriptions for Medicare beneficiaries receiving long-term care (LTC) is vitally important. Both patients living in LTC facilities and those receiving services through Medicaid home and community-based waivers should be included in this category. Access to a LTC pharmacy provider through the Prescription Drug Plan (PDP) or Medicare Advantage

Prescription Drug (MA-PD) plan, and appropriate formulary drugs including infusion therapy, are critically important for this population.

MMA requires the states to pay a phased-down state contribution toward the prescription costs of dual eligibles. The calculation of this "clawback" as set out in the proposed rule does not accurately represent the actual costs to either Medicare or to the state in providing this prescription benefit. While CMS staff have indicated that the MMA limits the information used to calculate the payment, Section 1935(c)(3) of the Social Security Act as amended by the MMA states that the Secretary may use "other data" to determine the appropriate amount. Ohio believes that this language allows more information to be used that may more accurately represent the actual costs that states would have incurred for prescription drugs for dual eligibles in the absence of Medicare Part D.

Subpart B: Eligibility and Enrollment

Section II.B.2 of the preamble referring to **Section 423.34(d)** of the proposed regulations discusses the process for auto-enrollment of full-benefit dual eligibles, and solicits comment regarding whether the federal government (CMS or its contractor) or the States (or their contracted entities) should have responsibility for administering the "random" automatic enrollment process for full benefit dual-eligible individuals who do not otherwise enroll in an MA-PD or PDP. Ohio strongly opposes this additional administrative burden, which CMS accurately describes as "a new national workload of indeterminate size," on the States. The governing legislation is clear that this responsibility should fall upon the federal government. Section 1860D-1(b)(1)(C) of the Act directs that, if there is more than one prescription drug plan available to a full-benefit dual eligible individual who has failed to enroll in a PDP or MA-PD plan, "*[t]he Secretary* shall enroll such an individual on a random basis among all such plans in the PDP region" (emphasis added).

Given this express designation of responsibility, neither the Secretary nor CMS has authority to impose responsibility for the auto-enrollment function on the States. The preamble to the proposed rule suggests that administrative costs of auto-enrollment activities by the states might have to be borne, at least in some substantial part, by the States themselves. Moreover, even if administrative costs of carrying out this function were to be 100% federally reimbursed (as would be more appropriate, given that the Part D program falls within the federal Medicare program, not the joint state/federal Medicaid program), it would nevertheless constitute a substantial, additional administrative burden on the States that they are not equipped to perform.

As the preamble to the proposed regulation acknowledges, CMS' assumption of the auto-enrollment responsibility will further the goals of national uniformity in, and facilitate federal oversight over, the process. Auto-enrollment will require accurate and timely information flow between CMS and the States in any event. There is no reason to assume that transmission of accurate Medicaid eligibility data from the States to CMS would be inherently any more problematic than transmission of accurate and timely Part D data from CMS to the States.

Recommendation: CMS should facilitate the auto-enrollment process for dual eligibles, either directly or through a contractor. Ohio believes there is no legitimate rationale for transferring to the States an administrative responsibility that Congress clearly indicated should fall upon the federal government.

Section II.B.2 of the preamble referring to **Section 423.34(d)** of the proposed regulations also discusses the timing of the auto-enrollment for dual eligibles, referring to a process to begin at "the end of the individual's initial enrollment period." We have concerns about the enrollment and the auto-enrollment process as established by this section of the draft regulations in relation to providing adequate communication and assistance in enrolling dual eligibles. First, we are concerned about the timing of the automatic enrollment process for dual eligibles because they will lose Medicaid prescription drug coverage on January 1, 2006. They must enroll, preferably through their own selection, prior to losing their Medicaid prescription drug coverage. The scheduled auto-enrollment process beginning on May 16, 2006, is too late to dovetail with the loss of their Medicaid prescription drug coverage. If this date is to work, CMS must communicate with dual eligibles concerning this change in their prescription drug benefits far in advance of the proposed October 15, 2005, mailing. Second, the proposed rule lists a plethora of concerns around auto-enrolling a full benefit dual eligible in an MA-PD or a PDP, specifying that involuntarily dis-enrolling a dual eligible from one plan in order to auto-enroll them into a plan charging a lower premium is not a viable option under the statute. Though finding a plan and premium that will fit within the low-income subsidy is a concern and further illustrates the need to assist dual eligibles in understanding their options. For this population, the concern is finding a plan which will cover all their medications as previously covered under their Medicaid drug benefit, thereby making the transition to Medicare drug coverage a seamless one.

Recommendation: CMS should change the scheduled auto-enrollment date or change the date that dual eligibles lose their Medicaid coverage, and provide in-person assistance (through federally contracted independent enrollment brokers) in order to adequately educate dual eligibles on their options and minimize the need for the auto-enrollment. In order to provide dual eligibles with the information they need to make an informed choice, PDPs, MA-PDs, CMS and SHIP agencies should not deluge dual eligibles with mailed notices and expect they will understand that they will lose their Medicaid prescription drug coverage, and that they must find a PDP or MA-PD that covers their medications.

Section II.B.10 of the preamble discusses the information that CMS will make available to PDPs and MA-PDs. Divulging beneficiary-specific information to PDPs and MA-PDs could be particularly risky for dual eligible beneficiaries. MA-PD plans have an incentive to enroll dual eligibles because they will receive an additional capitation payment (Medicaid add-on) for these higher risk beneficiaries. The dual eligible population is more vulnerable (due to age, limited English proficiency, limited education, etc.) to the risk of enrolling in a plan that does not meet their needs and having to pay out-of-pocket if their medications are not covered by the plan marketed to them. Some Medicare managed care plans have a reputation for being especially aggressive with regard to enrolling dual eligibles without providing clear information on plan limitations. Dual eligibles will require greater protections and individual assistance to select the plan that most meets their needs.

Recommendation: CMS should establish special protections for the dual eligible population, including prohibitions against direct marketing to dual eligibles by PDPs and MA-PDs.

Subpart C: Voluntary Prescription Drug Benefit and Beneficiary Protections

Section II.C.1.a of the preamble solicits "comments concerning any drugs that may require specific guidance with regard to their coverage under Part D, and any gaps that may exist in the combined 'Part D & B' coverage package." As proposed in MMA, the definition of a Part D drug excludes those drugs which may be excluded under section 1927(d)(2) of the Social Security Act. By excluding these drugs, Medicare beneficiaries may not have access to drugs such as phenobarbital (a barbiturate) or clonazepam (a benzodiazepine) for seizures, or potassium (a mineral) for the heart. For many dual eligible beneficiaries, these drugs are vitally important. The low income subsidies have no provisions for extended coverage to include these drugs. While these drugs are optional for state Medicaid programs, Ohio and most other states do cover these drugs for Medicaid consumers as an important part of the benefit package. Please also see comments below under the heading "Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation" information pertaining to Section II.F of the preamble regarding alternative coverage. Ohio believes that basic alternative coverage including the Medicaid-optional drugs is actuarially equivalent to standard coverage.

Clarification of coverage of prescription drugs under Medicare Part B is essential. The rules regarding Part B coverage are confusing, and if left to the interpretation of PDPs and MA-PDs, drugs not covered under Part B may be excluded from Part D plans. If these drugs are excluded from Part D coverage, our fear is that Medicare beneficiaries would be denied coverage.

Recommendation: CMS should include coverage for "Medicaid-optional" drugs in the Part D benefit for dual eligibles, as part of the standard package or a basic alternative plan, or within an extended package available with the low income subsidies. CMS should also clarify coverage of prescription drugs under Medicare Part B to ensure that all appropriate drugs are covered under either Part B or Part D.

Section II.C.1.c of the preamble asks for "comments regarding our definition of the term long-term care facility in **section 423.100**."

Specifically, comments were solicited concerning whether Intermediate Care Facilities for the Mentally Retarded (ICFs/MR) should be considered LTC facilities. These facilities are residential facilities providing long term care to residents, so as such are LTC facilities. Since virtually all residents of ICFs/MR in Ohio are dual eligibles, and therefore eligible for the low-income subsidies, they should be afforded the same benefits as residents of nursing facilities and skilled nursing facilities, along with all other beneficiaries receiving LTC.

As a result of the U.S. Supreme Court decision *Olmstead v. L.C.*, 527 U.S. 581 (1999), Ohio and other states have been moving seniors and persons with disabilities from institutions into less

restrictive placements. Ohio has implemented waiver programs for home and community based care as an alternative to placement in a nursing home. These alternatives provide consumers with a choice of placement, but allow them to receive the same level of care as those who reside in institutions.

Exclusive contracts with a LTC pharmacy should not be the deciding factor on whether or not to extend the definition of LTC facility to forms of housing other than traditional nursing homes; the beneficiaries' qualification for Medicare and their health care needs should be the deciding factors. Rather than defining "long-term care facility," it may be more useful to define "long-term care." States can identify dual eligible individuals who are institutionalized, and can also identify those individuals that, if it were not for the *Olmstead* decision or an 1115 waiver, would be institutionalized. These individuals are low-income Medicare beneficiaries; having a Medicare prescription benefit at zero out-of-pocket cost will allow their income to be used for daily living expenses and not on prescriptions.

Dual eligible residents of LTC facilities in Ohio are required to use all income toward the cost of care, except for a personal needs allowance of $40 per month. This amount is not enough to pay for the cost of medications obtained from out-of-network pharmacies or non-covered drugs. The personal needs allowance for patients under home and community based services waivers is higher, but is still not high enough to pay the added cost of medications that have previously been covered under the Medicaid pharmacy benefit. Parity between institutionalized and waiver serviced beneficiaries must be maintained. These most needy Medicare beneficiaries must be offered a comprehensive benefit plan with zero out-of-pocket costs.

Recommendation: CMS should include ICFs/MR in its definition of LTC facilities. Furthermore, CMS should define "long-term care" to include both patients in residential facilities as well as those who receive a level of care through a home and community based waiver that would be equivalent to care in a residential LTC facility. All Medicare beneficiaries who are either institutionalized or in Medicaid home and community based waivers should be afforded the same prescription benefits including zero copayments.

Section II.C.4.a of the preamble referring to **Section 423.120** of the proposed regulations discusses access to LTC pharmacies, and whether CMS should require, or merely encourage, PDPs and MA-PDs to include LTC pharmacies in their networks. A requirement that PDPs and MA-PDs include one or more LTC pharmacy providers will ensure access to LTC pharmacy services for all Medicare Part D beneficiaries. By merely encouraging this arrangement, Medicare beneficiaries who enter LTC arrangements while enrolled in a PDP or MA-PD without a contracted LTC pharmacy will be left with only potentially expensive out-of-network options. In addition, a PDP or MA-PD could effectively discriminate against patients in LTC by declining to contract with a LTC pharmacy. The rules governing PDPs and MA-PDs must include beneficiary protections against the few PDPs and MA-PDs which may choose to provide less-than-appropriate care. By requiring each PDP and MA-PD to include at least one LTC pharmacy in its network, beneficiaries will retain a measure of protection. In addition to requiring at least one LTC provider, PDPs and MA-PDs should also be required to contract with any LTC pharmacy that agrees to the PDP's or MA-PD's standard contract.

Recommendation: CMS should require each PDP and MA-PD to include at least one LTC pharmacy in its network, and to contract with any LTC pharmacy that agrees to the PDP's or MA-PD's standard contract.

Section II.C.4.a of the preamble referring to **Section 423.120** of the proposed regulations discusses access to federally qualified health centers (FQHCs), and whether CMS should require, or merely encourage, PDPs or MA-PDs to include FQHC pharmacies in their networks. Similar to the LTC pharmacy question, a requirement that PDPs and MA-PDs include FQHC pharmacy providers will ensure access to pharmacy services for all Medicare Part D beneficiaries. Recognizing that FQHC pharmacies would need different contractual terms, PDPs and MA-PDs should be required to approach these pharmacies and attempt to reach agreement about terms.

Recommendation: CMS should require each PDP and MA-PD to approach all FQHCs in its service area to attempt to negotiate a contract.

Section II.C.4.a of the preamble referring to **Section 423.120** of the proposed regulations discusses access to home infusion pharmacies, and whether CMS should require, or merely encourage, PDPs and MA-PDs to include home infusion pharmacies in their networks. Also similar to the LTC pharmacy question, a requirement that PDPs and MA-PDs include home infusion pharmacy providers will ensure access to pharmacy services for all Medicare Part D beneficiaries. By merely encouraging this arrangement, Medicare beneficiaries who require home infusion services while enrolled in a PDP or MA-PD without a contracted home infusion pharmacy will be left with only potentially expensive out-of network options. By requiring each PDP and MA-PD to include at least one home infusion pharmacy in its network, beneficiaries will retain a measure of protection.

Recommendation: CMS should require each PDP and MA-PD to include at least one home infusion pharmacy in its network.

Section II.C.4.b of the preamble referring to **Section 423.120** of the proposed regulations "invite[s] comments regarding standards and criteria that [CMS] could use to determine that a PDP sponsor or MA organization's formulary classification system that is not based on the model classification system does not in fact discriminate against certain classes of Part D eligible beneficiaries." To be sure that an appropriate formulary system is in place, CMS should consider the United States Pharmacopeia (USP) model guidelines to be the minimum acceptable to meet the criteria. This means that the PDP's or MA-PD's proposed classification system must contain at least as many **equivalent** categories and classes of drugs as USP's model. In addition, CMS must verify that a variety of dosage forms are available. Appropriate drug therapy may involve the use of alternate dosage forms such as injectable and easier-to-swallow oral forms (e.g. liquids or rapidly dissolving tablets) for patients unable to swallow tablets or capsules. Drugs for topical, ophthalmic, nasal, otic, vaginal, and rectal administration should also be included in PDP and MA-PD formularies.

Part of the goal of CMS' approval of PDP and MA-PD formulary classifications must be protection from unintended consequences of cost containment. Particularly in an elderly

population such as the one served by Medicare, inappropriate drug therapy may lead to hospitalization, worsening morbidity, and mortality. The added costs of these consequences would be borne by Medicare Parts A and B, rather than by the Part D PDP. This misaligned financial incentive must be mitigated by requirements to provide drugs in appropriate categories.

With the continued trend toward prescription drugs being granted over-the-counter (OTC) status, it is important that PDPs and MA-PDs not be able to exclude a required category or class of drugs because OTC options are available. These required categories and classes should be included in every plan's list of covered drugs.

Recommendation: CMS should use USP's model guidelines as the baseline for what is acceptable. PDP and MA-PD formularies must include a variety of dosage forms in at least as many equivalent categories and classes of drugs as USP's guidelines. The formulary classification must protect both the beneficiary and Medicare Parts A and B from unintended consequences of cost containment.

Subpart F: Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation

Section II.F.4 of the preamble referring to **Section 423.265** of the proposed regulations discusses actuarial equivalence of plans. This section considers differences in plan cost sharing that may be considered actuarially equivalent, but gives little information about plans that may choose to provide coverage of optional drugs under basic alternative plans. Section 1860D-2(a)(2)(A)(ii) of the Social Security Act as amended by MMA provides for "[c]overage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A)" regarding Medicaid-optional drugs. By including these drugs, to be used as alternatives to other Part D drugs, PDPs and MA-PDs will provide a more comprehensive benefit without incurring higher costs than the basic plan. This option should be considered in the regulations and Part D plans should be encouraged to provide this coverage. As mentioned above, coverage of drugs such as phenobarbital (a barbiturate) and clonazepam (a benzodiazepine) are necessary for appropriate care of seizure disorders. OTC drugs such as laxatives, aspirin, and antacids provide cost-effective care for common ailments. The availability of drugs for cough and cold symptoms will reduce inappropriate and unnecessary prescribing of antibiotics which may cause antibiotic resistance and increase hospitalizations and other health care costs. While state Medicaid programs have the option to not cover classes of drugs including those listed here, most provide at least limited coverage. Ohio provides a comprehensive benefit including a selection of agents used for the symptomatic relief of cough and colds, prescription vitamins and mineral products, nonprescription drugs, barbiturates, and benzodiazepines.

Recommendation: CMS should issue regulations encouraging basic alternative coverage including optional drugs. A benefit plan providing this alternative coverage is actuarially equivalent to the standard plan, and offers Medicare beneficiaries a more comprehensive benefit package. PDPs and MA-PDs should be encouraged to provide this basic alternative coverage.

Subpart J: Coordination under Part D Plans with Other Prescription Drug Coverage

Section II.J.6.b of the preamble referring to **Section 423.464** of the proposed regulations invites comments regarding coordination of benefits between state Medicaid programs and PDPs and MA-PDs. While this section is specific to coordination after the implementation of Part D, it is also important to consider the transition into Part D. Dual eligible beneficiaries in Ohio and most other states have a comprehensive drug benefit including open formulary and zero out-of-pocket cost for most prescriptions. This benefit will be replaced by a Part D plan which will probably provide a much more limited formulary and will require copayments for each prescription. Medicare must ensure that the transition from Medicaid prescription coverage to Part D is seamless, and no beneficiary will be unable to obtain medications. The transition process needs to ensure that no dual eligible experiences a lapse in coverage for any reason.

This seamless transition will only be accomplished with an organized, easy-to-understand auto-enrollment process. Because Medicaid coverage will end on December 31, 2005, it is imperative that all dual eligibles be enrolled in a PDP or MA-PD before Part D coverage begins. Once enrolled, the PDP or MA-PD should cover the beneficiary's existing medications during a transition period during which the PDP or MA-PD, beneficiary, and beneficiary's physicians work together to change the drug regimen to conform to the plan's formulary or to receive prior authorizations for necessary medications. Appeals and redeterminations need to be done on an accelerated timeline during the transition period, and beneficiaries must be informed of their right to appeal.

During this transition period, dual eligibles should not be subject to higher out-of-pocket costs for out-of-network pharmacies. While beneficiaries may decline the PDP or MA-PD chosen for them in an auto-enrollment process, it will take some time for the beneficiary to choose a more appropriate PDP or MA-PD that includes his or her preferred pharmacy. For dual eligibles in LTC facilities, extra protections during this transition period are even more important because they are generally locked in to a single pharmacy provider which has contracted with the facility.

Recommendation: CMS should ensure a seamless transition period for dual eligible beneficiaries. This transition period should include expedited appeals, an open formulary, and no penalties for out-of-network pharmacy use. This transition period should last for at least six months, to give the beneficiary, physicians, and the PDP or MA-PD enough time to change any drugs that are nonformulary or to appeal the formulary decision.

Section II.J.6.b of the preamble referring to **Section 423.464** of the proposed regulations invites comments regarding coordination between state Medicaid programs and PDPs and MA-PDs. This coordination of benefits must allow states flexibility to either wrap around or not wrap around the Part D benefit. State assistance may take the form of a State Pharmaceutical Assistance Plan (SPAP) as defined in the regulations, a Medicaid state plan, or another state-financed arrangement. **Regardless of the form of assistance, states should have the ability to choose not to wrap around the benefit while being satisfied CMS has assured that the state's Medicare beneficiaries are receiving appropriate drug coverage.** States should also

have the flexibility, if they do choose to wrap around the benefit, to either pay the difference between the low-income premium subsidy and the premium for a basic or extended plan, or to pay on a per-claim basis. Related to states' decision not to wrap around the Part D benefit, CMS should provide a State Plan Amendment option to exclude dual eligibles, or any consumer eligible for Medicare, from any outpatient drug coverage under Medicaid.

Recommendation: CMS should write regulations protecting the states' ability to either wrap around or not wrap around the Part D benefit, and to choose the structure of any wrap around benefit. For states that choose not to wrap around, CMS should provide protection through the state plan to exclude any Medicare-eligible consumer from Medicaid pharmacy services.

Subpart S: Special Rules for States – Eligibility Determinations for Low-Income Subsidies and General Payment Provisions

Section II.S.1 of the preamble referring to **Section 423.904** of the proposed regulations discusses states' obligations for processing applications for the low-income subsidies. States should be able to meet this obligation by simply accepting applications and forwarding them to the Social Security Administration (SSA) for eligibility determinations to be made. Similarly, all redeterminations and appeals should be done by SSA. This approach will encourage consistency to a national standard and provide accountability to all Medicare beneficiaries. Any provision in the law that a state must perform any eligibility determination for a federal program is an unfunded mandate, and as such should be eligible for 100% federal reimbursement for any state resources expended. Staff time for Ohio to implement this program will include creating rules within the Ohio Administrative Code, training of front-line workers, training of supervisory staff, and time for hearings, appeals, and oversight. In order to accomplish this unfunded mandate, information system changes would need to be made in a short amount of time. If states are to be required to begin accepting applications by July 1, 2005, these system changes are not possible. Ohio also needs time to obtain state statutory authority to perform any functions related to the Medicare benefit but unrelated to state programs. In Ohio, we have the authority to administer the Medicaid program, including the Medicare premium assistance program, but not to administer Medicare. The requirement for states to perform any function regarding eligibility for Medicare is unnecessarily burdensome.

Recommendation: CMS should issue regulations which are clear that a state's only obligation in processing applications for low-income subsidies is to accept applications to be forwarded to SSA for processing. Any resources contributed by a state to the Medicare program should be eligible for 100% federal reimbursement.

Section II.S.4 of the preamble referring to **Section 423.908** of the proposed regulations discusses the calculation of the Phased-Down State Contribution. The calculation, as proposed in rule, closely follows the instructions from MMA. However, the authorizing legislation does contain a provision, in its amendment to Section 1935(c)(3) of the Social Security Act, to use "information reported by the State in the medicaid financial management reports (form CMS-64) for the 4 quarters of calendar year 2003 *and such other data as the Secretary may require*" (emphasis

added). Ohio believes that this language allows the Secretary to consider information that does not appear on the forms CMS-64 for calendar year 2003. The intent of the legislation is to approximate the amount that would have been spent by states for Part D drugs for dual eligibles in the absence of Medicare Part D, based on the experience of 2003. Congress clearly recognized that the forms CMS-64 would not contain the full picture of states' experience in 2003. For example, drug rebates are billed approximately two months after the end of the quarter during which they were earned. Thus, rebates for much of 2003 were not billed or received until well into 2004. Federal rebate liabilities have been steadily increasing. By considering only the rebates that were received in 2003, the calculation more closely reflects 2002 experience.

A second issue is that many states, including Ohio, implemented or planned cost-saving measures in 2003 which will reduce pharmacy costs into the future. For example, Ohio implemented a Preferred Drug List (PDL) program in April 2003 which has shown savings of about 5% in overall pharmacy program costs. As with the federal rebates, the supplemental rebates associated with the PDL were not billed until several months later, so most of the revenue was received in 2004 and reported on forms CMS-64 for quarters in 2004. The Ohio PDL has been introduced in phases, with the first phase in April 2003, second phase in October 2003, and the third phase to be implemented in October 2004. Savings projections for calendar year 2005 are close to 8% of overall program costs. These additional savings should be considered by the Secretary under the "other data" provision of MMA, because they would more closely reflect the costs to Ohio for the pharmacy benefit for dual eligibles in the absence of Medicare Part D. Along with the PDL, a copayment of $3 was instituted for drugs requiring prior authorization. This copayment has improved our cost savings by encouraging Medicaid consumers to use less expensive drugs that do not require a copayment. These savings should also be considered.

A third consideration for the calculation of the phased-down payment is the inflation factor used. The legislation directs the Secretary to use the "most recent National Health Expenditure projections" to determine the inflation factor. State Medicaid programs in general, and Ohio Health Plans in particular, have consistently contained growth to a factor lower than the National Health Expenditure projections. Ohio's recommendation is that CMS consider each state's performance relative to the National Health Expenditure data, and to use a factor appropriate to each state, not to exceed the national projection.

Each state should be required to submit data that explains adjustments to be made to the "clawback" calculation. Because there is no provision for the baseline amount to be recalculated in the future, it is imperative that the liability be accurately calculated. To consider only information that was submitted in standard reports will not reflect the full experience of the states in 2003. Because of the significance of the 2003 baseline number, CMS should develop an appeals process for the phased-down state contribution calculation. This process will enable states to have a process through which to resolve any disagreement with CMS' calculations.

Recommendation: CMS should use the statutorily authorized consideration of "other data" provided by the states to determine an accurate, fair representation of the state's cost for

pharmacy benefits for dual eligibles in the absence of Medicare Part D. Each state's calculation should be different based on experience. This one-time calculation to be used in perpetuity must accurately reflect state experience. As such, a process should be developed for states to appeal CMS' determination of the payment amount.

Conclusions

Ohio Health Plans look forward to working with CMS on the implementation of Medicare Part D. Preserving access to prescription drugs for dual eligibles, the most disadvantaged seniors in our state, is a priority. It is imperative that these and all Medicare beneficiaries have access to a comprehensive drug benefit that is affordable. The cost of providing this benefit should not be unfairly shifted to states through an inappropriate Phased-Down State Contribution payment. Please consider these recommendations before issuing final regulations. If you have any questions, please do not hesitate to contact me at (614) 466-4443.

Respectfully Submitted,

Barbara Coulter Edwards
Deputy Director for Ohio Health Plans
Ohio Department of Job and Family Services

Submitter : Dr. James Nawarskas **Date & Time:** 10/04/2004 08:10:36

Organization : New Mexico Society of Health-System Pharmacists

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment for important comments

CMS-4068-P-1252-Attach-1.doc

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014
www.cms.hhs.gov/regulations/ecomments

To Whom It May Concern:

The purpose of this letter is to comment on the Medication Prescription Drug Improvement and Modernization Act of 2003 (MMA), specifically the Medication Therapy Management Program (MTMP).

The New Mexico Society of Health-System Pharmacists represents pharmacists that practice in a variety of health care settings (hospitals, federal clinics and health systems, academia, managed-care organizations, etc.). The mission of our organization is to advance the provision of pharmaceutical care and achieve optimal patient outcomes.

Currently, under New Mexico law, pharmacists can have full prescriptive authority under the supervision of a physician to provide medication therapy management limited to the scope of the physician's practice. Additionally, all registered pharmacists in New Mexico can have prescriptive authority for the following: pediatric and adult immunizations, emergency contraception, and tobacco cessation products.

Representing the New Mexico Society of Health-System Pharmacists, we make the following recommendations for successful implementation of the MTMP which will in turn lead to improved patient care.

It is our position that CMS should include in the rules:

1. **That all pharmacists are included as qualified providers of MTMP**. Pharmacists in health systems currently provide MTM services in anticoagulation clinics, cardiovascular risk reduction clinics, congestive heart failure clinics, asthma clinics, etc. These services have been repeatedly associated with improvements in the quality of patient care and reductions in healthcare costs.
2. **Targeted beneficiaries should include all patients with at least one chronic disease**. Current plans to identify beneficiaries qualified to receive MTMP focus on patients having multiple chronic conditions, receiving multiple medications and who are expected to incur high prescription drug costs. Under-use of medications often is as serious a drug-related problem as is over-use and therefore MTM eligibility should ***not*** be based solely on number of medications currently prescribed.
3. **Reimbursement rates must be determined nationally by CMS using any willing provider guidelines and ensuring appropriate coverage areas**. Ensuring standardized rates of reimbursement would inhibit PDPs from contracting with groups purely based on cost at the sacrifice of MTMP quality.

Reimbursement rates should be based upon the complexity of the service provided and commensurate with reimbursement for other healthcare providers.

4. **The patient must have freedom of choice of providers**. This would encourage competition between providers based on quality, ultimately leading to improved patient outcomes.
5. **CMS must ensure that contractors have full coverage for patient and provider access in rural and underserved areas**.

Thank you for allowing us the opportunity to provide comments on the proposed rules.

Sincerely,

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New Mexico Society of Health-Systems Pharmacists
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CMS-4068-P-1253

Submitter : Mr. Paul Latchford **Date & Time:** 10/04/2004 08:10:09

Organization : Monumental Life Insurance Company

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4068-P-1253-Attach-1.doc

Monumental Life Insurance Company

Direct Response Division
520 Park Avenue
Baltimore, Maryland 21201-4500

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: to CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

RE: Comments on Medicare Modernization Act of Proposed Rule Part 403

To Whom It May Concern:

We are writing to comment on the proposed rules of August 3, 2004, which would amend 42 CFR 403.205. CMS proposes to amend the federal regulatory definition of a "Medicare Supplemental Policy" to include a stand-alone limited health benefit policy or plan. Additionally, CMS proposes a disclosure form to be sent by Medigap carriers regarding Medicare Part D.

Proposed Changes to Medicare Supplemental Definition

CMS should make no changes to the current definition of Medicare Supplemental Policy except to conform to the MMA changes regarding what is not a Medicare Supplement Policy.

The MMA requires that the definition of Medicare Supplemental Policy only change to add a prescription drug plan under Part D as a type of coverage not included in the definition of the Medicare Supplemental Policy and to replace the term Medicare+Choice with Medicare Advantage. Any other changes to the definition of Medicare Supplemental Policy proposed by CMS are not authorized by the MMA. The agency does not have statutory authority to advance any changes above and beyond the two provided pursuant to the MMA.

CMS proposes to amend the definition of Medicare Supplemental Policy by including a rider attached to an individual or group policy, a stand alone limited health benefit plan or policy that supplements Medicare benefits and is sold primarily to Medicare beneficiaries or that otherwise meets the definition of the Medicare supplement policy as defined in the section, and any rider attached to a supplemental policy to become an integral part of the basic policy. This is already addressed as a matter of state law.

Additionally, CMS proposes to delete section 403.205(d)(1 through 5). In the current law these subparts are specifically listed as exclusions from the definition of Medicare Supplemental Policy. CMS has no statutory authority to delete these provisions and therefore may not removed pursuant to the proposed rule.

Notice to Medigap Prescription Policyholders.

We recommend that CMS retain the version of the "notice" required by section 104 of the MMA for Medigap carriers that was adopted by the NAIC and submitted to CMS. The NAIC approved version of the notice meets all of the statutory requirements of the MMA. We should not as Medigap carriers be required to make any assessments regarding the "value" of coverage nor to promote Medicare Advantage. The notice should go no further than to meet such requirements.

We appreciate the opportunity to offer comments on these proposals and thank you for your consideration of these comments.

Sincerely
Paul Latchford
Vice President and Counsel

CMS-4068-P-1254

Submitter : **Kevin Cranston** **Date & Time:** **10/04/2004 08:10:37**

Organization : **Massachusetts Department of Public Health**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Massachusetts Department of Public Health, HIV/AIDS Bureau

CMS-4068-P-1254-Attach-1.doc

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

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RONALD PRESTON
SECRETARY

CHRISTINE C. FERGUSON
COMMISSIONER

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014

File Code: CMS-4068-P

To Whom It May Concern:

On behalf of the state of Massachusetts, I appreciate the opportunity to comment on the proposed regulations entitled, "42 CFR Parts 403, 411, 417 and 423 Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule," 69 FR 46632. I am extremely concerned that many of the proposed regulations could negatively impact drug coverage for people living with HIV in our state, as well increasing the financial burden on the already strapped Massachusetts AIDS Drug Assistance Program (ADAP).

1.) Explicitly excluding ADAPs from being able to provide wrap-around coverage in a manner that would allow beneficiaries to reach the catastrophic limit seriously undermines the federal government's priority of providing comprehensive health care to people living with HIV/AIDS. ADAPs are an integral component of the safety net for people living with HIV/AIDS in this country and have a long history of filling gaps left by other federal programs, including Medicaid and Medicare. We strongly recommend that the final rule count cost-sharing subsidies from ADAPs as incurred costs for beneficiaries.

Massuchusetts is very concerned that the regulation also disallows state-appropriated dollars spent by ADAPs to be counted as incurred costs. It is discriminatory and unacceptable to single out state dollars used to provide medications to people living with HIV/AIDS while at the same time allowing state dollars to be used for State Pharmaceutical Assistance Programs' (SPAPs) expenditures on behalf of a beneficiary. Under the proposed regulations, SPAPs are allowed to wrap-around in a way that all costs spent on the behalf of a beneficiary count as incurred costs. States should have the flexibility to provide prescription drugs to a variety of populations, including people living with HIV/AIDS, with the state dollars appropriated. It is inexcusable to

exempt people living with HIV/AIDS from receiving this type of assistance from their state, while allowing people with other medical conditions to benefit from the use of state dollars. Ironically, persons with AIDS who live in states with SPAPs and who are eligible for assistance will have SPAP costs count toward incurred costs, while those who rely on ADAP will not.

2.) While we understand that CMS is hopeful that all prescription drug plans (PDPs) will include all necessary HIV-related drugs on their formularies, it is not required. Therefore, even individuals who benefit from the low-income protections included in the benefit may find themselves turning to ADAPs to receive the remaining necessary medications.

Massachusetts strongly supports the CMS recommendation to implement "open formularies" for special populations and strongly recommends that people with HIV/AIDS be defined as a special population. We feel this is critical to ensuring that Medicare beneficiaries with HIV/AIDS have continued and unhindered access to all of the drugs that are medically necessary for treating the disease. Furthermore, an "open formulary" will prove cost effective because it will prevent the use of more intensive and costly health care resources such as inpatient hospitalization that will occur if Medicare beneficiaries with HIV/AIDS are denied access to medically necessary prescription drugs. While the private drug plans are not at risk for this potential cost shifting, the federal government will incur these costs either through higher Medicaid expenditures or higher Medicare Part A and B expenditures.

3.) Strengthening the language regarding coverage of drugs for off-label use. It is imperative that prescription drug plans be required to cover medically accepted uses of drugs for off-label use that are standard practice in the medical community. For HIV disease, as with many complex conditions, clinical practice frequently progresses ahead of label indications as physicians learn what drug combinations best target their patient's symptoms and side effects. As an example, tenofovir (Viread) has proven effective for treating hepatitis B for people with HIV, although treatment for hepatitis B is not yet an indicated use of the drug.

4.) Imposition of co-payments. People with HIV/AIDS depend on a daily regimen of multiple medications (most of which are non-generic). Even minimal co-payments will create a financial burden for individuals who will be left to choose between paying for medications and meeting other needs, like food and housing. Dual eligibles must maintain the protection that they currently have under Medicaid and not be denied a drug for failure to pay cost sharing.

Again, thank you for the opportunity to submit comment on the proposed rule to implement the Medicare Part D prescription drug benefit. Please contact me at kevin.cranston@state.ma.us if you need further information.

Sincerely,

Kevin Cranston, MDiv
Acting Director

HIV/AIDS Bureau

CMS-4068-P-1255

Submitter : Mr. Kenneth Whittemore, Jr. **Date & Time:** 10/04/2004 08:10:56

Organization : SureScripts

Category : Health Care Industry

Issue Areas/Comments

Issues 1-10

BACKGROUND

RE: CMS?4068?P; Medicare Program; Medicare Prescription Drug Benefit; 42 CFR, Part 423, Section 159, Electronic Prescription Program

This letter is in response to the proposed rule that the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register, Volume 69, Number 148, beginning on page 46632 on August 3, 2004. SureScripts appreciates the opportunity to comment on the proposed rule with respect to those provisions that will support the implementation of an electronic prescription program designed to improve the overall prescribing process for millions of Medicare beneficiaries. In fact, SureScripts has already testified before, and offered additional advice and assistance to, the National Committee on Vital and Health Statistics Subcommittee on Standards and Security as it gathered input this past summer on electronic prescribing standards that might be used for the electronic prescribing program for Medicare. We look forward to continuing to work with CMS to implement said standards and these proposed rules in a manner that improves the safety, efficiency, and quality of the overall prescribing process for all essential stakeholders.

CMS-4068-P-1255-Attach-1.doc

SureScripts
The prescription for better healthcare™

October 4, 2004

Submitted Electronically

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS—4068—P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: CMS—4068—P; Medicare Program; Medicare Prescription Drug Benefit; 42 CFR, Part 423, Section 159, Electronic Prescription Program

Dear Dr. McClellan:

This letter is in response to the proposed rule that the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register, Volume 69, Number 148, beginning on page 46632 on August 3, 2004. SureScripts appreciates the opportunity to comment on the proposed rule with respect to those provisions that will support the implementation of an electronic prescription program designed to improve the overall prescribing process for millions of Medicare beneficiaries. In fact, SureScripts has already testified before, and offered additional advice and assistance to, the National Committee on Vital and Health Statistics Subcommittee on Standards and Security as it gathered input this past summer on electronic prescribing standards that might be used for the electronic prescribing program for Medicare. We look forward to continuing to work with CMS to implement said standards and these proposed rules in a manner that improves the safety, efficiency, and quality of the overall prescribing process for all essential stakeholders.

Introduction

SureScripts was founded in August of 2001 by the National Community Pharmacists Association (NCPA) and the National Association of Chain Drug Stores (NACDS), which represent the interests of 55,000 chain and independent pharmacies. The company is committed to building relationships within the healthcare community and working collaboratively with key industry stakeholders and organizations to improve the safety, efficiency and quality of healthcare by improving the overall prescribing process. At the core of this improvement effort is SureScripts Messenger™ Services, a healthcare infrastructure that establishes electronic communications between pharmacists and physicians and enables the two-way electronic exchange of prescription information. You and your staff can find more information about SureScripts at www.surescripts.com.

SureScripts Responses to CMS Requests for Comment on the Proposed Rule

(1) CMS: We are particularly interested in comments that help us identify consensus or reach consensus on e-prescribing standards ahead of the statutory timeframe, and to help us identify and evaluate industry experience based on pilot programs engaged in e-prescribing activities in 2004 and 2005.

SureScripts selected the nationally recognized NCPDP SCRIPT Standard to serve as the foundation for its transaction engine software in 2001, and has been actively and effectively using the standard in commerce with its various physician and pharmacy technology partners since June 2003. SCRIPT currently facilitates the electronic transmission of new prescriptions, prescription refill requests and authorizations, prescription fill status notifications, prescription change request and approvals and cancellation notifications between physicians, dispensing pharmacies and pharmacists. Future enhancements to SCRIPT could address other data communication possibilities that may include patient eligibility, compliance, lab values, diagnosis, disease management protocols, patient drug therapy profiles, prescription transfers, etc.

The NCPDP SCRIPT Standard was developed through a consensus process among community pharmacy organizations, PBMs, health plans, pharmacy software vendors, database providers, and other stakeholders. It adheres to EDIFACT syntax requirements, utilizes standard EDIFACT and ASC X12 data tables, and is an American National Standard (ANS). This being the case, and in light of the success that our organization has had in employing the standard for the past sixteen months, SureScripts believes that there *is* consensus in the industry that the NCPDP SCRIPT Standard is the best standard to meet the e-prescribing needs of ambulatory Medicare beneficiaries and the physicians and pharmacists who serve them. Therefore, we encourage CMS to identify the NCPDP SCRIPT Standard as one that can be adopted ahead of the statutory timeframe.

(2) CMS: Therefore, to the extend we determine, after consultation with affected standard setting organizations and industry users, that there already is adequate industry experience with certain standards, we may propose to finalize those standards through notice and comment rulemaking even if we have not completed the pilot testing of other standards so that a portion of the standards adoptions process could be expedited. We seek comments on the desirability of this strategy, including any concerns about potential unintended consequences.

In its September 2, 2004 letter to Secretary Tommy Thompson of the Department of Health and Human Services, the National Committee on Vital and Health Statistics did identify two existing industry standards as "foundation standards" that are ready for use by the industry and could, therefore, be finalized through notice and comment rulemaking prior to the completion of pilot testing of other standards. These standards were (1) the most current version of NCPDP SCRIPT for new prescriptions, prescription renewals, cancellations, and changes between physicians and dispensers and (2) the ASC X12N 270/271 Health Care Eligibility Inquiry and Response Standard Version 004010X092A1 for conducting eligibility inquiries from physicians to

payers/PBMs. We strongly agree that it would be desirable for all stakeholders if CMS were to finalize the adoption of the NCPDP SCRIPT Standard, see no potential unintended consequences of doing so, and hence encourage the agency to proceed accordingly at this time.

(3) CMS: In order to facilitate electronic prescribing by a PDP or MA-PD sponsor, we invite public comment on additional steps to spur adoption of electronic prescribing, overcome implementation challenges, and improve Medicare operations.

Inasmuch as CMS has already added regulations at § 423.159(b) that would allow an MA-PD plan to provide separate or differential payment to a participating physician who prescribes covered Part D drugs in accordance with electronic prescription standards, we also encourage CMS to allow MA-PD plans to make similar incentive payments to participating pharmacies. Both the upfront and ongoing costs of implementing electronic prescribing will be substantial for community pharmacies (and quite likely of greater magnitude than for physicians), so such payments to pharmacies would be entirely supportable and justified.

(4) CMS: We note that any payments must be in compliance with other Federal and State laws, including "the physician self-referral prohibition at section 1877 of the Act" and the Federal anti-kickback provisions at section 1128B(b) of the Act. We are soliciting the public's view of the application of these legal authorities to the differential payments described in this section. We will share any comments regarding the anti-kickback statute with the Office of Inspector General.

Some relief from the anti-kickback statute in support of electronic prescribing would aid adoption by physicians. We are aware that hospitals, health systems, and other stakeholders are reluctant to embark on aggressive electronic prescribing initiatives on the advice of counsel because of the provisions in anti-kickback statutes. We encourage broad relief from those statutory elements that are constraining investment in electronic prescribing.

We also encourage any such relief to be mindful of the operational difficulties that would require electronic prescribing systems to be able to parse functionality on the basis of that used to benefit only Medicare beneficiaries, versus all patients. We encourage as broad a relief as possible. We also encourage that specific emphasis be placed on relief that is tied to physician and staff training, physician utilization and bi-directional communication with pharmacies.

(5) CMS: The electronic prescribing process and the technology that enables it must be cost effective, the systems must be fast and easy to use, and alerts and other data passed back to the prescriber must demonstrate value. We invite comments on these challenges and on possible Federal activities that would promote the effective use of e-prescribing by providers, including publishing best practices, and making technical information on e-prescribing products available.

The history of electronic prescribing efforts over the past decade clearly shows that the way in which electronic prescribing technologies are—or are not—effectively woven into health care providers' workflows has a strong effect on whether said technologies are adopted. On the

physician side, the time it takes to create a prescription electronically must be nearly as brief as it now takes them to write prescriptions by hand, otherwise there is a barrier to the adoption of the technology. On the pharmacy side, it is apparent that the way in which pharmacy management systems are updated to accommodate electronic prescribing can also have a significant impact on adoption and utilization. Because both physician and pharmacy systems are proprietary in nature, the companies who market these technologies rarely, if ever, share successful design features with competitors. Therefore, CMS's publishing of best practices so that all electronic prescribing companies can offer systems that address the majority of providers' needs, as well as making technical information on e-prescribing products available so that providers can make informed comparisons, should support the effective adoption and use of electronic prescribing.

(6) CMS: In addition, receptivity to the use of electronic prescribing by consumers is not well understood, especially among the elderly and disadvantaged populations. We seek additional information on how those populations may view electronic prescribing and what step may be taken to get them to use this modality and, thus, take advantage of the safety and quality benefits it offers.

In August of 2002, SureScripts released the results of a survey that Harris Interactive conducted for the company to identify the attitudes and perceptions that the public held toward electronic prescribing. The study found that Americans associated electronic prescribing with a number of benefits including:

- 61 percent felt they would have less waiting time at the pharmacy when electronic prescribing is used
- 51 percent believed that electronic prescribing would yield faster prescription renewals
- 40 percent said electronic prescribing would minimize opportunities for errors associated with handwritten prescriptions
- 26 percent responded that electronic prescribing would allow more time to discuss the medicines with their pharmacists

Though this small study was not targeted toward elderly or disadvantaged populations, it did show that the public in general does have some understanding of the benefits that they can expect to experience when health care providers communicate using electronic prescribing.

(7) CMS: We also invite comments on how to promote the use of electronic prescribing by providers, health plans and pharmacies and other entities involved in the provision and payment of health care to Medicare beneficiaries. Beyond the grants authorized in § 423.159(b) of this proposed rule, we invite comments on what incentives could be used to spur more widespread adoption, especially for early implementers.

SureScripts encourages CMS to support the use of incentives for physician practices that adopt electronic prescribing. We caution, however, that incentives that are merely hardware or software license fee giveaways may fall short of creating the longer term utilization of the

technology we all want. We do encourage CMS to consider incentive programs that contain one or more of the following elements:

- Incentives for both physician and staff use
- Incentives that require some minimum utilization of the technology, for example a minimum number of prescriptions per month
- Incentives that require bi-directional communications with pharmacies to encourage real collaboration
- Incentives that support the training of physicians and physician practice staff
- Incentives that support both the communications of new prescriptions, but also those resulting from the refill authorization process (renewals)

With respect to pharmacies, currently over 75 percent of community pharmacies in the United States have software that enables them to communicate with physicians using electronic prescribing. Given this good faith effort on the part of the pharmacy profession to become ready to use electronic prescribing, it would make good sense for CMS to further stimulate the process by offering community pharmacies financial incentives to use the technology. This is especially important because community pharmacies will be supporting a disproportionate share of the overall e-prescribing infrastructure and transaction costs.

(8) CMS: We also invite your comments on what educational efforts or data analyses might be undertaken to help health practitioners understand, or empirically confirm, and ultimately realize, the benefits of electronic prescribing.

Although there are some reports in the literature that speak to the benefits of electronic prescribing to patients, physicians, pharmacists, and other stakeholders, few could be considered authoritative. In fact, most of these reports are anecdotal in nature. Because there is such a dearth of solid research on the benefits of electronic prescribing, SureScripts has undertaken two research projects to obtain much more definitive data on the benefits of electronic prescribing. The first project is our Prescription Process Validation Project, which is more qualitative in nature, and the second is our Pharmacy ROI Project, which is more quantitative in nature. We expect to have completed both of these projects no later than early spring of 2005, and it would be our pleasure to share the results of these studies with CMS. If this would be of interest to CMS, please let us know and we will contact you as soon as we have results that merit your attention.

Additional SureScripts Comments

(9) Commercial messaging at the point of care

Congress clearly stated its concern about the potential for the commercial abuse of the electronic prescribing process by including language in the MMA that electronic prescribing standards "allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems to reduce medication errors, to avoid adverse

drug interactions, and to improve medication use." Therefore, commercial messaging at the point of care during the prescribing process should not be allowed. Point of care is defined as both at the physician office as well as at the pharmacy. Commercial messaging consists of two varieties:

- Any message delivered at the point of care that is paid to be delivered by a third party during the prescribing process should be considered a commercial message. There is a potential for messages that could be paid for by manufacturers, payers, pharmacies, PBMs, or any other party interested in determining the decision made for a particular medication or a particular pharmacy where the medication would be dispensed.
- Any message to persuade a decision at the point of care after a decision or selection of pharmacy or selection of medication is made by a provider of care should be considered a commercial message. In other words, if pop-up messages occur after a physician selects a pharmacy or after a physician selects a medication, such pop-ups should be considered a commercial message.

In addition to these types of commercial messages, an inappropriate commercial bias can be also be injected into the electronic prescribing process if physicians are not shown all relevant information. For example, showing only part of a formulary could lead a physician and the patient to assume medications not listed in an electronic prescribing application are not covered when, in fact, they may just have a higher copay than the preferred medication. Hence, physicians should be presented complete formulary information at the beginning of the prescribing process.

(10) The community pharmacist's role in the prescribing process should be supported by the proposed rule

CMS should ensure that the final e-prescribing rules support the integral role that pharmacists play in the prescribing process. These rules should facilitate the collaboration of physicians and pharmacists so that physicians have all the relevant information necessary to make truly informed prescribing decisions. Community pharmacists frequently have the most complete record of a patient's medication history because they routinely monitor and coordinate multiple physician medication therapies and provide counseling to patients regarding <u>all</u> of their medication therapies. Typically, payer payment history databases exclude:

- Medications that the patient received prior to coverage by the current PBM
- Medications that are covered under worker's compensation or a spouse's plan
- Medications that cost less than the PBM copayment and are paid for with cash
- Medications paid for by PhRMA company patient assistance programs
- Non-covered and/or "sensitive" medications that patients pay for with cash
- Medications covered by a major medical plan rather than a PBM plan
- Experimental medications not covered by PBMs
- Over-the-counter medications, vitamins, minerals, and other nutritional products

Payers also do not have information that patients provide specifically to the pharmacist during patient counseling, such as potential allergies, sensitivities, and other adverse reactions.

In order to provide the safest and most effective therapies to Medicare beneficiaries, physicians must be able to effectively interact with pharmacists to conduct drug utilization review and to ensure that prescribing decisions are appropriate. To support these efforts, e-prescribing standards should ensure that pharmacists have complete access to all of a patient's medical information and medication history. This will enhance the quality of care provided to patients and help ensure that the drug utilization review process is both cost-effective and comprehensive. Therefore, we strongly urge CMS to develop and implement e-prescribing rules that support this important bi-directional exchange of information.

Conclusion

SureScripts appreciates the opportunity to continue to provide advice and assistance to CMS as it works to implement the electronic prescription program requirements of the MMA through this proposed rule. We hope CMS will continue to take advantage of the experience that SureScripts can share with respect to the real-world implementation of electronic prescribing for the purposes of improving the safety, efficiency, and quality of the overall prescribing process. Please do not hesitate to have your staff contact us should they have any questions regarding the comments we have offered above or if the are any other ways that we can assist them in this important work.

Sincerely,

Ken Whittemore, Jr.
VP, Professional and Regulatory Affairs

ken.whittemore@surescripts.com

CMS-4068-P-1256

Submitter : Mr. Scott Shields **Date & Time:** 10/04/2004 08:10:49

Organization : Aventor

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

On behalf of Dey, L.P., we are pleased to provide CMS with comments to CMS-4068-P. We have attached our full comments and an executive summary of the comments.

CMS-4068-P-1256-Attach-2.doc

CMS-4068-P-1256-Attach-1.doc

Executive Summary
Comments on "Medicare Program; Medicare Prescription Dug Benefit; Proposed Rule"
(CMS-4068-P)

Dey, L.P. appreciates the opportunity to comment on the following issues addressed in the above-referenced proposed rule and its preamble:[1]

- Subpart C – Benefits and Beneficiary Protections
  - Section 423.100 (Definition of "Covered Part D Drug")
  - Section 423.120 (Access to Covered Part D Drugs)

- Subpart D – Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans
  - Section 423.153 (Cost and Utilization Management, Quality Assurance, Medication Therapy Management Programs, and Programs to Control Fraud, Abuse, and Waste)

Key Overall Point: CMS acknowledges the statutorily-mandated distinction between Part B and Part D drugs. Our principal concern is that the agency inappropriately suggests that certain Part B drugs with characteristics such as those described in the proposed rule's preamble – i.e., drugs covered as incident to a physician's service or furnished through an item of DME – could be covered under Part D.

"Covered Part D Drug": Dey supports the principle enunciated in the rulemaking that Part D "wraps around" Part B, providing beneficiaries with drug coverage that is seamless. However, portions of the preamble extend this "wrap around" principle beyond reasonable bounds. Specifically, the preamble cites examples that could be interpreted to confer Part D coverage on infusion and injectable drugs in situations that are currently within the Part B claims administration authority of the DMERCs. Similarly, in addressing dispensing fees for Part D drugs, CMS identifies options that, if implemented with respect to infusion drugs, could be applied more broadly – and inappropriately – to other Part B services.

> *Recommendation*: CMS should make clear that DME drugs used in situations now covered under Part B are excluded from coverage under Part D.

Access to Covered Part D Drugs: The rulemaking appropriately addresses means for ensuring that beneficiaries have access to Prescription Drug Plans (PDPs) that include in their networks' long-term care pharmacies and home infusion pharmacy providers. However, because these pharmacies/providers offer drug-related services that are typically covered under Part B, CMS should take special care to ensure that Part D coverage does not substitute for coverage available under Part B. In fact, we read the preamble's language on these points almost to invite such substitution. For example, CMS seeks comments on whether PDPs should receive performance incentives for producing Medicare savings under Parts *A and B* – virtually an open invitation to replace Part B drug coverage with Part D coverage if the PDP believes it will save money.

[1] 69 Fed Reg 46632 (Aug. 3, 2004).

The Medicare Modernization Act (MMA) clearly did not contemplate this type of Part D-Part B substitution. Indeed, the MMA, in establishing a Chronic Care Improvement Program, provided a separate means for CMS (on a demonstration basis) to test methods for identifying clinical and economic synergies among Parts A, B, and D.

> *Recommendation*: CMS should make clear that PDPs may not substitute Part D drug coverage in situations in which Part B drug coverage is available.

Medication Therapy Management: CMS solicits comments on whether the terms "multiple covered Part D drugs" and "multiple chronic diseases" should be defined by the agency itself or by PDPs. Both terms implicate use of disease management tools – tools that Dey supports. However, we are concerned that inappropriately inserting these tools into Medicare Part D, but not into Part B, could exert a counterproductive, asymmetrical effect. That is, by rewarding PDPs for exacting savings on a drug used in a situation that makes it Part D-covered (when, in other situations, it is Part B-covered) could discourage PDPs from considering the clinical factors DMERCs have long taken into account in administering Part B drug claims.

> *Recommendation*: CMS, not PDPs, should define the key terms. In so doing, the agency should maintain a level playing field among Medicare contractors, preventing PDPs from inappropriately reducing utilization for a subset of the situations in which a drug is used.

Drug Utilization Management: The preamble, in addressing industry standards for drug utilization management, suggests incentives to reduce costs "when medically appropriate" – a phrase not defined.

> *Recommendation*: The phrase "medically appropriate" should be defined to include criteria for ensuring that compounding of drugs is performed in a fashion consistent with patient safety and FDA's requirements.

DATE: October 4, 2004

Centers for Medicare and Medicaid Services

Department of Health and Human Services

Attention CMS-1429-P

P.O. Box 8012

Baltimore, Maryland 21244-8012

Re: [CMS--4068-P] Medicare Program; Medicare Program; Medicare Prescription Drug Benefit

Dear Sir or Madam:

Dey, L.P. is pleased to submit the following comments regarding the above-referenced proposed rule (Proposed Rule).[1] Dey, L.P. welcomes the opportunity to work with the Centers for Medicare and Medicaid Services (CMS) as it develops policy for drugs currently covered as a Part B benefit with the potential for coverage as a Part D benefit in 2006.

Dey, L.P. develops, manufactures, and markets prescription pharmaceuticals for the treatment of respiratory illnesses, including chronic obstructive pulmonary disease (COPD), a condition that represents a significant financial burden for the Medicare program and a serious threat to patient longevity and quality of life.

We propose that CMS clarify in the final rule to specifically exclude from Part D those drugs covered under Part B because they are incident to durable medical equipment (DME).

We are providing comments on three sections of the Proposed Rule that hold implications for the availability of drugs provided as a Part B benefit that may, under some circumstances, be provided as a Part D benefit:

1. Section 423.100, regarding the definition of a covered Part D drug;
2. Section 423.120, regarding access to covered Part D drugs; and
3. Section 423.153 in Subpart D Cost Control and Quality Improvement Requirements for Prescription Drug Plans

Various examples in the proposed rule could establish a precedent for changing coverage from an existing benefit (Part B) to a new one (Part D), thereby violating the "wrap around" principle that CMS has enunciated for Part D.

We suggest that CMS specify clearly in the final rule that drugs currently covered under Part B, either incident to a physician service, or incident to the DME benefit, be excluded from Part D coverage until such time as the Secretary issues the report on this subject (required under the Medicare Modernization Act) and the Congress acts to give CMS the authority to implement any recommended changes stemming from the report.[2]

[1] Proposed Rule, 69 Fed Reg 46631 (Aug. 3, 2004).
[2] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, sec. 101(d).

1. **Subpart C. Voluntary Prescription Drug Benefit and Beneficiary Protections**

   a. ***Proposed Section 423.100 Definition***[3]

The proposed rule includes a definition of two terms that would benefit from more specificity:

- "Covered Part D Drug,"[4] and
- "Dispensing fee."[5]

Covered Part D Drug

CMS addresses the complex issue of drugs that can be covered under Part A, B or D, depending on the form of administration and site of service. While the Part D benefit is expected to be a "wrap-around" to the other benefits, the rulemaking contains descriptions of infusion or injectable drugs that have characteristics similar to a nebulized drug, and others that are administered through DME, where the drug product could be picked up at a pharmacy and be self-administered at home.

Our concern is that the examples include situations that are currently within the purview of the DMERCs and are intended to be addressed in subsequent regulations regarding the competitive acquisition programs for Part B drugs, supplies, medical equipment and related services. We recognize that some drug delivery mechanisms are not covered under Part B, and that beneficiaries could benefit from the "wrap-around" nature of the Part D benefit.

[3] 69 Fed Reg 46646.
[4] 69 Fed Reg 46646.

However, a drug administered through DME should remain a Part B covered service when it is used in a setting which is currently covered by the DMERCs; furthermore, we propose that it should be specifically excluded from Part D. Coverage for these products has evolved over many years, and the coverage criteria and decisions reflect the complex issues that need to be considered in order to structure a program that does not disrupt existing services. This consideration is beyond the scope of reform contemplated by Congress, prior to an analysis by the Secretary.

Part D Dispensing Fee

We commend CMS for clearly stating that the definition of a dispensing fee would apply specifically to Part D, and we agree with the agency's preference for the first of the three options described in the proposed rule; i.e., a single fee associated solely with dispensing of the prescription. We recognize the need for CMS to consider Options 2 and 3 (involving the necessary equipment and supplies and the necessary professional services of a nurse or pharmacist) for home infusion drugs.

However, if Options 2 and 3 are part of the final rule, PDPs should be excluded from applying such fees to reimburse for the costs of services currently subject to Part B coverage. Our concern is that permissible instances in which Options 2 and 3 may be needed (e.g., to reimburse for the costs of supplies and services associated with home infusion drugs that may not be covered currently under Part B) could be applied more broadly and inappropriately to other Part B covered services. Our concern is specifically

[5] 69 Fed Reg 46647.

grounded in the reimbursement circumstances surrounding Dey's product, DuoNeb® Inhalation Solution ("DuoNeb"), used in the treatment of COPD. We presented these concerns in our September 17, 2004 letter in response to **[**CMS-1429-P] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005. A summary of the rationale is provided in Exhibit A.

b. Proposed Section 423.120 Access to Covered Part D Drug[6]

Our concerns relate to two provisions regarding the ways in which Medicare beneficiary access to pharmacies can be assured. Specifically, we have concerns regarding CMS preamble language pertaining to availability of PDP access to 1) long term care pharmacy, and 2) home infusion pharmacy providers.

1) Long Term Care Pharmacy

While it is appropriate for CMS to consider whether the new Medicare Prescription Drug Plans (PDPs) should be required to include long-term care pharmacies in their plans and to take into account how the PDP might reimburse these pharmacies for services such as infusion therapy and 24 hour medication delivery, our concern is that such services should be excluded from Part D coverage if Part B coverage is available.

2) Home Infusion Pharmacy

The issue is the same for home infusion pharmacies, although we note with some concern that CMS is seeking comments on ways to encourage PDPs, who do not have a medical benefit and therefore cannot realize efficiencies from reduced hospital costs, to establish

contracts with home infusion pharmacies. The potential to offer performance incentives for Part D contractors for savings under Part A or Part B goes beyond the scope of what MMA contemplated. These types of savings could more appropriately be captured under the Chronic Care Improvement Program, which MMA established as a demonstration.

2. Subpart D. Cost Controls and Quality Improvement Requirements for Prescription Drug Benefit Plans

a) Proposed Section 423.153 Cost and Utilization Management, Quality Assurance, Medication Therapy Management Programs and Programs to Control Fraud, Abuse and Waste

Two provisions of this proposed section could be detrimental to Medicare beneficiaries' continued access to Part B covered drugs and related services:

- Cost Effective Drug Utilization Management[7] (relating to the use of compounded drugs); and
- Medication Therapy Management[8] (relating to providing appropriate nebulizer utilization).

Cost Effective Drug Utilization Management

CMS solicits comments on industry standards for cost effective drug utilization management, which includes the use of incentives to reduce costs, "when medically

[6] 69 Fed Reg 46655.
[7] 69 Fed Reg 46666.
[8] 69 Fed Reg 46668.

appropriate," which is not defined. We suggest that the term "medically appropriate" should specify criteria as to when using compounded drugs would be considered a medically appropriate incentive to reduce costs.

Specifically, we believe CMS should ensure that compounding is done on a patient-name prescription basis, and that pharmacies use all compounding and admixing precautions to ensure product sterility and freedom from microbe ingress contamination. Patient safety is crucial, and the quality of the compounded product should be comparable to a commercial drug product.

Another area of concern regarding compounding is that the FDA prohibits pharmacy compounding of two or more separate FDA-approved products when a combination product approved by the FDA is commercially available.[9]

Specifically, in the past six months alone, the FDA has cited and sent warning letters to several pharmacies for the following compounding violations: preparing drug products that are commercially available, and compounding drugs "without the necessary controls to ensure drug product sterility and potency."[10,11,12]

[9] Food and Drug Administration. Compliance Policy Guidance for FDA Staff and Industry. Sec. 460.200 (Pharmacy Compounding). June 7, 2002. Accessed August 10, 2004 at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html.
[10] FDA warning letter to Axium Healthcare Pharmacy, June 7, 2004, at http://www.fda.gov/cder/warn/2004/AXIUM%20%20wl.pdf.
[11] FDA warning letter to Gentere, Inc., July 13, 2004, at http://www.fda.gov/foi/warning_letters/g4863d.htm.
12 FDA warning letter to delta Pharma, Inc., September 17, 2004, at http://www.fda.gov/foi/warning_letters/g4965d.htm.

Violations of the FDA policy against compounding commercially-available drugs affect DuoNeb, since it is a currently marketed, sterile, non-allergenic, premixed combination drug; these manufacturing processes are designed to lower the risk of drug cross-contamination and to minimize waste. The premixed, unit-dose combination of the two agents within DuoNeb enhances patient safety by minimizing the chance for medication errors, and it eliminates the need for the Medicare patient to nebulize two different solutions, resulting in faster treatment times and improved compliance.

As for the second category of violation – compounding drugs "without the necessary controls to ensure drug product sterility and potency" – quite obviously patient safety is at risk, and a threat to public health is created. We also note that, in 2002, the FDA sampled 29 drugs from compounding pharmacies and found that 10 were subpotent.[12] In all, the compounded drugs sampled by the FDA registered a 34 percent failure rate – far in excess of the comparable two percent rate for commercially-available drugs.[13]

These examples highlight the complexity unique to prescription drugs covered under Part B and the need for greater clarity and precision in the Part D proposed rule.

Medication Therapy Management Program

CMS solicits comments on whether it should define the terms "multiple covered Part D drugs" and "multiple chronic diseases", or allow the PDPs to define the terms as part of their bids to CMS. While we support the use of appropriate disease management tools

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[12] Report: Limited FDA Survey of Compounded Drug Products. Food and Drug Administration. Accessed August 24, 2004 at http://www.fda.gov/cder/pharmcomp/survey.htm.
[13] *Id.*

such as the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, our concern is that CMS maintain a level playing field among its contractors and not create an advantage for PDPs who potentially could be rewarded for reducing nebulizer use among a sub-set of COPD patients, without adequately considering clinical factors such as those included in the DMERC coverage policies.

Conclusion

Dey, L.P. appreciates the opportunity to comment on these three proposed sections that – absent additional clarification – could affect Medicare beneficiaries' access to life-saving and quality-of-life enhancing medications. We base our observation on examples contained in the proposed rule that, while casually presented, belie the underlying complexity that results when coverage could be provided under different benefits, depending on the route of administration and site of service. Coupled with the concerns we raised in our response to the proposed rule on Part B payment, we are compelled to reiterate our recommendation that CMS develop a cohesive strategy for inhalation drug therapy based on clinical guidelines and correct assumptions as to the medical necessity of nebulizer-based therapy by some patients. In addition, including pharmacy compounding as an activity whose costs may be included in the dispensing fee could be troublesome, given that on certain occasions pharmacy compounding is not appropriate and should not be reimbursed by PDPs.

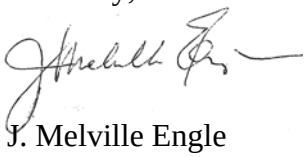
We urge CMS to revisit the proposed changes regarding a revised (or incremental) dispensing fee by conducting a study of the appropriate activities and their costs, and by considering the considerable operating and patient-support expenses borne by pharmacies.

The concept of a "service fee" may be a more appropriate description of the various pharmacy activities and expenses.

Dey, L.P. believes that CMS needs to be more specific in the final regulation about the Part D benefit for those prescription drugs that can be covered under the Part B benefit. The MMA includes several provisions related to the latter that will be implemented over the next few years and also calls for the Secretary to study these issues and report to Congress. We know the complexity of the issues related to inhalation products and support an approach that considers them in the overall context of respiratory disease costs to the Medicare program. It is important to get the right prescriptions to patients using the most appropriate delivery mechanism, be it nebulizers, MDIs, or dry powder inhalers (DPIs), all of which are found in clinical practice guidelines and will be included in Medicare's benefits as of 2006. CMS and its contractors need to strive for consistency with existing Medicare policies and FDA polices to ensure that payment policy changes do not create incentives for activities that are not consistent with the coverage of products under existing benefits and the assurances provided to the public by the FDA.

Thank you for the opportunity to present our views with respect to these selected provisions detailing how the Part D benefit will be implemented.

Sincerely,



J. Melville Engle

President and CEO

Nebulizers versus MDIs

We feel compelled to correct the record regarding the stance CMS has taken regarding the relative and comparative value of nebulizers versus MDIs. In the portion of the Proposed Rule preamble pertaining to MMA Section 305, CMS states that Medicare beneficiaries have a "strong" financial incentive to use nebulizers since the alternative inhalation drug delivery mechanism, metered dose inhalers (MDIs), currently are not covered under Part B, and beneficiaries will have to wait until January 2006 to be covered under the new Part D drug benefit. CMS also states that, based on a literature review, nebulizers are no more effective than MDIs in delivering bronchodilators, and CMS predicts a substantial shift from nebulizers to MDIs once the latter become covered under Part D beginning in 2006.[14] We fear CMS may underestimate the clinical value, patient preference and improved outcomes for nebulized respiratory medication which is based on a reduction of symptoms and improved quality of life, not financial incentives.

While it is true that some studies have shown that nebulizers and inhalers are equally effective, the performance of inhalers was augmented by spacers.[15,16,17] Spacers are designed to deliver MDI-delivered medication more easily and effectively. In common

[14] Proposed Rule, 69 Fed Reg 47546, 47548.
[15] Turner MO, Patel A, Ginsburg S, Fitzgerald JM. Bronchodilator delivery in acute airflow obstruction. A meta-analysis. *Arch Intern Med*. 1997 Aug 11-25;157(15):1736-44.
[16] Duarte AG, Momii K, Bidani A. Bronchodilator therapy with metered-dose inhaler and spacer versus nebulizer in mechanically ventilated patients: comparison of magnitude and duration of response. *Respir Care*. 2000 Jul;45(7):817-23.
[17] Schuh S, Johnson DW, Stephens D, Callahan S, Winders P, Canny GJ. Comparison of albuterol delivered by a metered dose inhaler with spacer versus a nebulizer in children with mild acute asthma. *J Pediatr*. 1999 Jul;135(1):22-7.

practice, studies have shown that patients only use spacers to be used with inhalers approximately 50 percent of the time.[18,19] **Without** accessories such as spacers, much of the medication is left in the mouth and throat, thus reducing absorption and efficacy.[20]

In addition, the literature is replete with studies showing that many patients, up to 89%, do not employ proper inhaler technique.[21,22,23] Therapeutic benefit depends on sufficient deposition of drugs in the medium and small airways; this is largely determined by a competent inhaler technique.[24,25] The most recent report of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) states that "COPD patients may have more problems in effective coordination and find it harder to use a simple Metered Dose Inhaler (MDI) than do healthy volunteers or younger asthmatics."[26]

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[18] Dow L, Phelps L, Fowler L, Waters K, Coggon D, Holgate ST. Respiratory symptoms in older people and use of domestic gas appliances. *Thorax* 1999; 54: 1104-1106. Fifty-four percent of the study population using MDIs used spacers; 45 percent of the study population using MDIs did not us a spacer.
[19] Bynum A, Hopkins D, Thomas A, Irwin C, Copeland N. The Effect of Telepharmacy Counseling on Metered-Dose Inhaler Technique Among Adolescents with Asthma in Rural Arkansas. Presentation. The University of Arkansas for Medical Sciences. 2000 American Telemedicine Association Annual Meeting. Accessed September 15, 2004 at http://www.atmeda.org/news/2000_presentations/Rural/Bynum.pps. Fifty-one percent of the study population did not use spacers with MDIs.
[20] Selroos O, Halme M. Effect of a volumatic spacer and mouth rinsing on systemic absorption of inhaled corticosteroids from a metered dose inhaler and dry powder inhaler. *Thorax*. 1991 Dec;46(12):891-4.
[21] Erickson SR, Horton A, Kirking DM. Assessing metered-dose inhaler technique: comparison of observation vs. patient self-report. *J Asthma.* 1998;35(7):575-83.
[22] ICSI Health Care Guidelines: Chronic Obstructive Pulmonary Disease, Third Edition/Dec 2003. Accessed September 2, 2004 at http://www.icsi.org/knowledge/detail.asp?catID=29&itemID=157.
[23] Johnson DH, Robart P. Inhaler technique of outpatients in the home. *Respir Care*. 2000 Oct;45(10):1182-7.
[24] Newman SP, Pavia D, Clarke SW. How should a pressurized beta-adrenergic bronchodilator be inhaled? *Eur J Respir Dis* 1981;62:3–20.
[25] Newman SP, Moren F, Pavia D, et al. Deposition of pressurized aerosols in the human respiratory tract. *Thorax* 1981;36:52–5.
[26] Global Initiative for Chronic Obstructive Lung Disease, Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2004 Update), at 68, available at http://www.goldcopd.com.

Market research has confirmed the practical superiority of nebulizers to MDIs, as judged from the patients' perspective. One study compared the value of nebulizer systems with MDIs from the patient's perspective, based on an analysis of 1,369 questionnaires.[27] According to the study, nebulizer systems were preferred and considered by patients to be more effective at symptom control than MDIs. Key findings were as follows:

- Fifty-seven percent (57%) of patients surveyed said their symptoms were better controlled with a nebulizer system than with an MDI.
- Eighty-two percent (82%) said the nebulizer system controlled their symptoms for a longer period of time than the MDI.
- Over 80% of patients said the nebulizer system had given them a better quality of life than an MDI alone. Nearly 70% of patients surveyed said the nebulizer system had helped them avoid a trip to the emergency room.
- Fifty-six percent (56%) of these patients said use of a nebulizer system helped to avoid hospitalization.
- Fifty-eight percent (58%) of these patients had avoided unscheduled office visits by using their nebulizer systems.

In short, nebulizers are the preferred method of delivery of bronchodilators for a large proportion of COPD patients, including Medicare beneficiaries. In the preamble, CMS expresses concern that the access of beneficiaries to nebulized bronchodilators in 2005 might be restricted, due to the reduction in Part B payment rates for frequently used

[27] Safian Communications, Inc. Patient Assessment of Efficacy of Nebulizer Systems on Their Respiratory Health. April 1995 (report available on request).

bronchodilators.[28] We agree this is a serious concern, but we submit that it is not a short-term problem that will disappear in 2006. Beneficiaries' continued need for nebulized bronchodilators, even after MDIs become covered under Part D, will make it all the more essential that CMS adequately reimburse providers for these drugs under Part B on an ongoing basis.

[28] Proposed Rule, 69 Fed Reg 47549.

EXHIBIT B

Circumstances Where Compounded Combination Albuterol and Ipratropium Should Not Be Covered Under Medicare

FDA Prohibition of Certain Types of Pharmacy Compounding

Certain types of pharmacy compounding are discouraged by FDA policy, as articulated in Compliance Policy Guide (CPG), Section 460.200, issued on June 7, 2002.[29] The CPG contains factors that the agency considers in deciding whether to exercise its enforcement discretion. One factor is whether a firm **compounds drug products that are commercially available, or which are essentially copies of commercially available FDA-approved products**.[30]

If one or more of the factors identified in CPG section 460.200 are present, such compounding pharmacies may be manufacturing drugs which are subject to the new drug application (NDA) requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA), but for which the FDA has not approved an NDA, or which are misbranded or adulterated. If the FDA has not approved the manufacturing and processing procedures used by these facilities, the FDA has no assurance that the drugs produced are safe and efficacious. Safety and efficacy issues pertain to such factors as chemical stability, purity, strength,

[29] Compliance Policy Guidance for FDA Staff and Industry. Sec. 460.200 (Pharmacy Compounding). Food and Drug Administration. June 7, 2002. Accessed August 10, 2004 at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html.

[30] Emphasis supplied. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.

bioequivalency, and bioavailability. Dey, L.P. is concerned that patients may be receiving unsafe, unsterile drugs of unknown potency and composition, a needless risk when, in the case of pharmacy-compounded albuterol and ipratropium, an FDA-approved inhalation solution is available in DuoNeb® Inhalation Solution.

Based on 1) the NDA requirements of the FFDCA, and 2) CPG §460.200, pharmacy-compounded combinations of albuterol and ipratropium that contain equivalent amounts of the active ingredients in DuoNeb® Inhalation Solution are prohibited by the FDA.

Medicare Denial of Payment for Certain Types of Pharmacy Compounding

If the FDA prohibits pharmacy-compounded combinations of albuterol and ipratropium, then chapter 15, section 50.4.7 of the Medicare Benefit Policy Manual, entitled "Denial of Medicare Payment for Compounded Drugs Produced in Violation of Federal Food, Drug, and Cosmetic Act," should apply. The applicable portion of §50.4.7 reads as follows:

> Section 1862(a)(1)(A) of the Act requires that drugs must be reasonable and necessary in order to be covered under Medicare. This means, in the case of drugs, the FDA must approve them for marketing. Section 50.4.1 instructs carriers and intermediaries to deny coverage for drugs that have not received final marketing approval by the FDA, unless instructed otherwise by CMS. The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §180, instructs carriers to deny coverage of services related to the use of noncovered drugs as well. Hence, if DME or a prosthetic device is used to administer a noncovered drug, coverage is denied for both the nonapproved drug and the DME or prosthetic device.[31]

[31] Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual. Chapter 15 (Covered Medical and Other Health Services); §50.4.7 (Denial of Medicare Payment for Compounded Drugs

In order to provide consistency across all benefit categories, all Medicare contractors, including PDPs should adhere to provisions such as those in the Medicare Benefit Policy Manual. This would ensure that any claim for a drug that requires FDA approval but is not FDA-approved would be denied, regardless of the benefit category under which the claim was made. For example, payment for combination products such as albuterol and ipratropium, and the delivery system used to administer the drugs, should be limited to FDA-approved formulations.

Produced in Violation of Federal Food, Drug, and Cosmetic Act). Rev. 13. May 28, 2004. Accessed August 11, 2004 at http://www.cms.hhs.gov/manuals/102_policy/bp102c15.pdf.

CMS-4068-P-1257

Submitter : Diane Paulson **Date & Time:** 10/04/2004 08:10:00

Organization : Medicare Advocacy Project, GBLS

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-4068-P-1257-Attach-1.doc

CMS-4068-P-1257-Attach-2.doc

Medicare Advocacy Project
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197 Friend Street, Boston, MA 02114
(617) 371-1234, or toll-free (800) 323-3205
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September 30, 2004

http://www.cms.hhs.gov/regulations/ecomments

Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-4068

Dear Madam or Sir:

On behalf of the clients represented by the undersigned, we wish to submit the following comments on your proposed rule for the Medicare Prescription Drug Benefit. The Medicare Advocacy Project has over 15 years of experience advocating on behalf of Medicare beneficiaries, particularly those with low incomes; the Massachusetts Law Reform Institute is a statewide advocacy organization representing low income individuals, including elders and persons with disabilities; and the Disability Law Center (DLC) is a private, nonprofit protection and advocacy agency that provides free legal assistance to individuals with disabilities throughout Massachusetts. A key mandate of DLC is ensuring that people with disabilities are able to access needed supports to live and work in the community. Because of the limited time allowed and the magnitude of the proposed rule, we are not commenting on CMS-4069, dealing with Establishment of the Medicare Advantage Program. Neither are we commenting on all the sections of the proposed prescription drug rule. Rather, we are focusing on the impact of the rule on low income beneficiaries and persons with disabilities, particularly in the Eligibility and Enrollment and Grievances, Coverage Determination, and Appeals sections. In addition, we support and agree with the more detailed and comprehensive comments submitted on one or both of the proposed rules by the Medicare Consumers Working Group and the Center for Medicare Advocacy, Inc.

We also request that time be provided for another comment period due to the many unaddressed or only vaguely addressed issues. The final regulations could include a number of errors and provisions that result in unintended consequences because so much of the final regulations will not have been seen by the public. We urge CMS to issue the next version of these regulations in a format that will allow one more round of comment, even if a shortened comment period. This is a very complex program with significant ramifications for a large number of citizens. We are concerned that failure to provide for additional public input when the regulations are more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

PART 423-VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

General comments.

1. Many pro-consumer statements in the preamble do not appear in the proposed rule. These protections bear no weight unless captured in the regulations. More should be done to reflect the Preamble's good intentions in the body of the regulations. For example:

> The Preamble discusses providing affected enrollees, prescribers, pharmacists, and pharmacies with written notice when a drug will be removed from the formulary or moved to a different tier for cost-sharing. The regulatory language does not specify that the notice should be in writing. Requirement for written notice is critical and should be specified.
>
> The Preamble gives examples of situations when a plan will be required to allow an enrollee to use a non-network pharmacy. These include situations such as when an enrollee's plan does not contract with the long-term care pharmacy which an enrollee in a nursing home must use. The regulations should include the examples CMS discusses in the preamble.

2. There are a number of areas where the law is unclear or contradictory and these areas are creating serious problems for the regulation drafters. CMS should take advantage of the law's provision calling for the submission of technical and corrective amendments. While this was supposed to have been done by June 8, 2004, it should still be done, and Congress should address these issues as soon as possible.

3. Simplicity, as well as additional support for information and counseling, is necessary to ensure that beneficiaries are reached in a comprehensible way. The sheer size and complexity of these regulations is a testament to the fact that this new law is incredibly confusing. If beneficiaries are confused, enrollment and use of the new program will be very difficult, particularly for lower income, sicker, and limited English proficiency beneficiaries. Thus whenever it is possible, CMS should seek to simplify the new program.

Addressing some of our specific concerns:

Subpart B-Eligibility and Enrollment

1. The draft regulations addressing enrollment of beneficiaries into private drug plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDPs) do not adequately address the need for hands-on outreach, particularly to low-income beneficiaries, or to beneficiaries with special needs, such as mental illness. More attention must be given to developing materials and education and enrollment campaigns focused on informing beneficiaries with disabilities, including mental illness and cognitive impairments, and those with other special needs about the new drug benefit and helping them to enroll in the best plan available.

2. Of particular concern, is enrollment of the dual eligibles. Beneficiaries covered by both Medicare and Medicaid are by definition poor and cannot afford to pay privately fo fill any gaps in medication. Congress and the Administration promised that dual eligible beneficiaries would be better off with this new Part D drug benefit than they were receiving drug coverage through Medicaid. To honor this promise, coverage of medications for dual eligibles and other special populations must be grandfathered into the new Part D benefit. In addition, CMS must require plans to establish an alternative flexible formulary for dual eligibles as suggested in the preamble to the proposed regulations. This flexible formulary would incorporate utilization management techniques that focus on improving inefficient and ineffective provider prescribing practices but

do not restrict access to medications through prior authorization, fail first, step therapy, or therapeutic substitution requirements.

3. The regulations do not adequately address how drug coverage for the dual eligibles will be transferred to Medicare on January 1, 2006. There are issues both of timing and implementing the enrollment process in a way that will ensure that these beneficiaries do not confront a loss of benefits or a gap in drug coverage, either of which could have disastrous health consequences. Specific comments on enrollment of dual eligibles and our recommendations appear in our comments on §§423.34, 423.36, 423.48 and on Subpart P.

A. We are concerned with ensuring continuity of care for dual eligibles and access to needed prescriptions. These issues and concerns apply equally to all dual eligibles, and particularly to those with special health care needs, as well as to other populations with specific needs (See our comments in Subpart C, §423.120.)

B. The proposed regulations would force dual eligibles to enroll (or be automatically enrolled) in the "benchmark" or average cost plans in their areas because the low-income subsidy they will receive will only cover the premium for these plans. The formularies for these plans will not be as comprehensive as the drug coverage these individuals currently have through Medicaid. Even though Massachusetts has restricted access to drugs in its Medicaid program with preferred drug lists and prior authorization requirements, Massachusetts has taken many steps to ensure that special populations can readily access medically necessary drugs. For example, individuals who have been stabilized on one antidepressant are not required to try another one.

C. Without access to the coverage they need, dual eligibles will be forced to switch medications, which for certain populations, such as beneficiaries with HIV/AIDS or mental illness can have serious adverse consequences. Also, failing to ensure continuity of care for dual eligibles may benefit the plans, but will undoubtedly lead to Medicare and/or state increased costs for more physician and emergency room visits, and hospitalizations. The regulations do provide a special enrollment period for dual eligibles to use "at any time" (§423.36). However, being able to enroll in a different Part D plan is inadequate to meet the special needs of dual eligibles.

D. In the preamble to the proposed regulations, CMS points to an exceptions process as a means of securing coverage of off-formulary medications (See our comments to **Subpart M-Grievances, Coverage Determination and Appeals**) But the process proposed is extremely complex and cumbersome to navigate for someone having a psychiatric crisis, facing cognitive impairments, or in the midst of aggressive chemotherapy-to list just a few examples. Moreover, the timelines established are inordinately drawn out; for example, an expedited determination could take as long as two weeks. Drug plans are not required to provide an

emergency supply of medications until at least two weeks following a request. Exception, grievance and appeal processes should not be used to substituted for open formulary access to medications.

§423.34 Enrollment Process.

§423.34 (b) Enrollment.
The final rule should provide that an authorized representative may complete the enrollment form on behalf of a Part D eligible individual.

§423.34(c), Notice Requirement.
The notice must be in writing and inform an individual who is denied enrollment of his or her appeal rights, including the right to appeal the imposition of a penalty for late enrollment.

§423.34(d) Enrollment requirement for full benefit dual eligibles.
In the Preamble, CMS requested comments on whether CMS or the states should perform automatic enrollment of dual eligibles. State officials have more readily available data identifying the dual eligibles in their state and they also will be involved in the enrollment process because they are already required to perform low-income subsidy enrollment. In addition, there is an incentive for them to enroll these individuals in Medicare drug plans because without drug coverage they will increase utilization of other Medicaid services. Thus, states should be afforded the ability to conduct auto-enrollment and receive full federal financing for this function. In addition, CMS should develop its own systems for automatic enrollment of dual eligibles in states that do not elect to do so. Also, because the proposed rule leaves unanswered key questions about who will conduct automatic enrollment of dual eligibles and how it will occur, CMS must give the public the opportunity to provide input on any proposal it develops on this issue before publishing a final regulation.

§423.34(d)(1) General Rule.
The draft regulations provide that dual eligibles will be automatically enrolled in a Part D plan if they do not enroll themselves, by the end of the initial enrollment period, which, under §423.36, is May 15, 2006. However, their Medicaid prescriptions drug coverage will end on January 1, 2006. This proposed timeline for automatic enrollment must be changed because it could expose millions of dual eligibles to a four and half month coverage gap that could have serious health consequences for this vulnerable population. Given the difficulty of reaching this population coupled with inadequate provisions for outreach and education, it is almost certain that a substantial number of dual eligibles will face a several month gap in coverage between the end of Medicaid's drug benefit and automatic enrollment. This is untenable, and directly in conflict with Congress' and the Administration's promise that dual eligibles will be better off under Medicare Part D. The transfer of drug coverage from Medicaid to Medicare Part D should be delayed. Absent a delayed transition date for dual eligible drug coverage, however, dual eligibles should be randomly assigned and enrolled in a plan that best suits their needs as early as November 15, 2005 but no later than December 1, 2005. While we would prefer to provide individuals an extended period to make informed choices, it is critical to complete auto-enrollment as early as possible to leave as much time as possible to distribute plan information

and cards to beneficiaries, allow them to switch plans, and educate them about their new drug coverage before January 1, 2006. To make this process work more smoothly, states can begin profiling individual drug histories to prepare for random auto-assignment among plans that are appropriate for the individual even before plan information is released on October 15, 2005. Additionally, CMS should fund a campaign of individualized counseling and assistance both before and after auto-enrollment to explain to individuals their choices and how to enroll in a plan; explain, if applicable, how to get benefits under the plan to which they have been auto-assigned; and explain, if applicable, that they can choose a different plan from the one to which they have been auto-assigned and assist in choosing and enrolling in such a plan.

§423.34(d)(1)(ii)
CMS must develop a solution to the issue of automatic enrollment of dual eligibles who are enrolled in MA plans that have a prescription drug benefit with a premium that is above the low-income benchmark. The solution should be the one least disruptive to medical care and should not force a dual eligible to choose among continued MA enrollment, paying added premiums, or foregoing drug coverage. For institutionalized dual eligibles, the difference between the premium and the premium subsidy should be considered an incurred medical expense and deducted from their monthly "patient paid amount" to the facility. For non-institutionalized dual eligibles, in states with pharmacy assistance programs (SPAPs) which will wrap around Part D coverage and will cover dual eligibles, the SPAPs should be authorized to pay the difference. For medically needy individuals, the cost differential would be an incurred medical expense contributing toward their spenddown, if appropriate. Otherwise, individuals should be counseled about the premium discrepancy and about their right to withdraw from the MA plan and return to original Medicare. Ideally, dual eligibles who want to remain in the MA plan should be allowed to do so and not have to pay any amount by which the MA-PD basic premium exceeds the low-income benchmark amount.

§423.34(d)(2), When there is more than one PDP in a PDP region.
Because not every PDP plan may be appropriate for each dual eligible (for example, due to formulary restrictions), CMS should limit "on a random basis" to "among such plans in the region that meet the beneficiary's particular drug needs." Also, this subsection undermines the §423.859 right of assured access to a choice of at least two qualifying plans, by acknowledging that there may be regions where there is only one PDP in a PDP region with a monthly beneficiary premium at or below the premium subsidy amount.

§423.36 Enrollment Periods.

§423.36(a)(3)(ii) Exception.
It is not clear who these beneficiaries would be.

§423.36(c) Special Enrollment Periods.
This section should be expanded to provide "special enrollment exceptions" for individuals disenrolled by a PDP (such as for disruptive behavior) so that the individual will have an opportunity to join another PDP and continue with necessary medications. These "special enrollment exceptions" are necessary given the high risk of discrimination presented by the

provisions for involuntary disenrollment. CMS should provide a special enrollment period for these beneficiaries. It should include a reasonable time period for plan selection and be exempt from late enrollment penalties. It should also be expanded to make clear that involuntary loss of creditable prescription drug coverage includes loss because the beneficiary, or beneficiary's spouse, stops working; because COBRA coverage ends or because the premiums became unaffordable.

§423.36(c)(4) Special Enrollment Periods and Dual Eligibles.
We support granting dual eligibles special enrollment periods. However, this provision does not adequately address their needs. It is unlikely that there will be much choice of low-cost drug plans in each region, particularly in rural areas which have not historically attracted many Medicare+Choice plans. For example parts of Cape Cod and Western Massachusetts have no Medicare+Choice plans. In addition, these individuals will not have the resources to pay for more comprehensive coverage. Moreover, the special enrollment provisions do not specify that dual eligibles would not be subject to a late enrollment fee if this complex process of disenrollment and reenrollment resulted in a gap in coverage of over 63 days.

In addition, full benefit dual eligibles should receive notice explaining their right to a special enrollment period when they enroll in a plan, and every time their PDP changes its plan in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

§423.36(c)(8)
The regulations should include a special enrollment period similar to the one for dual eligibles for all beneficiaries eligible for a full or partial-low income subsidy. This is necessary because if coverage for a drug is denied, these low-income beneficiaries will be unable to afford to pay for drugs during a period of appeal, or if their appeal is denied and they are locked into a plan that does not cover a drug they need.

Special enrollment periods should also be provided for all institutionalized individuals, not just institutionalized dual eligibles, since their access to needed drugs may be compromised by the design of the plans and by pharmacy access requirements, such as if their long-term care pharmacy is not required to be included in the network of all PDPs. Individuals with life-threatening situations and individuals whose situations are pharmacologically complex should have the same rights as well.

§423.38 Effective Dates.

§423.38(c) Special Enrollment Periods.
Effective date should be first day of first calendar month following special enrollment in which individual is eligible for Part D.

§423.42 Coordination of enrollment and disenrollment through PDPs

§423.42(c)(2)
Notice of disenrollment should be in writing.

§423.44 Disenrollment by the PDP.

§423.44(b)(2)(I)
CMS requested comments about the requirement to involuntarily disenroll individuals from a PDP if they no longer reside in the service area. This raises the issue of "snowbirds"-the large number of Medicare beneficiaries who move for large parts of the year. This is a problem in Massachusetts where many elders winter in warmer climates. The churning-the enrolling and disenrolling-that plans serving this population will face as they apply this section will be enormous. Because of different formularies between plans and problems of coordination, the regulations should seek to minimize plan changes and maintain continuity of care. This section, as written, could result in a significant number of plan changes, disrupting continuity of care.

Some suggested ways to address this issue better would be to require that plans as a condition of participation have a system of visitor or traveler benefits, consider exempting regional PDPs and PDPs with out-of-network services from the disenrollment requirement, require plans to provide prospective enrollees specific information on traveler benefits and "out-of-plan service policies" and clearly define the time period that a plan could consider an enrollee as "no longer resid(ing) in the PDP's service area." such that it accommodates seasonal travelers who maintain a residence in the service area.. In many cases, 90 day mail order service and arrangements with other plans will make enrolling and disenrolling unnecessary. However, beneficiaries must have a clear understanding of how a plan will serve them while temporarily out of the service area; how when they are traveling and need emergency pharmaceutical services their plan will (or will not) reimburse for those services.

§423.44(d)(2)
Provisions in the proposed regulations to allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" create enormous opportunities for discrimination against individuals with mental illnesses, Alzheimer's, and other cognitive conditions. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and accordingly be subject to a late enrollment penalty permanently increasing their premiums. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage. Moreover, CMS lacks statutory authority to authorize PDPs to involuntarily disenroll beneficiaries. Under the MMA, section 1860D-1(b) directs the Secretary to establish a disenrollment process for PDPs using rules similar to a specific list of rules for the Medicare Advantage program. This list does not include reference to section 1851(g)(3)(B) of the Social Security Act which authorizes MA plans to disenroll beneficiaries for disruptive behavior. Thus, these proposed regulations must not be included in the final rule.

Concerns with specific provisions in this section and recommendations for beneficiary protections, which, at a minimum should be provided, are as follows:

§423.44(d)(2)(vi) Reenrollment in the PDP.
In the preamble, CMS appears to be asking for comments on whether a PDP should be allowed to refuse reenrollment of an individual who has been involuntarily disenrolled if there is no other drug plan in the area. As discussed above, it is our position that there is no statutory basis for involuntarily disenrollment. If the regulations allow this for disruptive behavior, then the plans must be required to allow reenrollment. Those individuals most likely to be subject to involuntary disenrollment will not have the resources to pay for their medications out-of-pocket. These individuals are entitled to this benefit. Disruptive behavior does not disqualify you from access to prescription drug coverage and may in fact be an indication that one is in need of medical assistance. Individuals who are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period and may therefore be subject to a late penalty and increased premium as a result. This result is unfair in light of the fact that the disruptive behavior may have resulted from denial of access to needed medications. CMS should therefore provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior, must waive the late enrollment penalty for these individuals, and the regulations must include detailed articulated protections to lessen the risks inherent in authorizing sanctions for "disruptive behavior."

§423.44(d)(2)(vii) Expedited Process.
This provision should be deleted from the final rule. The proposal to establish an expedited disenrollment process in cases where an individual's disruptive or threatening behavior has caused harm to others or prevented the plan from providing services is undefined, and provides no standards, requirements or safeguards. It allows plans to employ this mechanism on the basis of behaviors described in the broadest of terms - terms which could easily be mis-applied or applied capriciously or punitively. Thus, it would undermine all the minimal protections that would otherwise apply.

§423.46 Late enrollment penalty.
CMS should delay implementation of this section for two years. The drug benefit is a new and complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. The Medicare-endorsed prescription drug discount card program has shown that, even with significant outreach, the majority of individuals eligible for the $600 low-income subsidy have not yet enrolled. We disagree that healthy beneficiaries will not apply. We believe that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness and cognitive disabilities. Implementation of the late enrollment penalty should be delayed for individuals eligible for the low-income subsidy who may not understand that they have to apply separately for the subsidy and a drug plan, thinking that application for the subsidy is sufficient.

This section should provide that when the late enrollment penalties are implemented, there will be an opportunity for enrollees to appeal late enrollment penalties; that late enrollment penalties will be coordinated with "special enrollment periods" to ensure that individuals who take advantage of the special enrollment periods do not face late penalties; that individuals who are involuntarily disenrolled are exempt from this penalty; and that if an employer or other entity

providing drug coverage to Medicare beneficiaries fails to provide adequate or correct notice of the creditable status of that coverage or a change in status of that coverage, and that coverage is not creditable, there are no late enrollment penalties.

§423.48 Information about Part D.
Medicare beneficiaries can only exercise an informed choice about their drug plan if they have adequate information about drug plan options available to them. The information should be provided annually, in writing, and include details about the plan benefit structure, cost-sharing and tiers, formulary, pharmacy network, and appeals and exception process. In order to assure that beneficiaries have the required information, the standards should be included in regulations that are binding and enforceable, and not in guidance. Minimally, the regulations should require plans to provide premium information, including whether individuals who receive the low-income subsidy will have to pay a part of the premium and, if so, the amount they will have to pay; the benefits structure and comparative value of the plans available to them; the coinsurance or copayment amounts they will need to pay for each covered Part D drug on the formulary; the specific negotiated drug prices upon which coinsurance calculations will be based and that will be available to beneficiaries if they confront the gap in coverage; formulary structure, the actual drugs on the formulary, and how the formulary can change during the plan year; participating pharmacies, mail order options, out-of-service options; and exception, appeals and grievance processes. Plans should be required to provide this information to potential enrollees in a clear manner using a standard format that will allow beneficiaries to easily compare plans. Plans should be required to provide information on negotiated prices in an easily accessible format.

The regulations should also include specific requirements for plans and states, as well as outline activities CMS will undertake, to ensure that every effort will be made to reach dual eligibles. By summer 2005 CMS and the states should launch a concerted outreach and assistance campaign for dual eligibles to alert them about the need to enroll in a Part D plan and to help them make appropriate choices. The outreach campaign would be intended to prevent default enrollment. In addition, as early as possible, and no later than October15, 2005 (assuming information is available), CMS or the states should mail standardized, easy-to-understand notices to dual eligibles that, among other things: inform them of their eligibility to receive the low income drug benefit if they enroll in a PDP or MA-PD; list choices of health plans (clearly denoting those that meet the benefit premium assistance limit) and contact information for each plan; explain that individuals will be randomly enrolled in a prescription drug plan beginning November 15 (or, if different, the appropriate date) if they fail to opt out or enroll in a plan themselves; explain how they may change their drug plans if they wish at any time; and inform them of where in their community they can go to get help with enrollment. These notices should be tested for readability by focus groups and experts. If the states are required to provide this information, CMS should reimburse 100 percent of the states' costs.

§423.50 Approval of marketing material and enrollment forms.
The marketing rules for the PDPs and MA-PDPs should be developed in the historical context of other Medicare programs. From selective marketing to outright fraud, Medicare programs historically have been afflicted with marketing abuses and scams. We urge that CMS be vigilant to identify and prohibit these problematic areas and practices as it develops final regulations.

§423.50 (e) Standards for PDP marketing.
Telemarketing should expressly be prohibited. Door-to-door solicitation is prohibited under this section and telemarketing presents many of the same dangers. The regulations should specifically prohibit prescription drug plans from initiating telephone or e-mail contact with potential enrollees, unless the potential enrollee requests contact through such means in response to a direct mail or other advertisement.

In the Preamble, CMS asked for comments on whether it would be advisable to permit prescription drug plan sponsors to market and provide additional products (such as financial services, long term care insurance, credit cards) in conjunction with Medicare prescription drug plan services. CMS should not allow plans to market other services, nor should it seek to encourage other entities, such as financial institutions, to participate as PDPs. The potential for abuse—both cherry picking of healthier beneficiaries into plans and avoidance of financial services to less healthy individuals—is enormous. CMS also asked for comments on the applicability of MA marketing requirements for PDP marketing. PDP marketing requirements should be at least as restrictive as MA marketing because of the high potential both for confusion and for individuals to be directed to—and locked-into—plans that do not best meet their needs. Beneficiaries look to providers for balanced, unbiased information, and they should be able to rely on the information that these sources provide. However, if providers or pharmacies are allowed to market plans, there is the potential for aggressive marketing of certain PDPs, regardless of whether or not that PDP is the best for the beneficiary. The adverse consequences of making a bad selection based on promotion from a trusted source are high.

§423.56 Procedures to determine and document creditable status of prescription drug coverage.

§423.56 (e) Notification.
It is essential that beneficiaries understand whether they have creditable coverage. Failure to understand the issue of creditable coverage can lead to a lifetime of higher Part D premiums. CMS must set forth specific requirements that plans provide information to Medicare beneficiaries enrolled in those plans clearly stating whether or not the coverage they have is creditable. Minimally, in 2005, information on whether coverage is creditable or not should be provided in more than one mailing, and included in such documents as quarterly retiree income statements, medical billing correspondence, etc. After 2005, CMS should develop standard notices, through its Beneficiary Notice Initiative, to be used. In years after 2006, when creditable status changes, special notification is needed to insure that beneficiaries know as soon as the decision is made to reduce coverage, so they can begin shopping for a PDP and avoid a lifetime of premium penalties. Because this is such important notification, it should be sent by registered mail, or e-mail with proof of receipt. Additionally where beneficiaries are not adequately informed by an employer or other entity that their coverage is not creditable, CMS should take action on behalf of all the individuals of that employer or other entity to provide a special enrollment period (SEP). Each individual adversely impacted by the failure of the employer or other entity to inform adequately should not have to apply or appeal for a SEP.

Subpart C-Benefits and Beneficiary Protections

§423.100 Definitions.
"Dispensing fee" should be broadly framed, in order to permit the payment of costs associated with home infusion therapy. Of the options provided in the preamble to the proposed rule, we support option 3. We do not believe that a narrowly crafted definition of dispensing fee is appropriate because the conference report at § 1860D-2(d)(1)(B) references negotiated prices in a manner that indicates that Congress intends to define negotiated prices in a way that arrives at the most accurate prices when considering a variety of both concessions and fees. Since the antibiotics, chemotherapy, pain management, parenteral nutrition and immune globulin and other drugs that are administered through home infusion are indisputably covered Part D drugs, and equipment, supplies and services are integral to the administration of home infusion therapies, costs associated with such administration should be included in the definition of dispensing fee, in order to arrive at the most accurate determination of the negotiated price. Option 1 makes an arbitrary and inappropriate distinction between costs associated with dispensing a covered Part D drug and associated costs for the delivery and administration of a covered Part D drug, and option 2 does not capture all the true costs associated with dispensing a covered Part D drug.

"Long-term care facility" should explicitly include ICF/MRs and assisted living facilities.
We recommend that the final rule include a definition of "long-term care facility" that explicitly includes intermediate care facilities for persons with mental retardation and related conditions (ICF/MRs) and assisted living facilities. This is important because many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

§423.104 Requirements related to qualified prescription drug coverage.
The final rule defines "person" so that family members can pay for covered Part D cost-sharing. The law precludes contributions from employer sponsored health plans from being counted as incurred costs and counting toward the deductible or out of pocket limit. Contributions from one employer-sponsored benefit should not receive differential treatment over contributions from another type of employer-sponsored benefit. Contributions from employer-sponsored group health coverage should be counted as an incurred cost, similar to contributions from HSAs, HRAs, and FSAs. The final rule should also count cost-sharing subsidies from AIDS Drug Assistance Programs (ADAPs) as incurred costs. The regulations also specifically state that state-appropriated dollars spent by ADAPs cannot be counted as incurred costs. It is discriminatory and unacceptable to single out state dollars used to provide medications to people living with HIV/AIDS and not allow them to count as incurred costs, while at the same time allowing state dollars paid by State Pharmaceutical Assistance Programs' (SPAPs)to count as incurred costs.

§423.104(e)(2)(ii) Establishing limits on tiered copayments.
The final rule should not allow Part D plans to apply tiered co-payments without limits. Rather, it must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs.

§423.104(h) Negotiated prices.(1) Access to negotiated prices.
No plan should be allowed to impose 100% cost-sharing for any drug. Such cost-sharing should be considered as per se discrimination against the group or groups of individuals who require that prescription.

§423.120 Access to covered Part D drugs.

§423.120(a) Assuring Pharmacy Access.
Pharmacy access standards must be met in each local service area, rather than by permitting plans to apply them across a multi-region or national service area. Permitting plans to meet the access standards across more than one local service area could cause individuals in some local service areas to not have convenient access to a local pharmacy. Also, only retail pharmacies should be counted for the purpose of meeting pharmacy access standards. It would undermine the principle that Medicare beneficiaries will have convenient access to a local pharmacy if the access standards could be met by counting pharmacies that serve only specific populations and which are not available to all parts of the general public. The final rule should require prescription drug plans to offer to contract with Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (I/T/U) pharmacies and make available a standard contract. Should the final rule not contain this requirement and in situations where an I/T/U pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy. The final rule should also require prescription drug plans to offer to contract with all LTC pharmacies and make available a standard contract. Over 80% of nursing home beds are in facilities that require the resident to use a long-term care pharmacy. Should the final rule not contain this requirement and in situations where a LTC pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy. Furthermore, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through higher cost-sharing for out-of-network access.

§1860D-11(e)(2)(D) authority to review plan designs to ensure that they do not substantially discourage enrollment by certain Part D eligible individuals.
CMS should use the authority provided under section 1860D-11(e)(2)(D) to review plan designs, as part of the bid negotiation process, to ensure that they are not likely to substantially discourage enrollment by certain Part D eligible individuals. Previous experience with Medicare+Choice plans shows that private insurers use a variety of techniques to discourage both initial and continued enrollment in a plan by enrollees with more costly health care needs. For example, Medicare+Choice plans have offset reduced cost-sharing for doctors visits with increased cost sharing for services such as skilled nursing facility care, home health care, hospital coinsurance, and cost sharing for covered chemotherapy drugs that are utilized by people with chronic and acute care needs. CMS should thus analyze formularies, cost-sharing tiers and cost-sharing levels, and how cost-sharing (including both tiers and levels) is applied to assure that people with the most costly prescriptions are not required to pay a greater percentage of the cost of those drugs. CMS also needs to assure that a variety of drugs are included in a

formulary at the preferred cost-sharing tier to treat chronic conditions and conditions that require more costly treatments. As stated above, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through higher cost-sharing for out-of-network access.

§423.120(a)(6) Level playing field between mail-order and network pharmacies.
The final rule should ensure that beneficiary out-of-pocket costs used for the purchase of covered Part D drugs count as incurred costs. A key principle of the MMA is that Medicare beneficiaries have convenient access to a local pharmacy. This principle is undermined by permitting plans to charge beneficiaries the cost differential for receiving an extended supply of a covered Part D drug through a network retail pharmacy versus a network mail-order pharmacy. However, notwithstanding this objection, the final rule should permit the cost differential charged to beneficiaries to count as an incurred cost.

§423.120(b) Formulary requirements.
We do not believe it is appropriate for the final rule to constrain prescribers' capacity to prescribe drugs for off-label uses. By not permitting a class to exist in the USP model guidelines solely because all commonly used medications are being used for off-label indications could lead plans to deny coverage for off-label uses. Off-label prescribing has become a common-and accepted-practice across the field of medicine. For example no drugs that are currently used in the treatment of lupus (a serious, life-threatening auto-immune disorder) have the treatment of lupus as an on-label indication. For the treatment of mania, certain anti-convulsants and calcium channel blockers have proven effective and certain anti-convulsants have proven effective for treatment of bipolar disorder, although these uses are not FDA-approved on-label indications. We thus oppose any provisions in the final rule that place new limits on the ability of prescribers to prescribe drugs for off-label uses-or that legitimize the denial of coverage for covered Part D drugs simply because they are used for an off-label indication.
We support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must be protected from tiered cost-sharing that could to these defined populations must be made available at the preferred level of cost-sharing for each drug. We recommend that this treatment apply to at least the following overlapping special populations: dual eligibles, institutionalized populations, persons with life-threatening conditions, and persons with pharmacologically complex conditions.

We recommend that if the final rule limits the notice requirements to persons directly affected by the change, then plans must be required to provide notice in writing, mailed directly to beneficiary, 90 days prior to the change, and the notice must inform the beneficiary of their right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary. We also recommend that the final rule place strict limits on mid-year formulary changes, requiring plans to justify a decision to remove drugs from a formulary such as the availability of new clinical evidence indicating that a particular covered Part D drug is unsafe or contraindicated for a specific use or when all manufacturers discontinue supplying a particular

covered Part D drug in the United States. Should the final rule fail to effect such a restriction, plans should be required to continue dispensing all discontinued drugs until the end of the plan year for all persons currently taking a discontinued drug as part of an ongoing treatment regimen.

§423.124 Special rules for access to covered Part D drugs at out of network pharmacies.
The final rule must establish requirements on plans to dispense a temporary supply of a drug (wherever a prescription is presented, irrespective of whether or not it is at a network pharmacy) in cases of emergency. If the emergency situation involves a coverage dispute, the plan must dispense refills until such time as the prescription expires or the coverage dispute is resolved, through either a plan decision to provide coverage for the drug or through completion of the appeal process. This requirement must also specify that a temporary supply must be dispensed even in cases where beneficiaries are unable to pay applicable cost-sharing.

The final rule should also limit out-of-network cost-sharing to no more than the difference between the maximum price charged to any in-network Part D plan in which the pharmacy participates and the in-network price. While we recommend that this limitation apply in all circumstances, at a minimum, it must be applied through the final rule, to the scenarios described in the preamble to the proposed rule.

§423.128 Dissemination of plan information.

§423.128 (d) Provision of specific information.
It is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center. The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program.

§423.128(e) Claims Information.
In addition to the required explanation of benefits elements in the proposed regulation, the explanation of benefits should also include information about relevant requirements for accessing the exceptions, grievance and appeals processes.

Subpart J-Coordination Under Part D With Other Prescription Drug Coverage

§423.464(e) Coordination with State Pharmaceutical Assistance Programs (SPAPs).

SPAPs and new SPAPs must be able to help beneficiaries 'fill in the donut,' and we appreciate CMS's efforts to coordinate this assistance. To assure that beneficiaries are receiving seamless coverage and not facing undue out of pocket expenses, an exchange of data between the PDP and the SPAP is necessary. This should include (but not be limited to) an exchange of eligibility files, exchange of claims payment and information about the drugs on the PDPs formulary and any changes to it. Also, AIDS Drug Assistance Programs (ADAPs) should be recognized as

State Pharmacy Assistance Programs and allowed to wrap around the Medicare Part D drug benefit.

Subpart M-Grievances, Coverage Determination, and Appeals

The proposed regulations fail to meet the requirements of the Due Process Clause of the Fifth Amendment to the United States Constitution. As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid recipients whose prescription requests are not being honored currently receive a 72-hour supply of medications pending the initial coverage request. They are entitled to notice, face-to-face hearings, and aid paid pending an appeal if their request is denied and they file their appeal within a specified time frame. All state Medicaid appeals processes are completed more expeditiously than Medicare appeals. The appeals process as described in Subpart M does not accord dual eligibles and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity for a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes. While we recognize that the most efficient means of protecting enrollees, amending MMA to provide for an appeals process similar to Medicaid, is beyond the authority of CMS, CMS can take steps in the final regulations to improve notice and the opportunity for speedy review.

Sections 1860D-4(f), (g), and (h) require that Part D plan sponsors establish grievance, coverage determination and reconsideration, and appeals processes in accordance with Sections 1852(f), (g) of the Social Security Act. As will be discussed in more detail below, CMS has failed to comply with the language of those provisions. Overall, the incredibly onerous exceptions process does not comply with the statutory requirements or meet the basic elements of due process. In addition, CMS, in implementing Section 1852(c) and in settlement of *Grijalva v. Shalala*, 153 F.3d 1115 (9th Cir, 1998), *vacated and remanded*, 526 U.S. 1096 (1999), adopted 42 C.F.R. §422.626, which establishes the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review for Part D. CMS needs to incorporate a similar process for Part D in order to establish a process in accordance with Section 1852(c). A similar fast-track process would also be more in keeping with due process requirements.

As a general comment, this entire subpart needs to be made much simpler. To have two tracks, depending on (1) whether one personally pays for a drug and files an appeal or (2) does not obtain the drug and files an appeal, is far too complicated. The time frames, paperwork, and processes should be simplified into one course of action that beneficiaries may hope to understand.

§423.560 Definitions.

This section defines "appeal" to exclude grievance and exceptions processes, and defines “authorized representative” as an individual authorized by an enrollee to deal with appeals. The definition of “authorized representative” needs to clarify that a doctor or representative, including a State Prescription Drug Plan (since the SPAP may be at risk in the event of PDP

actions) can be an authorized representative, and that authorized representatives can deal with exceptions and grievances as well as appeals.

§423.562 General provisions.

§423.562(b)(5)(iii)

Reconsideration by an Independent Review Entity (IRE) should be automatic, as in the Medicare+Choice plans

§423.562(c)(1)

This subsection precludes an enrollee who has no further liability to pay for prescription drugs from appealing. However, it is important to be able to appeal formulary changes. A comprehensive change in this limitation is essential to protect the health of beneficiaries. At a minimum, SPAPs should be able to appeal on behalf of an enrollee and the section should clarify that a low-income institutionalized individual can appeal a determination, even if she has no co-payment responsibilities.

§423.566 Coverage determinations.

§423.566(b) Actions that are coverage determinations.

This subsection needs to clarify further what constitutes a coverage determination. The proposed definition does not include in the list of coverage determinations from which an appeal can be taken a determination by the PDP that a drug is not a covered drug under Part D. An enrollee should be entitled to appeal to determine whether, in fact, a drug the plan claims is not covered under Part D is so covered. The definition should also clarify that denials of enrollment in a Part D plan, involuntary disenrollment from a Part D plan, and the imposition of a late enrollment penalty are coverage determinations subject to the appeals process. Finally, the regulation should state that the presentation of a prescription to the pharmacy constitutes a coverage determination. If the pharmacy does not dispense the prescription, then the request for coverage should be deemed denied, and the enrollee should be entitled to notice and to request a re-determination. Without such clarification, enrollees will not be informed of their rights, and the appeals process will become meaningless.

§423.568, Standard timeframes and notice requirements for coverage determinations.

§423.568(a) Timeframe for requests for drug benefits.

The plan should be required to provide oral notice as soon as it determines that it will extend the deadline for considering whether it will cover a drug, including notice of the right to request an expedited grievance. The oral notice should be followed-up in writing.

§423.568(b) Timeframe for requests for payment.

This section should be eliminated. There should be no distinction in time frames when an enrollee requests payment.

§423.568(c), Written notice for PDP sponsor denials.

Who gives notice? The proposed regulations place the responsibility for providing notice of a coverage determination on the plan sponsor. This presumes a situation in which the person presents a prescription, the pharmacy contacts the plan, and then the plan takes 14 days to decide whether or not to cover a drug. In reality, the pharmacy, in most instances, tells the enrollee that the plan will not cover the drug. Without notice provided by the pharmacy, most enrollees will not know to tell the pharmacy to submit the prescription anyway so they can get a notice from which to appeal. They also may not know or understand their right to seek expedited consideration of the initial coverage determination, or an exception if the drug is not on the formulary or on too high a tier. If the enrollee pays out of pocket and then seeks reimbursement from the plan, she will not be eligible for expedited consideration.

The regulations should require the plan sponsor to develop a notice explaining the right to seek a redetermination, and to ask for expedited review. The pharmacy should be required to give the notice to the enrollee. Any potential burden of such a requirement is reduced by the need to maintain electronic communications between the pharmacies and the plans in order to keep up-to-date with formularies, coinsurance, and calculations of an enrollee's out-of-pocket expenses.

The proposed regulations talk about using "approved notice language in a readable and understandable form." The regulations need to be more specific, including information about what is required to use the exceptions process. We suggest that notice should

Include information about exceptions and appeal rights immediately upon denial (including upon determination that a drug is not covered on formulary and including denials issued by the pharmacist), explain why coverage was denied and provide options in addition to the appeal procedures for obtaining necessary medications;

Include clinical or scientific basis for denial; and

Be available in multiple languages and note the availability of language services.

In addition, all notices need to be available in alternate formats to accommodate people with disabilities, and in languages other than English where a portion of the population is not English speaking. The requirements of plans and the rights of beneficiaries in this area must be spelled out in much more detail. There is also an overarching need to consider literacy problems and encourage simplicity.

§423.568(e) Effect of failure to provide timely notice.
It is nowhere spelled out how the beneficiary is apprised of this right.

§423.570 Expediting certain coverage determinations.

§423.570(a) Request for expedited determination.
CMS requests comments on who should be able to request determinations and re-determinations. An authorized representative should be able to request expedited consideration just as the authorized representative may request a coverage determination. In emergency situations, enrollees with mental health concerns and other vulnerable individuals may need someone else to act on their behalf.

§423.570(c) How the PDP sponsor must process requests.
All coverage determinations and appeals concerning drugs, including those in which the enrollee has paid for the drug, should be treated as requests for expedited review. An enrollee would suffer adverse consequences if required to wait for the longer time periods; many people will simply go without prescribed medications pending the outcome of the review. Doubling the timeframes and disallowing expedited review in cases when enrollees pay for their drugs out-of-pocket could adversely affect the health of those who forego other necessities like food and heat in order to pay for their medicine.

At a minimum, all requests for exceptions should be automatically given expedited consideration. Where someone seeks expedited review of a request to continue a drug that is no longer on the formulary, the plan should be required to process the request in 24 hours under the provision that requires an expedited review to be completed as fast as the beneficiary's condition requires. The enrollee should be given a 72-hour supply of the medicine, which is renewable if the plan decides to take longer than 72 hours. The medicine should be treated as an on-formulary drug.

If requests for an exception are not automatically treated as a request for expedited review, the rules should state that the doctor's certificate requesting expedited review and requesting an exception should be one and the same.

§423.570(d)(2)
A beneficiary should not have to wait for a written notice to learn of the right to file an expedited grievance and the right to resubmit a request with prescribing physician support.

§423.572 Timeframes and notice requirements for expedited coverage determinations.

§423.572 (b) Extensions of timeframe.
The timeframe (of 72 hours) can be extended by the plan up to 14 days on showing that an extension is in the interests of the enrollee. The regulations should be modified to read best interest of the enrollee and define interests of the enrollee to include those situations in which the drug plan seeks additional information to substantiate the enrollee's request, or when the enrollee requests additional time to gather supporting information. The regulations should also require the plan to inform the enrollee of the extension immediately, both orally and in writing, rather than "by the expiration of extension." Also, the written notice should include more than just the reasons for the delay.

There should be no extended time period for requests for payment of drugs already received. This imposes extreme hardship on low-income beneficiaries and those with multiple prescriptions who may choose to unnecessarily spend money on their medications because of the uncertainty and length of the appeals process rather than spend the money on other urgent necessities of life.
It is not clear from the proposed regulations what notice a beneficiary will receive when sometime during the year a plan changes its formulary and the drug(s) it covers. The statute says plans must make the change in information available on the internet, the Preamble discusses a

mailed notice, and the draft regulation simply says 'notice.' A change in formulary, or a change in the tiering of a drug on the formulary should be clearly explained to a beneficiary taking that drug which has been changed. That notice should be written notice and the receipt of that notice should serve as a trigger for the beneficiary's legal rights.

§423.572(d) Content of the notice of expedited determination.
See §423.568(c) comments above.

§423.572(e) Effect of failure to provide a timely notice.
How does a beneficiary know s/he can appeal the lack of timely notice?

§423.578 Exceptions process.
The proposed regulations do not explain how an enrollee will get notice about the exceptions process and/or that a drug is not included on the formulary. The only notice requirement is found in §423.120(b), which requires the plan sponsor to provide at least 30 days notice to CMS, affected enrollees, pharmacies, pharmacist and authorized prescribers before removing a drug or changing a drug's preferred or tiered status. Although the preamble talks about written, mailed notice, and the statute requires posting on the Internet, the regulatory language merely says that notice must be given.

To meet basic due process requirements concerning termination of benefits, the notice of the change must be in writing and must include an explanation of how to use the exceptions process, including the requirements for a doctor's certificate, the right to a hearing, and the reasons why a drug is not included on or removed from the formulary, or why the tier is changing, and the evidence required to establish an exception.

Proposed section §423.120(b) provides insufficient time for the notice, given the substantial burden placed on the enrollee to either get a new prescription or to gather the medical evidence. Many beneficiaries will not be able to get a doctor's appointment within 30 days, and many will not be able to change drugs without a medical evaluation. The final regulations should state that notice must be provided 90 days in advance of the change.

In addition, the exception process section should include a subsection on notice that (1) refers to §§423.120(b) and (2) requires plan sponsors to develop a notice that explains the exceptions process, the situations in which someone may seek an exception, and the information that is required to support an exception request, which the pharmacy will give to an enrollee who requests coverage for a non-formulary drug or requests to be assessed a lower cost-sharing amount.

§423.578 (a)(2).
This subsection fails to meet the statutory requirement that the Secretary establish guidelines for an exception process. The plan statutory language is not permissive; it does not say that plans may establish additional criteria if they wish. It says that the Secretary is to establish criteria and the plans are to abide by them. Plans should have no discretion whatsoever. The fact that they may establish differing tiered structures is not relevant to the statutory right to request an

exception to whatever structure they devise. In fact, the flexibility accorded to plans is why beneficiaries need strong guidelines to protect their interests.

Where the proposed regulations include guidance for criteria, the criteria listed exceed the scope of the statute. The proposed regulations list a "limited number of elements that must be included in any sponsor's exception criteria," but this list includes criteria that do not apply based on the statutory provision that states an exception applies if a physician determines that a preferred drug would not be as effective or would have adverse effects or both.

The proposed rules also fail to provide adequate guidance to physicians concerning whether the standard requiring the doctor to certify that a preferred drug would not be as effective or would cause adverse effects has been met.

The final regulation should require that the lowest co-pay that applies should apply to drugs for which an enrollee has won an exception to the tiered cost-sharing structure. That's the whole point of this process - to infuse some equity upon a showing that none of the other medications covered are as effective or may cause harm.

The final rule should also include the following omitted criteria: regulations permitting continued access to a drug at given price when there is a mid-year formulary change, and regulations requiring sponsors to give enrollees an opportunity to request exceptions to a plan's tiered cost-sharing structure other than on a case-by-case basis.

§423.578(b) Request for exceptions involving a nonformulary drug.
This subsection fails to meet the statutory requirement that the Secretary establish guidelines for an exception process. In the preamble, CMS states that "[r]equiring sponsors to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied" and will help ensure these formularies "are based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs ." However, the proposed regulations give drug plans complete discretion in determining the criteria they will use to determine exceptions requests. In addition, independent review entities "would not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." By failing to adequately define the criteria plans may use to consider exceptions requests or provide any meaningful oversight over these criteria, these proposed regulations would not ensure that formularies are based on scientific evidence and would not establish a transparent process. The regulations as written subvert CMS's stated goals.

The proposed rules set an impossibly high bar for receiving an exception by requiring prescribing physicians to produce clinical evidence and medical and scientific evidence to demonstrate that the on-formulary drug is likely to be ineffective or have adverse effects on the beneficiary. Clinical trials generally do not include older people, people with disabilities and people with co-morbidities. While some such evidence does exist, it has not been developed for all drugs and conditions. However, a physician may have extensive experience treating these kinds of patients with the condition or illness at issue and this experience should be given at least

equal weight in making such determinations. In fact, the statutory standard requires deference to the doctor's determination that all on-formulary medications would not be effective or cause adverse consequences. This required deference is not reflected in the proposed rules. It is also important that the final rules recognize the existence of individual differences in reactions to the same drug and that exceptions be available to someone who can not tolerate or who does not benefit from a drug even though that drug is beneficial to most people.

The NPRM proposes to authorize plans to require a long list of information in the written certification from the prescribing physician that an off-formulary drug is needed. This list is overly long and repetitive and may encourage drug plans to establish burdensome paperwork requirements as a hurdle to prevent physicians and consumers from following through on an exceptions request. Moreover, this proposed rule also leaves the required contents entirely up to the plan's discretion by including the catch-all phrase - "any other information reasonably necessary". The requirements for this written certification should be standardized to facilitate use of the exceptions process by providers and consumers. These standards would also help achieve CMS's stated goal of establishing a transparent process.

An important provision was left out of the requirements for receiving a dosing exception. The proposed rule states that in order to receive an exception, the physician must demonstrate that the number of doses available is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. This rule must also allow exceptions if the prescribing physician demonstrates that the number of doses available would cause an adverse reaction or harm to the enrollee - as provided in the proposed rules for other kinds of exceptions requests.

The final regulation should clarify that formulary use includes not just dose restriction, but the format of the dosage (liquid vs capsule, etc.) and packaging, such as bubble wraps for long-term care facility residents.

§423.578(c)(2) When a sponsor does not make a timely decision.
The regulation provides for a one month's supply of a drug, but only if the plan does not act timely on an exceptions determination. If the request for an exception is not given expedited treatment, the sponsor can take two weeks to issue a decision, meaning the enrollee would wait two weeks before getting the supply of medicine. Even if the exception is treated as a request for expedited review, the enrollee would still have to wait 72 hours (unless s/he could show the decision needed to be made more quickly because of her/his condition.) Most people wait to the last minute to refill a prescription, often because of drug plan and pharmacy restrictions.

It is also unclear how an enrollee knows about these rights when a sponsor does not make a timely decision.

The enrollee should be entitled to a one month's supply upon presenting the request for a refill and upon presenting a new prescription for a non-formulary drug. Plans should be required to make exception determinations and notify the enrollee in 24 hours as required under Medicaid for prior authorization determinations. 42 U.S.C. §1386r-8(d)(5)(A).

We cannot overemphasize the importance of drug coverage and ensuring no gaps in the intake of medication. In mental health and HIV/AIDS, for example, it is essential that medications be available quickly and without interruption. In the HIV/AIDS sector, for example, consistent research proves that the risk of drug resistance and resulting treatment failure significantly increases with each missed dose of therapy.

423.578(c)(3), When an exception request is approved.
The lowest coinsurance amount should apply anytime an enrollee wins an exception through this process because the drug at issues has been determined medically necessary with no on-formulary drug as a suitable alternative. The exception for the non-formulary drug thus meets the criteria for an exception to the tiered cost-sharing structure as well.

The regulation needs to clearly set forth the requirement that notice be provided when a decision is made on an exception request. The notice should explain that the decision is a coverage determination and explain the appeal rights that are available.

We commend CMS for specifying that, once an exception request is granted, a plan sponsor may not require the enrollee to keep requesting exceptions in order to continue receiving the drug. However, we are concerned that the "exception" to this protection which allows the plan to discontinue a drug if safety considerations arise, is too broad. The final regulation should be revised to permit reversal of a previously granted exception only if the FDA determines that the drug is no longer safe for treating the enrollee's disease or medical condition.

We are concerned that the timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed provisions raise similar concerns. It is extremely unfair to require longer time frames if a beneficiary has paid out of pocket for a needed medication when their alternative would be to wait two weeks to a month for a determination or an emergency one-month supply of the needed drug. Beneficiaries' health and safety may well be at risk if they are forced to forego other necessities because of the added, and most likely very significant, expense of paying out of pocket for their medicines. Although the proposed regulations include some provisions for an emergency supply of medications while a plan is considering an exceptions request, it is unreasonable and bad health policy to make beneficiaries wait two to four weeks before the drug plan must provide an emergency supply. In addition, plans should be required to demonstrate that an extension of the standard time frame for exceptions determinations is in the best interest of the enrollee and the final rule must charge independent review entities with exercising oversight over these extensions. Plans should be required to make determinations regarding exceptions requests and notify the enrollee of these determinations in 24 hours as required under Medicaid for determinations regarding prior authorization requests (42 U.S.C. 1396r-8(d)(5)(A)).

§423.580 Right to a redetermination
The proposed regulations only authorize an enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) to request a redetermination or an expedited redetermination. The enrollee's authorized representative must also be allowed to request a redetermination and an expedited redetermination. Since the proposed regulations would allow an enrollee's authorized

representative to file a request for Determinations and Exceptions, it does not make sense to not allow an enrollee's representative to pursue a claim further through the redetermination, reconsideration, and higher levels of appeal. In fact, the proposed regulations define an authorized representative as an individual authorized to act on behalf of an enrollee "in dealing with any of the levels of the appeals process".

§423.584 Expediting certain re-determinations.
The regulations need to describe in detail the notice responsibilities for both standard and expedited re-determinations, including what must be provided in the notice. This is crucial, given that the next level of review to the IRE is not automatic, as it is with Medicare Advantage plans. The notice should explain the reason for the denial, including the medical and scientific evidence relied upon, the right to request review, or expedited review, to the IRE, including timeframes and the right to submit evidence in person and orally.

§423.584(a) Who may request an expedited redetermination.
See §423.580 regarding allowing an individual's authorized representative to request an expedited re-determination.

§423.584(d)(2).
The information in the letter should also be provided orally. The enrollee should not have to wait three days for this information.

§423.586 Opportunity to submit evidence.
The regulations should establish clear criteria for informing the enrollee and the physician that they can submit evidence in person, as well as clear procedures for in-person review.

§423.590 Timeframes and responsibility for making redeterminations.
The regulation should be amended so that a plan can only extend the timeframe for a re-determination if requested to do so by the enrollee, or if the plan can demonstrate that the extension is in the best interest of the enrollee (for example, the plan needs to obtain additional information to support the enrollee's request). As previously stated, all re-determination requests, and particularly those involving exceptions, should be treated as expedited, and plans should not be given more time to resolve re-determination requests involving payment requests.

§§423.590(c) Effect of failure to meet timeframe for standard redetermination and (e) Failure to meet timeframe for expedited redetermination.
Again, how does enrollee know this and know what to do?

§423.600 Reconsideration by an independent review entity (IRE).
CMS needs to clarify in the final regulations that the role of the IRE is to provide independent, de novo review, especially in regard to the exceptions process. The preamble states that "…The IRE's review would focus on whether the PDP had properly applied its formulary exceptions criteria for the individual in question…..the IRE will not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." If the IRE does not review all the

evidence and issue a reconsideration decision based on its own analysis, then enrollees will be denied independent review, and the requirements of due process will not have been met.

Further, because, as noted above, CMS is required by the statute to set standards for the exceptions process, the IRE must have authority to determine whether the PDP's exceptions criteria comply with the statute. Otherwise, enrollees will have no mechanism for review of arbitrary and improper standards.

Since the Part D process is supposed to follow the MA process, the regulations should follow the MA regulations and require that denials automatically be sent to the IRE for reconsideration. The regulations as written create a barrier to the first level of independent review for enrollees who have difficulty following the complicated process. We dispute CMS's statement in the preamble that many of the drug appeals will involve small monetary amounts. Rather, most will involve medications for chronic conditions that enrollees take on an on-going basis; the yearly sum of the cost-sharing will be quite substantial, especially considering the income level of most people with Medicare. In addition, by requiring the enrollee to file a request for ALJ review, the first truly independent review available, CMS can satisfy the statutory requirement that the enrollee files the appeal.

If the final regulations continue to place the burden of requesting a reconsideration on the enrollee, they need to clarify that an authorized representative can act on the enrollee's behalf. Again, without such clarification, enrollees who lack the capacity to file a reconsideration request will be denied their due process rights. In addition, the prescribing doctor should also be permitted to request a reconsideration, especially since the enrollee needs the doctor's statement in order to request IRE review of an unfavorable exception request.

Finally, the enrollee should be allowed to request a reconsideration orally, especially where the request is for an expedited review.

§423.600(b).
We are pleased that CMS is requiring the IRE to solicit the view of the treating physician. We believe the IRE should also be required to solicit the view of the enrollee. However, because in our experience the MA independent contractor is often reluctant and unwilling to accept the views of and evidence from the beneficiary, the final regulation needs to be more specific. The regulation needs to specify how this will occur, including contact by telephone, email, or face-to-face meeting.

§§423.600(d).
The regulations need to establish a set timeframe by which the IRE must issue its decision in order for this process to be transparent. Enrollees will have no knowledge of the contract between CMS and the IRE and thus will not know how long they will have to wait for a reconsideration decision. Also, if contractual, the time frame can change with each new contract, putting enrollees at greater risk of adverse health consequences from being denied needed medicines. The regulation should also state that an enrollee may appeal to an ALJ if the IRE fails to act within the regulatory time frame and how the enrollee will be apprised of this right.

§423.602 Notice of reconsideration determination by the independent review entity.
The language concerning what the notice must entail is ambiguous. The notice must "inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under 423.610." Does this mean that the notice tells you that you can go to an ALJ, but only if your claim is large enough? Or does this mean the IRE only has to tell you about your right to an ALJ hearing if your claim meets the threshold amount? The latter interpretation is problematic for several reasons, including the fact that you can aggregate claims. The final regulation should state that the notice must inform the enrollee of his or her right to an ALJ hearing, and the procedure for requesting such a hearing, including the dollar amount required to request a hearing.

§423.610 Right to an ALJ Hearing.
Congress recognized the special needs of the low income, and how even small copayment amounts can cause many lower income individuals to forgo filling prescriptions. We urge CMS to provide exceptions to the ALJ threshold requirements for those receiving the Medicare subsidy. For example, the amount at controversy for a lower-income individual could be deemed to be the amount that would be at controversy if the individual were a non-subsidy eligible individual receiving the standard benefit.

It is unclear what §423.610(c) intends when it says, "Two or more appeals may be aggregated by the enrollee… if (I) the appeals have previously been reconsidered by an IRE…" Does this mean that an enrollee will have to file a new appeal each month for a prescription to treat an on-going chronic condition? Such a requirement would be unduly burdensome for enrollees, drug plans, the IRE, and the ALJs. The final regulation needs to clarify that when the plan denies coverage, in order to satisfy the jurisdictional amount an enrollee should be able to add up the cost of the medicine for a year, if the medicine treats an on-going chronic condition, or for the number of refills authorized if the underlying condition is not chronic.

Subsection (ii) says the request for the hearing must list all of the appeals to be aggregated and must be filed within 60 days after all of the IRE reconsideration determinations being appealed have been received. If you are consolidating appeals, and the first denial is in April and the last one you need to get to the jurisdictional amount is in August, will you still be timely? Or does it have to be 60 days from the first denial in April?

§423.612 Request for an ALJ Hearing.
The regulation should specify that, if an appeal is filed with the PDP, the PDP must submit the file to the IRE within 24 hours of receipt of the request, and the IRE must transmit the file to the ALJ within 24 hours. Our experience is that, without set time frames, some current reviewing entities take long periods of time, adding to the delay in the processing and resolution of ALJ appeals.

The regulations also need to require the IRE to include all of the information in the file, such as doctor's statements, statements by the enrollee, and any other evidence submitted by the enrollee, including information not relied upon in making its decision. It has been our experience that

contracting entities, including MA plans, often omit evidence submitted by the enrollee when transferring a file to the ALJ or other level of review.

§§423.634, Reopening and revising determinations and decisions and 423.638 How a PDP sponsor must effectuate expedited redeterminations or reconsidered redeterminations.
Subsection (c) in both of these draft regulations allows the PDP to take up to 60 days to implement a reversal by the IRE, an ALJ, or higher. That's totally unacceptable, since further delays may cause increased health consequences to people who have foregone medication pending appeal. Favorable decisions should be implemented in the same 72 hour time period as reversals at earlier levels of review.

Subpart P - Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§432.772 Definitions.
"Family size." We support defining family members as relatives in the household receiving at least half of their support from the applicant or applicant's spouse. In order to minimize burdens on beneficiaries, the regulations should specify that applicants will be able to self-attest to the status of dependents, without providing further documentation.

"Full subsidy eligible individuals." The definition should refer to the language of §§423.773(b) and(c), in order to avoid ambiguity.

"Income." The definition should make clear that income not actually owned by the applicant, even if his or her name is on the check, should not be counted.

"Institutionalized individual." The definition should include those individuals eligible for home and community based services under a Medicaid waiver (see, e.g., definition of "institutionalized spouse" at 42 U.S.C. § 1396r-5(h)(1)(A)), since those individuals must meet the acuity standards for Medicaid coverage in a nursing facility, and should include individuals in ICF-MRs and individuals in any institution in which they are entitled to a personal needs allowance.

The definition should not include the language "for whom payment is made by Medicaid throughout the month" since an individual could conceivably be a full benefit dual eligible recently returned from a hospital stay whose nursing facility stay would be paid for by Medicare Part A for the entire month. Even though in that month all their drugs are likely to be paid for by Medicare Part A, as a practical matter, for continuity and minimum disruption, they should not lose their status as an "institutionalized individual." The same reasoning should apply to a full benefit dual eligible individual who might be hospitalized during an entire month, during which their entire stay would also be paid for by Medicare Part A.

"Personal representative." The portion of the definition that permits an individual "acting responsibly" on behalf of an applicant needs further clarification as to who would determine that the individual is acting responsibly and what circumstances would constitute a per se conflict of interest.

"Resources." We support the limitation of countable resources to liquid assets. However the definitions of liquid assets and what it means to be able to be converted into cash in 20 days need to be clarified. The final rule should include a specific list of countable resources to promote clarity for state and beneficiaries. Resources should not include burial plots, burial funds or life insurance of any value, nor should it include any officially designated retirement account, such as an IRA, 401(k), 403(b) etc. Alternatively, the respective exclusions for the value of life insurance and burial funds should be increased to a reasonable amount, such as $10,000 per asset. Most potential low-income beneficiaries have assets below this level.

Excluding these resources will ease the application process for consumers and eligibility workers, as well as reduce administrative costs by reducing the time and effort required to verify assets. This is consistent with both Congress's and CMS's intent. Resource assessments should not include any consideration of transferred assets, as would otherwise be required under SSI rules.

We note that a current draft of the SSA application for the low-income subsidy inquires whether an applicant has life insurance with a face value of $1,500 or more. CMS must ensure that any proposed SSA application is harmonized with these rules on assets and income. As noted above, life insurance should not count towards assets, and this question should be eliminated.

§423.773 Requirements for eligibility.
We support the proposal to make dual eligibles (both full dual eligibles and those in Medicare Savings Programs (MSPs)) automatically eligible for the low-income subsidy. As we explain below, however, we believe a great deal more specificity is needed in this section. We are particularly concerned that the proposed rule leaves room for ambiguity regarding these beneficiaries' status. We believe that the proposed eligibility rules for partial dual eligibles will result in inequities and confusion. In addition, the draft regulations do not adequately explain how low-income beneficiaries are to be notified about their eligibility, nor do they explain how prescription drug plans are to determine which beneficiaries are enrolled in the low-income subsidy. The proposed rules also do not adequately protect low-income beneficiaries whose enrollment is delayed or is processed erroneously.

§423.773(a) Subsidy eligible individual.
Although the statute defines a subsidy eligible individual as one enrolled in a Part D plan, the requirement in Subpart S that states take applications for the low-income subsidy beginning July 1, 2005, before Part D plans are available to be enrolled in makes it clear that CMS believes people should be able to apply for the low-income subsidy without being enrolled in a Part D plan. This is actually imperative, as otherwise, an individual would be forced to pay a plan premium that the subsidy, in fact, pays for them. The subsidy eligibility determination would be done "conditionally" - conditioned upon the individual enrolling in a Part D plan. The regulations should reflect this reality and clearly direct both SSA and state Medicaid programs determining eligibility that the individual can both apply and be determined subsidy eligible before she or he has enrolled in a plan

§423.773(b) Full subsidy eligible individual.

The indexing of resources should indicate that rounding is always up to the next multiple of $10.

§423.773(c) Individuals treated as full subsidy eligible.
This section should conform to Subpart S § 423.904(c)(3) which requires states to notify all deemed subsidy eligible individuals of their subsidy eligibility. It should specify that the notice must be given by July 1, 2005 for those individuals eligible at that time. For those who subsequently become eligible, notice should be given at the same time the individual is notified of their eligibility for the benefit that qualifies them to be treated as a full subsidy individual. The notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. For those who will lose Medicaid coverage January 1, 2006, the notice should explain their appeal rights as well. Individuals should also be told of their right to appeal the level of subsidy to which they are entitled.

Section 209(b) states and non-1634 states must coordinate with the Social Security Administration to determine how to provide notice to SSI recipients who are not receiving Medicaid and who therefore do not appear on the state's Medicaid rolls.

§423.773 states that both full benefit dual eligibles and MSP beneficiaries are eligible for the low income subsidy, but it does not explicitly state that these beneficiaries are automatically enrolled in the subsidy program. The regulations should be absolutely clear that an individual treated as full subsidy does not have to take any further action with respect to the subsidy (i.e., make application or in any other way verify their status), but only to enroll in a Part D plan. This will help smooth the transition from Medicaid drug coverage for dual eligibles, and should improve participation for others.

§423.773(c)(3).
We support the decision reflected in this proposed subsection to deem MSP beneficiaries automatically eligible for the low-income subsidy. We are concerned, however, that inequities and confusion among beneficiaries may result because SSA will not apply the more generous income and asset MSP eligibility rules in place in some states (for example, Alabama, Arizona, Delaware, and Mississippi, which have eliminated consideration of assets for MSPs). Eligibility requirements should be the same for all subsidy-eligible individuals in a state, regardless of where and how they apply. Under the proposed regulations, in states that have adopted less restrictive income and asset methodology, people whose assets or income are slightly above the limits set in § 423.773 would be enrolled in a less generous subsidy, or have their application rejected entirely, if they apply directly through SSA, because SSA will apply the national guidelines proposed in §423.773. However, the same people would have their application accepted if they applied through their states' Medicaid offices, were screened and then enrolled in an MSP, and were then automatically eligible for the low-income subsidy.

To resolve this problem, we propose that SSA apply state-specific income and asset eligibility rules in determining eligibility for the low-income subsidy, an option discussed, though rejected, in the preamble. This means that for applicants from states that have eliminated the asset test or

increased disregards under §1902®)(2) for MSP eligibility, SSA should apply the state's rules to determine eligibility. This option is permitted under §1860D-14(a)(3)(E)(iv) of the statute.

Alternatively, the regulations should provide that subsidy applicants who appear to have excess assets or incomes would either be screened by SSA for eligibility in an MSP program, or have their applications forwarded to the state Medicaid agency to be screened for MSP eligibility. States would be precluded from requiring beneficiaries to resubmit information, such as income and asset levels, that they have already provided to SSA. Applicants would be enrolled in the appropriate MSP program, and then be enrolled in the appropriate low-income subsidy under proposed § 423.773(c). Adopting this policy, which is not precluded by statute, will ensure that all subsidy applicants are treated equitably, as well as increase participation in MSPs.

As part of this alternative policy, the low-income subsidy application should allow an applicant to opt out of screening and enrollment for an MSP, as some applicants may not wish to participate in an MSP. Under §1860D-14(a)(3)(v)(II) of the statute, beneficiaries who are determined eligible for MSPs may be enrolled in the low-income subsidy. There is no requirement that beneficiaries actually enroll in an MSP. Therefore, applicants who meet eligibility requirements for an MSP, but who decline to enroll in the program, should still be automatically eligible for the low-income subsidy.

Because enrollment in an MSP can affect the amount of assistance a beneficiary may receive through other public assistance program, such as Section 8 housing vouchers or food stamps, there will be a profound need for beneficiary counseling during the enrollment process. We recommend that CMS plan for this need by making funds available to local agencies, including state health insurance assistance programs (SHIPs), and other community-based organizations.

This draft regulation states that a state Medicaid agency must notify full benefit dual eligibles that they are eligible for the low-income subsidy and should enroll in a Part D plan. The regulations do not state, however, when this notice should be issued, or what the notice should say. Consistent with our comments above and those accompanying 423.904(c)(3), the notification should be sent to beneficiaries on or near July 1, 2005, when states will have made the automatic eligibility determinations.

We also suggest that CMS develop model notices based on input from beneficiaries, which would explain the purpose of new subsidy simply and clearly. The notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. It should also explain as simply as possible what level of subsidy the beneficiary will receive, and the beneficiary's appeal rights if she believes the subsidy level is in error.

The draft regulation fails to address eligibility issues for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) state. These beneficiaries should be informed of their likely eligibility for a low-income Medicare subsidy and given an opportunity to enroll. When they have met their spenddown, they should be informed of their entitlement to a lower co-payment, if applicable, as a deemed subsidy eligible.

Our recommendations for redeterminations of these beneficiaries are discussed below, in §423.774.

§423.773(d) Other subsidy eligible individuals.
The indexing of resources should indicate that rounding is always up to the next multiple of $10.

§423.774 Eligibility determinations, redeterminations, and applications.

§423.774(a) Determinations of whether an individual is a subsidy eligible individual.
This subsection provides that determinations of eligibility for the subsidy are to be made by state Medicaid agencies or by SSA, depending on where an individual applies. We believe that in order to ensure prompt enrollment in both the subsidy and ultimately in a plan, the regulations should specify that a determination notice must be sent to the applicant no later than 30 days after the application is filed. Because determinations for the low-income subsidy should be a simple process, very little time should be required to render a decision. Both SSA and states should be required to notify CMS with 24 hours of a individual being determined eligible for the subsidy.

§423.774(b) Effective date of initial eligibility determination.
In order to avoid delays in the ability of beneficiaries to use their subsidy benefits while their application is pending, the final rule should offer beneficiaries the option of applying through a presumptive eligibility system. Such a system would be especially helpful to beneficiaries who have enrolled in a Part D plan but are not yet receiving the low-income subsidy. Applicants can complete a short form at a provider's office or other location in which they declare their family size, income and assets. If their income and assets are below the relevant eligibility levels, they are found presumptively eligible. Applicants may still be required to complete a full application within a prescribed period of time (typically 30 to 60 days) if additional information is required. In the meantime, however, beneficiaries are given temporary cards that they can present to health care providers and receive services immediately. Experience has shown that the error rate for these enrollment systems is very low. In the rare cases where beneficiaries are later found ineligible, they and their providers are held harmless for the benefits they receive during the presumptive eligibility period.

Applicants for the low-income subsidy could be found presumptively eligible at state Medicaid offices, SSA offices, pharmacies, or other providers. If the low-income subsidy application form is simple enough, applicants could complete the form itself and self-attest to their income and assets. If they appear to be eligible, they would be enrolled in the appropriate subsidy while their application is processed. They would receive some form of temporary certification stating that they have been presumptively enrolled, which their pharmacy would accept while their application is processed. Such a system would encourage beneficiaries to apply, as they would be able to see the benefits of the system immediately.

§423.774(c) Redetermination and appeals of low-income subsidy eligibility.
There should be a provision for prompt reconsideration of a subsidy eligibility determination, for beneficiaries who believe they have either been erroneously denied eligibility or approved for the

wrong subsidy category. The provisions applying the appeal rules of state Medicaid plans or SSA do not provide for a prompt reconsideration process. Because obtaining prescription drugs is so vital, and especially because low-income beneficiaries are unable to pay the costs of their prescription drugs out of their own pockets, a quick reconsideration process is essential.

The draft regulation refers to redeterminations and appeals under the state Medicaid plan. This is inadequate, as frequent redeterminations in place in some states will cause some beneficiaries to drop out of the program. To maximize enrollment, the rule should establish that all determinations are for one year, per the Secretary's authority under the statute. We also urge CMS to adopt an annual, passive, and simple redetermination for all beneficiaries, whether they have enrolled through SSA or states. Should it be necessary, the Secretary should direct the Commissioner of SSA to create such a system. Under a passive redetermination system, beneficiaries would be sent a statement of the relevant information on file and asked to respond only if any of that information had changed over the year. If they do not respond, their coverage would continue unchanged for another year.

If states are not required to adopt passive redeterminations, we urge that redeterminations be made as they are under the state's MSP programs, or under the most passive, simplified redetermination process used for any category of coverage under the state plan.

§423.774(d), Application requirements.
This section should make clear to both states and SSA that no documents should be required of the individual as long as the applicant authorizes the agency to verify information from financial and other institutions. Documentation production should be only the absolute last resort.

Also, as we mentioned in our comments to §423.773 above, the proposed rule does not address eligibility determinations and recertification periods for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) state. Once beneficiaries become deemed subsidy eligible individuals by completing their spenddown, they should retain that status for a full year, until their next redetermination for the low-income subsidy, regardless of whether they go off Medicaid. Otherwise, individuals who go in and out of medically needy status, depending on the length of their state's budget period, will have extremely confusing changes regarding their Medicare low-income drug subsidy.

§423.800 Administration of Subsidy.

§423.800(a), Notification of eligibility for low-income subsidy.
We are concerned that there is no provision in §423.800(a) specifying a time period by which CMS must notify a plan that an enrollee is eligible for a subsidy. This is an essential step in the process, because without the subsidy, prohibitive costs will prevent low-income beneficiaries from using their Part D benefits. We propose that CMS be required to inform Part D plans of beneficiaries' enrollment in the subsidy no later than 24 hours after the application for the subsidy is approved. As this will likely be an electronic notification, it should not be burdensome. It is vital that plans know which beneficiaries are enrolled in the subsidy, so that these low-income beneficiaries do not have to pay the full cost of their prescriptions while their subsidy application is process.

§23.800(e), Reimbursement for cost sharing paid before notification of eligibility for low-income subsidy.
The draft reimbursement provisions are inadequate to protect low-income beneficiaries. The proposed regulation would require plans to reimburse low-income beneficiaries for excess copayment and premium amounts made after the effective date of the subsidy application. This is not a realistic solution to the problem facing beneficiaries who have prescription drug needs before their Part D plans are notified that the beneficiaries are subsidy-eligible and need to have their records adjusted accordingly. Low-income beneficiaries will not be able to afford to pay these costs out of their own pockets with the expectation of being reimbursed later. Instead, these beneficiaries will forego prescription drug coverage until their plan processes their subsidy, making the first month or more of their subsidy period meaningless.

Adoption of a presumptive eligibility system recommended above would alleviate this problem. As an additional alternative, the regulations should provide that beneficiaries may present their notice of approval for the subsidy to their pharmacy when they seek prescription drugs. Pharmacies should accept this notice as adequate to relieve the beneficiary from making a co-payment, and instead seek reimbursement for the beneficiary's plan.

Subpart S - Special Rules for States - Eligibility Determinations for Subsidies and General Payment Provisions

§423.904 Eligibility determinations for low-income subsidies.

§423.904(a) General Rule.
This subsection should cross reference the entire Subpart P, or, at a minimum the definitions included in §423.772.

§423.904(b) Notification to CMS.
The rule should direct states to notify CMS of eligibility determinations within 24 hours of making them, as we previously recommended with respect to SSA determinations.

§423.904(c) Screening for eligibility for Medicare cost-sharing and enrollment under the State plan.
The proposed regulation regarding states' obligations to screen subsidy applicants and offer them enrollment in Medicare Savings Programs ("MSPs") are inadequate. In particular, the regulation should specify what "offer enrollment" means. We believe an applicant must be offered the opportunity to enroll during the same visit or contact (in office, by phone, or by mail), without providing any further documentation or completing any additional forms. Only if enrollment is easy and convenient will Congress's intent of increasing participation in MSPs be accomplished. Furthermore, because under the current rules, enrollment in an MSP may be the only entry into the subsidy for some beneficiaries, a quick and easy application for MSP programs is essential. As written, the regulation would permit states to say they have "offered enrollment" simply if they tell applicants that they might be eligible for an MSP and may return another time to complete another application form if they wish to apply. Such an outcome would defeat the

purpose of the screen and enroll provision included in the new §1935(a)(3) established in §103(a) of the statute. Instead, as proposed in our comments to Subpart P, the low-income subsidy application should include an "opt-out" provision, under which qualified applicants would be enrolled in an MSP unless they affirmatively decline to do so. This provision would explain that enrollment in an MSP may be another way to qualify for the low-income subsidy.

As we explained in our comments to Subpart P, because enrollment in an MSP may affect receipt of other public benefits, there is a tremendous need for good quality counseling of beneficiaries. In addition, in order to ensure that enrollment requirements between MSPs and the low-income subsidy are aligned, states should not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective and can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP.

In the interest of further aligning eligibility rules for MSPs and the low-income subsidy and easing administrative burdens, we suggest that CMS direct states to apply the definitions of resources used in Subpart P, §423.772, in making their resource determinations for MSP applicants.

In addition, should CMS adopt a policy, as has been discussed publicly, under which most subsidy applications to state Medicaid agencies would be forwarded to SSA for the actual eligibility determination, the regulations should be clear that the screening for MSP eligibility must take place prior to the processing of the applications to SSA. Potential beneficiaries should not have to wait to be screened and offered enrollment in MSPs. Furthermore, an individual cannot be told, by either SSA or the state that she or he is ineligible for the low-income subsidy until MSP eligibility has been determined (if the individual wishes). It would be incredibly confusing for an individual to receive a notice from SSA that she is ineligible for a subsidy, have her MSP eligibility determined by the state, then receive a notice from the state that she is eligible for both MSP and the subsidy. Whatever the mechanics, the individual must be told that MSPs are a route to subsidy eligibility.

Finally, as we discussed in our comments to §423.773, SSA should also screen subsidy applicants for eligibility in MSPs as well, and develop a system with states to enroll eligible beneficiaries. Applicants should not miss out on the opportunity to enroll in MSPs because they apply through SSA rather than state Medicaid offices. The same concerns about beneficiary education and estate recovery discussed above apply to enrollment through SSA.

The regulations should also ensure that beneficiaries are screened for eligibility for full Medicaid and offered enrollment if they qualify, consistent with 42 C.F.R. §435.404. Ideally, all subsidy applicants would be screened for Medicaid, and offered enrollment if they qualify. Because the importance of maintaining a simple application process for the subsidy is paramount, CMS may wish to consider using a simple screening process based on information obtained through the subsidy application. This screening would trigger a follow-up with applicants who appear to be eligible for full Medicaid.

Many Medicare beneficiaries who are eligible for a low-income subsidy under the Part D Program will also be eligible for other important benefits. Some of these benefits, such as food stamps, are also administered by states and have eligibility rules that very closely correspond with the new eligibility rules for the Part D subsidies. Historically participation by seniors and people with disabilities in these programs has been low, despite the fact that the benefits that low-income Medicare beneficiaries would be able to receive could help them struggle less to make ends meet every month. The Part D enrollment process offers an historic opportunity to connect Medicare beneficiaries to these other programs.

Beyond saying that applications may be filed either with a State's Medicaid program or with SSA, the proposed rule has very little detail about how the application process is likely to work. We urge CMS to specify that the new eligibility process should dovetail with other programs so that low-income Medicare beneficiaries can be enrolled as seamlessly as possible in all the state- or SSA-administered benefits for which they qualify

423.904(d)(3)(ii), Cost-effectiveness of information verification.
This section should be modified to permit states to use the verification process established by the Social Security Administration to verify the income and assets of people who apply for a Part D subsidy through a state Medicaid agency.

PART 403-SPECIAL PROGRAMS AND PROJECTS

Subpart B-Medicare Supplemental Policies

Disclosure notices advising consumers of their statutory rights must be short, simple, easy to understand, and address as few issues as possible. The proposed disclosure notice concerning Medigap policies H, I, and J included in the Preamble is too long, provides unnecessary information, and includes information that may not be accurate for all beneficiaries. We suggest that the letter be modified as follows:

Delete the information about Medicare Part D at the beginning of the disclosure notice;
Delete statements about the value of Part D benefits, which are irrelevant to the issue of changes to Medigap;
Delete the second statement about the need to notify the Medigap issuer if a person later enrolls in Medicare Part D. This information is repetitive; and

Delete the information concerning enrollment issues about Medicare Part D which is unrelated to whether a Medigap policy provides creditable coverage.

In addition, we encourage CMS to develop a different notice for people who will have creditable coverage as their options will be different from those of people whose Medigap policies are not deemed to provided creditable coverage. The specific information this group of beneficiaries will need about their creditable coverage, and any required action, will vary depending on whether their coverage is employer sponsored retiree coverage, a Medigap Plan J, a pre-standard Medigap plan, or a Medigap with a rider or an innovative benefit.

The discussion in the Preamble to the Regulation beginning with Subpart T 4(c)(iii) references the difficulty of determining creditable coverage and the inability to even make that determination in advance of a final rule to implement Part D. We expect there will be confusion on this issue and that mistakes may be made by issuers in applying an actuarial test to groups of policies issued all over the country. We expect additional confusion due to the proposal to modify the definition of Medicare Supplement (Medigap) policies in §403.205 to include riders and freestanding benefits for prescription drugs. We are requesting two remedies for Medicare beneficiaries who are initially notified of creditable coverage when the coverage is no longer or never was creditable: a Special Enrollment Period in Part D and a guaranteed issue right to a Medigap policy without prescription drug benefits. We are also requesting the extension of the right to a guaranteed issue policy to Dual Eligibles who lose their eligibility to Medicaid benefits.

Thank you for the opportunity to submit comments on the proposed rule. We hope that this will not be the final opportunity to do so.

Very truly yours,

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September 30, 2004

http://www.cms.hhs.gov/regulations/ecomments

Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-4068

Dear Madam or Sir:

On behalf of the clients represented by the undersigned, we wish to submit the following comments on your proposed rule for the Medicare Prescription Drug Benefit. The Medicare Advocacy Project has over 15 years of experience advocating on behalf of Medicare beneficiaries, particularly those with low incomes; the Massachusetts Law Reform Institute is a statewide advocacy organization representing low income individuals, including elders and persons with disabilities; and the Disability Law Center (DLC) is a private, nonprofit protection and advocacy agency that provides free legal assistance to individuals with disabilities throughout Massachusetts. A key mandate of DLC is ensuring that people with disabilities are able to access needed supports to live and work in the community. Because of the limited time allowed and the magnitude of the proposed rule, we are not commenting on CMS-4069, dealing with Establishment of the Medicare Advantage Program. Neither are we commenting on all the sections of the proposed prescription drug rule. Rather, we are focusing on the impact of the rule on low income beneficiaries and persons with disabilities, particularly in the Eligibility and Enrollment and Grievances, Coverage Determination, and Appeals sections. In addition, we support and agree with the more detailed and comprehensive comments submitted on one or both of the proposed rules by the Medicare Consumers Working Group and the Center for Medicare Advocacy, Inc.

We also request that time be provided for another comment period due to the many unaddressed or only vaguely addressed issues. The final regulations could include a number of errors and provisions that result in unintended consequences because so much of the final regulations will not have been seen by the public. We urge CMS to issue the next version of these regulations in a format that will allow one more round of comment, even if a shortened comment period. This is a very complex program with significant ramifications for a large number of citizens. We are concerned that failure to provide for additional public input when the regulations are more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

PART 423-VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

General comments.

1. Many pro-consumer statements in the preamble do not appear in the proposed rule. These protections bear no weight unless captured in the regulations. More should be done to reflect the Preamble's good intentions in the body of the regulations. For example:

> The Preamble discusses providing affected enrollees, prescribers, pharmacists, and pharmacies with written notice when a drug will be removed from the formulary or moved to a different tier for cost-sharing. The regulatory language does not specify that the notice should be in writing. Requirement for written notice is critical and should be specified.
>
> The Preamble gives examples of situations when a plan will be required to allow an enrollee to use a non-network pharmacy. These include situations such as when an enrollee's plan does not contract with the long-term care pharmacy which an enrollee in a nursing home must use. The regulations should include the examples CMS discusses in the preamble.

2. There are a number of areas where the law is unclear or contradictory and these areas are creating serious problems for the regulation drafters. CMS should take advantage of the law's provision calling for the submission of technical and corrective amendments. While this was supposed to have been done by June 8, 2004, it should still be done, and Congress should address these issues as soon as possible.

3. Simplicity, as well as additional support for information and counseling, is necessary to ensure that beneficiaries are reached in a comprehensible way. The sheer size and complexity of these regulations is a testament to the fact that this new law is incredibly confusing. If beneficiaries are confused, enrollment and use of the new program will be very difficult, particularly for lower income, sicker, and limited English proficiency beneficiaries. Thus whenever it is possible, CMS should seek to simplify the new program.

Addressing some of our specific concerns:

Subpart B-Eligibility and Enrollment

1. The draft regulations addressing enrollment of beneficiaries into private drug plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDPs) do not adequately address the need for hands-on outreach, particularly to low-income beneficiaries, or to beneficiaries with special needs, such as mental illness. More attention must be given to developing materials and education and enrollment campaigns focused on informing beneficiaries with disabilities, including mental illness and cognitive impairments, and those with other special needs about the new drug benefit and helping them to enroll in the best plan available.

2. Of particular concern, is enrollment of the dual eligibles. Beneficiaries covered by both Medicare and Medicaid are by definition poor and cannot afford to pay privately fo fill any gaps in medication. Congress and the Administration promised that dual eligible beneficiaries would be better off with this new Part D drug benefit than they were receiving drug coverage through Medicaid. To honor this promise, coverage of medications for dual eligibles and other special populations must be grandfathered into the new Part D benefit. In addition, CMS must require plans to establish an alternative flexible formulary for dual eligibles as suggested in the preamble to the proposed regulations. This flexible formulary would incorporate utilization management techniques that focus on improving inefficient and ineffective provider prescribing practices but

do not restrict access to medications through prior authorization, fail first, step therapy, or therapeutic substitution requirements.

3. The regulations do not adequately address how drug coverage for the dual eligibles will be transferred to Medicare on January 1, 2006. There are issues both of timing and implementing the enrollment process in a way that will ensure that these beneficiaries do not confront a loss of benefits or a gap in drug coverage, either of which could have disastrous health consequences. Specific comments on enrollment of dual eligibles and our recommendations appear in our comments on §§423.34, 423.36, 423.48 and on Subpart P.

A. We are concerned with ensuring continuity of care for dual eligibles and access to needed prescriptions. These issues and concerns apply equally to all dual eligibles, and particularly to those with special health care needs, as well as to other populations with specific needs (See our comments in Subpart C, §423.120.)

B. The proposed regulations would force dual eligibles to enroll (or be automatically enrolled) in the "benchmark" or average cost plans in their areas because the low-income subsidy they will receive will only cover the premium for these plans. The formularies for these plans will not be as comprehensive as the drug coverage these individuals currently have through Medicaid. Even though Massachusetts has restricted access to drugs in its Medicaid program with preferred drug lists and prior authorization requirements, Massachusetts has taken many steps to ensure that special populations can readily access medically necessary drugs. For example, individuals who have been stabilized on one antidepressant are not required to try another one.

C. Without access to the coverage they need, dual eligibles will be forced to switch medications, which for certain populations, such as beneficiaries with HIV/AIDS or mental illness can have serious adverse consequences. Also, failing to ensure continuity of care for dual eligibles may benefit the plans, but will undoubtedly lead to Medicare and/or state increased costs for more physician and emergency room visits, and hospitalizations. The regulations do provide a special enrollment period for dual eligibles to use "at any time" (§423.36). However, being able to enroll in a different Part D plan is inadequate to meet the special needs of dual eligibles.

D. In the preamble to the proposed regulations, CMS points to an exceptions process as a means of securing coverage of off-formulary medications (See our comments to **Subpart M-Grievances, Coverage Determination and Appeals**) But the process proposed is extremely complex and cumbersome to navigate for someone having a psychiatric crisis, facing cognitive impairments, or in the midst of aggressive chemotherapy-to list just a few examples. Moreover, the timelines established are inordinately drawn out; for example, an expedited determination could take as long as two weeks. Drug plans are not required to provide an

emergency supply of medications until at least two weeks following a request. Exception, grievance and appeal processes should not be used to substituted for open formulary access to medications.

§423.34 Enrollment Process.

§423.34 (b) Enrollment.
The final rule should provide that an authorized representative may complete the enrollment form on behalf of a Part D eligible individual.

§423.34(c), Notice Requirement.
The notice must be in writing and inform an individual who is denied enrollment of his or her appeal rights, including the right to appeal the imposition of a penalty for late enrollment.

§423.34(d) Enrollment requirement for full benefit dual eligibles.
In the Preamble, CMS requested comments on whether CMS or the states should perform automatic enrollment of dual eligibles. State officials have more readily available data identifying the dual eligibles in their state and they also will be involved in the enrollment process because they are already required to perform low-income subsidy enrollment. In addition, there is an incentive for them to enroll these individuals in Medicare drug plans because without drug coverage they will increase utilization of other Medicaid services. Thus, states should be afforded the ability to conduct auto-enrollment and receive full federal financing for this function. In addition, CMS should develop its own systems for automatic enrollment of dual eligibles in states that do not elect to do so. Also, because the proposed rule leaves unanswered key questions about who will conduct automatic enrollment of dual eligibles and how it will occur, CMS must give the public the opportunity to provide input on any proposal it develops on this issue before publishing a final regulation.

§423.34(d)(1) General Rule.
The draft regulations provide that dual eligibles will be automatically enrolled in a Part D plan if they do not enroll themselves, by the end of the initial enrollment period, which, under §423.36, is May 15, 2006. However, their Medicaid prescriptions drug coverage will end on January 1, 2006. This proposed timeline for automatic enrollment must be changed because it could expose millions of dual eligibles to a four and half month coverage gap that could have serious health consequences for this vulnerable population. Given the difficulty of reaching this population coupled with inadequate provisions for outreach and education, it is almost certain that a substantial number of dual eligibles will face a several month gap in coverage between the end of Medicaid's drug benefit and automatic enrollment. This is untenable, and directly in conflict with Congress' and the Administration's promise that dual eligibles will be better off under Medicare Part D. The transfer of drug coverage from Medicaid to Medicare Part D should be delayed. Absent a delayed transition date for dual eligible drug coverage, however, dual eligibles should be randomly assigned and enrolled in a plan that best suits their needs as early as November 15, 2005 but no later than December 1, 2005. While we would prefer to provide individuals an extended period to make informed choices, it is critical to complete auto-enrollment as early as possible to leave as much time as possible to distribute plan information

and cards to beneficiaries, allow them to switch plans, and educate them about their new drug coverage before January 1, 2006. To make this process work more smoothly, states can begin profiling individual drug histories to prepare for random auto-assignment among plans that are appropriate for the individual even before plan information is released on October 15, 2005. Additionally, CMS should fund a campaign of individualized counseling and assistance both before and after auto-enrollment to explain to individuals their choices and how to enroll in a plan; explain, if applicable, how to get benefits under the plan to which they have been auto-assigned; and explain, if applicable, that they can choose a different plan from the one to which they have been auto-assigned and assist in choosing and enrolling in such a plan.

§423.34(d)(1)(ii)
CMS must develop a solution to the issue of automatic enrollment of dual eligibles who are enrolled in MA plans that have a prescription drug benefit with a premium that is above the low-income benchmark. The solution should be the one least disruptive to medical care and should not force a dual eligible to choose among continued MA enrollment, paying added premiums, or foregoing drug coverage. For institutionalized dual eligibles, the difference between the premium and the premium subsidy should be considered an incurred medical expense and deducted from their monthly "patient paid amount" to the facility. For non-institutionalized dual eligibles, in states with pharmacy assistance programs (SPAPs) which will wrap around Part D coverage and will cover dual eligibles, the SPAPs should be authorized to pay the difference. For medically needy individuals, the cost differential would be an incurred medical expense contributing toward their spenddown, if appropriate. Otherwise, individuals should be counseled about the premium discrepancy and about their right to withdraw from the MA plan and return to original Medicare. Ideally, dual eligibles who want to remain in the MA plan should be allowed to do so and not have to pay any amount by which the MA-PD basic premium exceeds the low-income benchmark amount.

§423.34(d)(2), When there is more than one PDP in a PDP region.
Because not every PDP plan may be appropriate for each dual eligible (for example, due to formulary restrictions), CMS should limit "on a random basis" to "among such plans in the region that meet the beneficiary's particular drug needs." Also, this subsection undermines the §423.859 right of assured access to a choice of at least two qualifying plans, by acknowledging that there may be regions where there is only one PDP in a PDP region with a monthly beneficiary premium at or below the premium subsidy amount.

§423.36 Enrollment Periods.

§423.36(a)(3)(ii) Exception.
It is not clear who these beneficiaries would be.

§423.36(c) Special Enrollment Periods.
This section should be expanded to provide "special enrollment exceptions" for individuals disenrolled by a PDP (such as for disruptive behavior) so that the individual will have an opportunity to join another PDP and continue with necessary medications. These "special enrollment exceptions" are necessary given the high risk of discrimination presented by the

provisions for involuntary disenrollment. CMS should provide a special enrollment period for these beneficiaries. It should include a reasonable time period for plan selection and be exempt from late enrollment penalties. It should also be expanded to make clear that involuntary loss of creditable prescription drug coverage includes loss because the beneficiary, or beneficiary's spouse, stops working; because COBRA coverage ends or because the premiums became unaffordable.

§423.36(c)(4) Special Enrollment Periods and Dual Eligibles.
We support granting dual eligibles special enrollment periods. However, this provision does not adequately address their needs. It is unlikely that there will be much choice of low-cost drug plans in each region, particularly in rural areas which have not historically attracted many Medicare+Choice plans. For example parts of Cape Cod and Western Massachusetts have no Medicare+Choice plans. In addition, these individuals will not have the resources to pay for more comprehensive coverage. Moreover, the special enrollment provisions do not specify that dual eligibles would not be subject to a late enrollment fee if this complex process of disenrollment and reenrollment resulted in a gap in coverage of over 63 days.

In addition, full benefit dual eligibles should receive notice explaining their right to a special enrollment period when they enroll in a plan, and every time their PDP changes its plan in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

§423.36(c)(8)
The regulations should include a special enrollment period similar to the one for dual eligibles for all beneficiaries eligible for a full or partial-low income subsidy. This is necessary because if coverage for a drug is denied, these low-income beneficiaries will be unable to afford to pay for drugs during a period of appeal, or if their appeal is denied and they are locked into a plan that does not cover a drug they need.

Special enrollment periods should also be provided for all institutionalized individuals, not just institutionalized dual eligibles, since their access to needed drugs may be compromised by the design of the plans and by pharmacy access requirements, such as if their long-term care pharmacy is not required to be included in the network of all PDPs. Individuals with life-threatening situations and individuals whose situations are pharmacologically complex should have the same rights as well.

§423.38 Effective Dates.

§423.38(c) Special Enrollment Periods.
Effective date should be first day of first calendar month following special enrollment in which individual is eligible for Part D.

§423.42 Coordination of enrollment and disenrollment through PDPs

§423.42(c)(2)
Notice of disenrollment should be in writing.

§423.44 Disenrollment by the PDP.

§423.44(b)(2)(I)
CMS requested comments about the requirement to involuntarily disenroll individuals from a PDP if they no longer reside in the service area. This raises the issue of "snowbirds"-the large number of Medicare beneficiaries who move for large parts of the year. This is a problem in Massachusetts where many elders winter in warmer climates. The churning-the enrolling and disenrolling-that plans serving this population will face as they apply this section will be enormous. Because of different formularies between plans and problems of coordination, the regulations should seek to minimize plan changes and maintain continuity of care. This section, as written, could result in a significant number of plan changes, disrupting continuity of care.

Some suggested ways to address this issue better would be to require that plans as a condition of participation have a system of visitor or traveler benefits, consider exempting regional PDPs and PDPs with out-of-network services from the disenrollment requirement, require plans to provide prospective enrollees specific information on traveler benefits and "out-of-plan service policies" and clearly define the time period that a plan could consider an enrollee as "no longer resid(ing) in the PDP's service area." such that it accommodates seasonal travelers who maintain a residence in the service area.. In many cases, 90 day mail order service and arrangements with other plans will make enrolling and disenrolling unnecessary. However, beneficiaries must have a clear understanding of how a plan will serve them while temporarily out of the service area; how when they are traveling and need emergency pharmaceutical services their plan will (or will not) reimburse for those services.

§423.44(d)(2)
Provisions in the proposed regulations to allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" create enormous opportunities for discrimination against individuals with mental illnesses, Alzheimer's, and other cognitive conditions. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and accordingly be subject to a late enrollment penalty permanently increasing their premiums. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage. Moreover, CMS lacks statutory authority to authorize PDPs to involuntarily disenroll beneficiaries. Under the MMA, section 1860D-1(b) directs the Secretary to establish a disenrollment process for PDPs using rules similar to a specific list of rules for the Medicare Advantage program. This list does not include reference to section 1851(g)(3)(B) of the Social Security Act which authorizes MA plans to disenroll beneficiaries for disruptive behavior. Thus, these proposed regulations must not be included in the final rule.

Concerns with specific provisions in this section and recommendations for beneficiary protections, which, at a minimum should be provided, are as follows:

§423.44(d)(2)(vi) Reenrollment in the PDP.
In the preamble, CMS appears to be asking for comments on whether a PDP should be allowed to refuse reenrollment of an individual who has been involuntarily disenrolled if there is no other drug plan in the area. As discussed above, it is our position that there is no statutory basis for involuntarily disenrollment. If the regulations allow this for disruptive behavior, then the plans must be required to allow reenrollment. Those individuals most likely to be subject to involuntary disenrollment will not have the resources to pay for their medications out-of-pocket. These individuals are entitled to this benefit. Disruptive behavior does not disqualify you from access to prescription drug coverage and may in fact be an indication that one is in need of medical assistance. Individuals who are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period and may therefore be subject to a late penalty and increased premium as a result. This result is unfair in light of the fact that the disruptive behavior may have resulted from denial of access to needed medications. CMS should therefore provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior, must waive the late enrollment penalty for these individuals, and the regulations must include detailed articulated protections to lessen the risks inherent in authorizing sanctions for "disruptive behavior."

§423.44(d)(2)(vii) Expedited Process.
This provision should be deleted from the final rule. The proposal to establish an expedited disenrollment process in cases where an individual's disruptive or threatening behavior has caused harm to others or prevented the plan from providing services is undefined, and provides no standards, requirements or safeguards. It allows plans to employ this mechanism on the basis of behaviors described in the broadest of terms - terms which could easily be mis-applied or applied capriciously or punitively. Thus, it would undermine all the minimal protections that would otherwise apply.

§423.46 Late enrollment penalty.
CMS should delay implementation of this section for two years. The drug benefit is a new and complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. The Medicare-endorsed prescription drug discount card program has shown that, even with significant outreach, the majority of individuals eligible for the $600 low-income subsidy have not yet enrolled. We disagree that healthy beneficiaries will not apply. We believe that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness and cognitive disabilities. Implementation of the late enrollment penalty should be delayed for individuals eligible for the low-income subsidy who may not understand that they have to apply separately for the subsidy and a drug plan, thinking that application for the subsidy is sufficient.

This section should provide that when the late enrollment penalties are implemented, there will be an opportunity for enrollees to appeal late enrollment penalties; that late enrollment penalties will be coordinated with "special enrollment periods" to ensure that individuals who take advantage of the special enrollment periods do not face late penalties; that individuals who are involuntarily disenrolled are exempt from this penalty; and that if an employer or other entity

providing drug coverage to Medicare beneficiaries fails to provide adequate or correct notice of the creditable status of that coverage or a change in status of that coverage, and that coverage is not creditable, there are no late enrollment penalties.

§423.48 Information about Part D.
Medicare beneficiaries can only exercise an informed choice about their drug plan if they have adequate information about drug plan options available to them. The information should be provided annually, in writing, and include details about the plan benefit structure, cost-sharing and tiers, formulary, pharmacy network, and appeals and exception process. In order to assure that beneficiaries have the required information, the standards should be included in regulations that are binding and enforceable, and not in guidance. Minimally, the regulations should require plans to provide premium information, including whether individuals who receive the low-income subsidy will have to pay a part of the premium and, if so, the amount they will have to pay; the benefits structure and comparative value of the plans available to them; the coinsurance or copayment amounts they will need to pay for each covered Part D drug on the formulary; the specific negotiated drug prices upon which coinsurance calculations will be based and that will be available to beneficiaries if they confront the gap in coverage; formulary structure, the actual drugs on the formulary, and how the formulary can change during the plan year; participating pharmacies, mail order options, out-of-service options; and exception, appeals and grievance processes. Plans should be required to provide this information to potential enrollees in a clear manner using a standard format that will allow beneficiaries to easily compare plans. Plans should be required to provide information on negotiated prices in an easily accessible format.

The regulations should also include specific requirements for plans and states, as well as outline activities CMS will undertake, to ensure that every effort will be made to reach dual eligibles. By summer 2005 CMS and the states should launch a concerted outreach and assistance campaign for dual eligibles to alert them about the need to enroll in a Part D plan and to help them make appropriate choices. The outreach campaign would be intended to prevent default enrollment. In addition, as early as possible, and no later than October15, 2005 (assuming information is available), CMS or the states should mail standardized, easy-to-understand notices to dual eligibles that, among other things: inform them of their eligibility to receive the low income drug benefit if they enroll in a PDP or MA-PD; list choices of health plans (clearly denoting those that meet the benefit premium assistance limit) and contact information for each plan; explain that individuals will be randomly enrolled in a prescription drug plan beginning November 15 (or, if different, the appropriate date) if they fail to opt out or enroll in a plan themselves; explain how they may change their drug plans if they wish at any time; and inform them of where in their community they can go to get help with enrollment. These notices should be tested for readability by focus groups and experts. If the states are required to provide this information, CMS should reimburse 100 percent of the states' costs.

§423.50 Approval of marketing material and enrollment forms.
The marketing rules for the PDPs and MA-PDPs should be developed in the historical context of other Medicare programs. From selective marketing to outright fraud, Medicare programs historically have been afflicted with marketing abuses and scams. We urge that CMS be vigilant to identify and prohibit these problematic areas and practices as it develops final regulations.

§423.50 (e) Standards for PDP marketing.
Telemarketing should expressly be prohibited. Door-to-door solicitation is prohibited under this section and telemarketing presents many of the same dangers. The regulations should specifically prohibit prescription drug plans from initiating telephone or e-mail contact with potential enrollees, unless the potential enrollee requests contact through such means in response to a direct mail or other advertisement.

In the Preamble, CMS asked for comments on whether it would be advisable to permit prescription drug plan sponsors to market and provide additional products (such as financial services, long term care insurance, credit cards) in conjunction with Medicare prescription drug plan services. CMS should not allow plans to market other services, nor should it seek to encourage other entities, such as financial institutions, to participate as PDPs. The potential for abuse—both cherry picking of healthier beneficiaries into plans and avoidance of financial services to less healthy individuals—is enormous. CMS also asked for comments on the applicability of MA marketing requirements for PDP marketing. PDP marketing requirements should be at least as restrictive as MA marketing because of the high potential both for confusion and for individuals to be directed to—and locked-into—plans that do not best meet their needs. Beneficiaries look to providers for balanced, unbiased information, and they should be able to rely on the information that these sources provide. However, if providers or pharmacies are allowed to market plans, there is the potential for aggressive marketing of certain PDPs, regardless of whether or not that PDP is the best for the beneficiary. The adverse consequences of making a bad selection based on promotion from a trusted source are high.

§423.56 Procedures to determine and document creditable status of prescription drug coverage.

§423.56 (e) Notification.
It is essential that beneficiaries understand whether they have creditable coverage. Failure to understand the issue of creditable coverage can lead to a lifetime of higher Part D premiums. CMS must set forth specific requirements that plans provide information to Medicare beneficiaries enrolled in those plans clearly stating whether or not the coverage they have is creditable. Minimally, in 2005, information on whether coverage is creditable or not should be provided in more than one mailing, and included in such documents as quarterly retiree income statements, medical billing correspondence, etc. After 2005, CMS should develop standard notices, through its Beneficiary Notice Initiative, to be used. In years after 2006, when creditable status changes, special notification is needed to insure that beneficiaries know as soon as the decision is made to reduce coverage, so they can begin shopping for a PDP and avoid a lifetime of premium penalties. Because this is such important notification, it should be sent by registered mail, or e-mail with proof of receipt. Additionally where beneficiaries are not adequately informed by an employer or other entity that their coverage is not creditable, CMS should take action on behalf of all the individuals of that employer or other entity to provide a special enrollment period (SEP). Each individual adversely impacted by the failure of the employer or other entity to inform adequately should not have to apply or appeal for a SEP.

Subpart C-Benefits and Beneficiary Protections

§423.100 Definitions.
"Dispensing fee" should be broadly framed, in order to permit the payment of costs associated with home infusion therapy. Of the options provided in the preamble to the proposed rule, we support option 3. We do not believe that a narrowly crafted definition of dispensing fee is appropriate because the conference report at § 1860D-2(d)(1)(B) references negotiated prices in a manner that indicates that Congress intends to define negotiated prices in a way that arrives at the most accurate prices when considering a variety of both concessions and fees. Since the antibiotics, chemotherapy, pain management, parenteral nutrition and immune globulin and other drugs that are administered through home infusion are indisputably covered Part D drugs, and equipment, supplies and services are integral to the administration of home infusion therapies, costs associated with such administration should be included in the definition of dispensing fee, in order to arrive at the most accurate determination of the negotiated price. Option 1 makes an arbitrary and inappropriate distinction between costs associated with dispensing a covered Part D drug and associated costs for the delivery and administration of a covered Part D drug, and option 2 does not capture all the true costs associated with dispensing a covered Part D drug.

"Long-term care facility" should explicitly include ICF/MRs and assisted living facilities.
We recommend that the final rule include a definition of "long-term care facility" that explicitly includes intermediate care facilities for persons with mental retardation and related conditions (ICF/MRs) and assisted living facilities. This is important because many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

§423.104 Requirements related to qualified prescription drug coverage.
The final rule defines "person" so that family members can pay for covered Part D cost-sharing. The law precludes contributions from employer sponsored health plans from being counted as incurred costs and counting toward the deductible or out of pocket limit. Contributions from one employer-sponsored benefit should not receive differential treatment over contributions from another type of employer-sponsored benefit. Contributions from employer-sponsored group health coverage should be counted as an incurred cost, similar to contributions from HSAs, HRAs, and FSAs. The final rule should also count cost-sharing subsidies from AIDS Drug Assistance Programs (ADAPs) as incurred costs. The regulations also specifically state that state-appropriated dollars spent by ADAPs cannot be counted as incurred costs. It is discriminatory and unacceptable to single out state dollars used to provide medications to people living with HIV/AIDS and not allow them to count as incurred costs, while at the same time allowing state dollars paid by State Pharmaceutical Assistance Programs' (SPAPs)to count as incurred costs.

§423.104(e)(2)(ii) Establishing limits on tiered copayments.
The final rule should not allow Part D plans to apply tiered co-payments without limits. Rather, it must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs.

§423.104(h) Negotiated prices.(1) Access to negotiated prices.
No plan should be allowed to impose 100% cost-sharing for any drug. Such cost-sharing should be considered as per se discrimination against the group or groups of individuals who require that prescription.

§423.120 Access to covered Part D drugs.

§423.120(a) Assuring Pharmacy Access.
Pharmacy access standards must be met in each local service area, rather than by permitting plans to apply them across a multi-region or national service area. Permitting plans to meet the access standards across more than one local service area could cause individuals in some local service areas to not have convenient access to a local pharmacy. Also, only retail pharmacies should be counted for the purpose of meeting pharmacy access standards. It would undermine the principle that Medicare beneficiaries will have convenient access to a local pharmacy if the access standards could be met by counting pharmacies that serve only specific populations and which are not available to all parts of the general public. The final rule should require prescription drug plans to offer to contract with Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (I/T/U) pharmacies and make available a standard contract. Should the final rule not contain this requirement and in situations where an I/T/U pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy. The final rule should also require prescription drug plans to offer to contract with all LTC pharmacies and make available a standard contract. Over 80% of nursing home beds are in facilities that require the resident to use a long-term care pharmacy. Should the final rule not contain this requirement and in situations where a LTC pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy. Furthermore, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through higher cost-sharing for out-of-network access.

§1860D-11(e)(2)(D) authority to review plan designs to ensure that they do not substantially discourage enrollment by certain Part D eligible individuals.
CMS should use the authority provided under section 1860D-11(e)(2)(D) to review plan designs, as part of the bid negotiation process, to ensure that they are not likely to substantially discourage enrollment by certain Part D eligible individuals. Previous experience with Medicare+Choice plans shows that private insurers use a variety of techniques to discourage both initial and continued enrollment in a plan by enrollees with more costly health care needs. For example, Medicare+Choice plans have offset reduced cost-sharing for doctors visits with increased cost sharing for services such as skilled nursing facility care, home health care, hospital coinsurance, and cost sharing for covered chemotherapy drugs that are utilized by people with chronic and acute care needs. CMS should thus analyze formularies, cost-sharing tiers and cost-sharing levels, and how cost-sharing (including both tiers and levels) is applied to assure that people with the most costly prescriptions are not required to pay a greater percentage of the cost of those drugs. CMS also needs to assure that a variety of drugs are included in a

formulary at the preferred cost-sharing tier to treat chronic conditions and conditions that require more costly treatments. As stated above, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through higher cost-sharing for out-of-network access.

§423.120(a)(6) Level playing field between mail-order and network pharmacies.
The final rule should ensure that beneficiary out-of-pocket costs used for the purchase of covered Part D drugs count as incurred costs. A key principle of the MMA is that Medicare beneficiaries have convenient access to a local pharmacy. This principle is undermined by permitting plans to charge beneficiaries the cost differential for receiving an extended supply of a covered Part D drug through a network retail pharmacy versus a network mail-order pharmacy. However, notwithstanding this objection, the final rule should permit the cost differential charged to beneficiaries to count as an incurred cost.

§423.120(b) Formulary requirements.
We do not believe it is appropriate for the final rule to constrain prescribers' capacity to prescribe drugs for off-label uses. By not permitting a class to exist in the USP model guidelines solely because all commonly used medications are being used for off-label indications could lead plans to deny coverage for off-label uses. Off-label prescribing has become a common-and accepted-practice across the field of medicine. For example no drugs that are currently used in the treatment of lupus (a serious, life-threatening auto-immune disorder) have the treatment of lupus as an on-label indication. For the treatment of mania, certain anti-convulsants and calcium channel blockers have proven effective and certain anti-convulsants have proven effective for treatment of bipolar disorder, although these uses are not FDA-approved on-label indications. We thus oppose any provisions in the final rule that place new limits on the ability of prescribers to prescribe drugs for off-label uses-or that legitimize the denial of coverage for covered Part D drugs simply because they are used for an off-label indication.
We support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must be protected from tiered cost-sharing that could to these defined populations must be made available at the preferred level of cost-sharing for each drug. We recommend that this treatment apply to at least the following overlapping special populations: dual eligibles, institutionalized populations, persons with life-threatening conditions, and persons with pharmacologically complex conditions.

We recommend that if the final rule limits the notice requirements to persons directly affected by the change, then plans must be required to provide notice in writing, mailed directly to beneficiary, 90 days prior to the change, and the notice must inform the beneficiary of their right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary. We also recommend that the final rule place strict limits on mid-year formulary changes, requiring plans to justify a decision to remove drugs from a formulary such as the availability of new clinical evidence indicating that a particular covered Part D drug is unsafe or contraindicated for a specific use or when all manufacturers discontinue supplying a particular

covered Part D drug in the United States. Should the final rule fail to effect such a restriction, plans should be required to continue dispensing all discontinued drugs until the end of the plan year for all persons currently taking a discontinued drug as part of an ongoing treatment regimen.

§423.124 Special rules for access to covered Part D drugs at out of network pharmacies.
The final rule must establish requirements on plans to dispense a temporary supply of a drug (wherever a prescription is presented, irrespective of whether or not it is at a network pharmacy) in cases of emergency. If the emergency situation involves a coverage dispute, the plan must dispense refills until such time as the prescription expires or the coverage dispute is resolved, through either a plan decision to provide coverage for the drug or through completion of the appeal process. This requirement must also specify that a temporary supply must be dispensed even in cases where beneficiaries are unable to pay applicable cost-sharing.

The final rule should also limit out-of-network cost-sharing to no more than the difference between the maximum price charged to any in-network Part D plan in which the pharmacy participates and the in-network price. While we recommend that this limitation apply in all circumstances, at a minimum, it must be applied through the final rule, to the scenarios described in the preamble to the proposed rule.

§423.128 Dissemination of plan information.

§423.128 (d) Provision of specific information.
It is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center. The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program.

§423.128(e) Claims Information.
In addition to the required explanation of benefits elements in the proposed regulation, the explanation of benefits should also include information about relevant requirements for accessing the exceptions, grievance and appeals processes.

Subpart J-Coordination Under Part D With Other Prescription Drug Coverage

§423.464(e) Coordination with State Pharmaceutical Assistance Programs (SPAPs).

SPAPs and new SPAPs must be able to help beneficiaries 'fill in the donut,' and we appreciate CMS's efforts to coordinate this assistance. To assure that beneficiaries are receiving seamless coverage and not facing undue out of pocket expenses, an exchange of data between the PDP and the SPAP is necessary. This should include (but not be limited to) an exchange of eligibility files, exchange of claims payment and information about the drugs on the PDPs formulary and any changes to it. Also, AIDS Drug Assistance Programs (ADAPs) should be recognized as

State Pharmacy Assistance Programs and allowed to wrap around the Medicare Part D drug benefit.

Subpart M-Grievances, Coverage Determination, and Appeals

The proposed regulations fail to meet the requirements of the Due Process Clause of the Fifth Amendment to the United States Constitution. As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid recipients whose prescription requests are not being honored currently receive a 72-hour supply of medications pending the initial coverage request. They are entitled to notice, face-to-face hearings, and aid paid pending an appeal if their request is denied and they file their appeal within a specified time frame. All state Medicaid appeals processes are completed more expeditiously than Medicare appeals. The appeals process as described in Subpart M does not accord dual eligibles and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity for a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes. While we recognize that the most efficient means of protecting enrollees, amending MMA to provide for an appeals process similar to Medicaid, is beyond the authority of CMS, CMS can take steps in the final regulations to improve notice and the opportunity for speedy review.

Sections 1860D-4(f), (g), and (h) require that Part D plan sponsors establish grievance, coverage determination and reconsideration, and appeals processes in accordance with Sections 1852(f), (g) of the Social Security Act. As will be discussed in more detail below, CMS has failed to comply with the language of those provisions. Overall, the incredibly onerous exceptions process does not comply with the statutory requirements or meet the basic elements of due process. In addition, CMS, in implementing Section 1852(c) and in settlement of *Grijalva v. Shalala*, 153 F.3d 1115 (9th Cir, 1998), *vacated and remanded*, 526 U.S. 1096 (1999), adopted 42 C.F.R. §422.626, which establishes the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review for Part D. CMS needs to incorporate a similar process for Part D in order to establish a process in accordance with Section 1852(c). A similar fast-track process would also be more in keeping with due process requirements.

As a general comment, this entire subpart needs to be made much simpler. To have two tracks, depending on (1) whether one personally pays for a drug and files an appeal or (2) does not obtain the drug and files an appeal, is far too complicated. The time frames, paperwork, and processes should be simplified into one course of action that beneficiaries may hope to understand.

§423.560 Definitions.

This section defines "appeal" to exclude grievance and exceptions processes, and defines “authorized representative” as an individual authorized by an enrollee to deal with appeals. The definition of “authorized representative” needs to clarify that a doctor or representative, including a State Prescription Drug Plan (since the SPAP may be at risk in the event of PDP

actions) can be an authorized representative, and that authorized representatives can deal with exceptions and grievances as well as appeals.

§423.562 General provisions.

§423.562(b)(5)(iii)

Reconsideration by an Independent Review Entity (IRE) should be automatic, as in the Medicare+Choice plans

§423.562(c)(1)

This subsection precludes an enrollee who has no further liability to pay for prescription drugs from appealing. However, it is important to be able to appeal formulary changes. A comprehensive change in this limitation is essential to protect the health of beneficiaries. At a minimum, SPAPs should be able to appeal on behalf of an enrollee and the section should clarify that a low-income institutionalized individual can appeal a determination, even if she has no co-payment responsibilities.

§423.566 Coverage determinations.

§423.566(b) Actions that are coverage determinations.

This subsection needs to clarify further what constitutes a coverage determination. The proposed definition does not include in the list of coverage determinations from which an appeal can be taken a determination by the PDP that a drug is not a covered drug under Part D. An enrollee should be entitled to appeal to determine whether, in fact, a drug the plan claims is not covered under Part D is so covered. The definition should also clarify that denials of enrollment in a Part D plan, involuntary disenrollment from a Part D plan, and the imposition of a late enrollment penalty are coverage determinations subject to the appeals process. Finally, the regulation should state that the presentation of a prescription to the pharmacy constitutes a coverage determination. If the pharmacy does not dispense the prescription, then the request for coverage should be deemed denied, and the enrollee should be entitled to notice and to request a re-determination. Without such clarification, enrollees will not be informed of their rights, and the appeals process will become meaningless.

§423.568, Standard timeframes and notice requirements for coverage determinations.

§423.568(a) Timeframe for requests for drug benefits.

The plan should be required to provide oral notice as soon as it determines that it will extend the deadline for considering whether it will cover a drug, including notice of the right to request an expedited grievance. The oral notice should be followed-up in writing.

§423.568(b) Timeframe for requests for payment.

This section should be eliminated. There should be no distinction in time frames when an enrollee requests payment.

§423.568(c), Written notice for PDP sponsor denials.

Who gives notice? The proposed regulations place the responsibility for providing notice of a coverage determination on the plan sponsor. This presumes a situation in which the person presents a prescription, the pharmacy contacts the plan, and then the plan takes 14 days to decide whether or not to cover a drug. In reality, the pharmacy, in most instances, tells the enrollee that the plan will not cover the drug. Without notice provided by the pharmacy, most enrollees will not know to tell the pharmacy to submit the prescription anyway so they can get a notice from which to appeal. They also may not know or understand their right to seek expedited consideration of the initial coverage determination, or an exception if the drug is not on the formulary or on too high a tier. If the enrollee pays out of pocket and then seeks reimbursement from the plan, she will not be eligible for expedited consideration.

The regulations should require the plan sponsor to develop a notice explaining the right to seek a redetermination, and to ask for expedited review. The pharmacy should be required to give the notice to the enrollee. Any potential burden of such a requirement is reduced by the need to maintain electronic communications between the pharmacies and the plans in order to keep up-to-date with formularies, coinsurance, and calculations of an enrollee's out-of-pocket expenses.

The proposed regulations talk about using "approved notice language in a readable and understandable form." The regulations need to be more specific, including information about what is required to use the exceptions process. We suggest that notice should

Include information about exceptions and appeal rights immediately upon denial (including upon determination that a drug is not covered on formulary and including denials issued by the pharmacist), explain why coverage was denied and provide options in addition to the appeal procedures for obtaining necessary medications;

Include clinical or scientific basis for denial; and

Be available in multiple languages and note the availability of language services.

In addition, all notices need to be available in alternate formats to accommodate people with disabilities, and in languages other than English where a portion of the population is not English speaking. The requirements of plans and the rights of beneficiaries in this area must be spelled out in much more detail. There is also an overarching need to consider literacy problems and encourage simplicity.

§423.568(e) Effect of failure to provide timely notice.
It is nowhere spelled out how the beneficiary is apprised of this right.

§423.570 Expediting certain coverage determinations.

§423.570(a) Request for expedited determination.
CMS requests comments on who should be able to request determinations and re-determinations. An authorized representative should be able to request expedited consideration just as the authorized representative may request a coverage determination. In emergency situations, enrollees with mental health concerns and other vulnerable individuals may need someone else to act on their behalf.

§423.570(c) How the PDP sponsor must process requests.
All coverage determinations and appeals concerning drugs, including those in which the enrollee has paid for the drug, should be treated as requests for expedited review. An enrollee would suffer adverse consequences if required to wait for the longer time periods; many people will simply go without prescribed medications pending the outcome of the review. Doubling the timeframes and disallowing expedited review in cases when enrollees pay for their drugs out-of-pocket could adversely affect the health of those who forego other necessities like food and heat in order to pay for their medicine.

At a minimum, all requests for exceptions should be automatically given expedited consideration. Where someone seeks expedited review of a request to continue a drug that is no longer on the formulary, the plan should be required to process the request in 24 hours under the provision that requires an expedited review to be completed as fast as the beneficiary's condition requires. The enrollee should be given a 72-hour supply of the medicine, which is renewable if the plan decides to take longer than 72 hours. The medicine should be treated as an on-formulary drug.

If requests for an exception are not automatically treated as a request for expedited review, the rules should state that the doctor's certificate requesting expedited review and requesting an exception should be one and the same.

§423.570(d)(2)
A beneficiary should not have to wait for a written notice to learn of the right to file an expedited grievance and the right to resubmit a request with prescribing physician support.

§423.572 Timeframes and notice requirements for expedited coverage determinations.

§423.572 (b) Extensions of timeframe.
The timeframe (of 72 hours) can be extended by the plan up to 14 days on showing that an extension is in the interests of the enrollee. The regulations should be modified to read best interest of the enrollee and define interests of the enrollee to include those situations in which the drug plan seeks additional information to substantiate the enrollee's request, or when the enrollee requests additional time to gather supporting information. The regulations should also require the plan to inform the enrollee of the extension immediately, both orally and in writing, rather than "by the expiration of extension." Also, the written notice should include more than just the reasons for the delay.

There should be no extended time period for requests for payment of drugs already received. This imposes extreme hardship on low-income beneficiaries and those with multiple prescriptions who may choose to unnecessarily spend money on their medications because of the uncertainty and length of the appeals process rather than spend the money on other urgent necessities of life.
It is not clear from the proposed regulations what notice a beneficiary will receive when sometime during the year a plan changes its formulary and the drug(s) it covers. The statute says plans must make the change in information available on the internet, the Preamble discusses a

mailed notice, and the draft regulation simply says 'notice.' A change in formulary, or a change in the tiering of a drug on the formulary should be clearly explained to a beneficiary taking that drug which has been changed. That notice should be written notice and the receipt of that notice should serve as a trigger for the beneficiary's legal rights.

§423.572(d) Content of the notice of expedited determination.
See §423.568(c) comments above.

§423.572(e) Effect of failure to provide a timely notice.
How does a beneficiary know s/he can appeal the lack of timely notice?

§423.578 Exceptions process.
The proposed regulations do not explain how an enrollee will get notice about the exceptions process and/or that a drug is not included on the formulary. The only notice requirement is found in §423.120(b), which requires the plan sponsor to provide at least 30 days notice to CMS, affected enrollees, pharmacies, pharmacist and authorized prescribers before removing a drug or changing a drug's preferred or tiered status. Although the preamble talks about written, mailed notice, and the statute requires posting on the Internet, the regulatory language merely says that notice must be given.

To meet basic due process requirements concerning termination of benefits, the notice of the change must be in writing and must include an explanation of how to use the exceptions process, including the requirements for a doctor's certificate, the right to a hearing, and the reasons why a drug is not included on or removed from the formulary, or why the tier is changing, and the evidence required to establish an exception.

Proposed section §423.120(b) provides insufficient time for the notice, given the substantial burden placed on the enrollee to either get a new prescription or to gather the medical evidence. Many beneficiaries will not be able to get a doctor's appointment within 30 days, and many will not be able to change drugs without a medical evaluation. The final regulations should state that notice must be provided 90 days in advance of the change.

In addition, the exception process section should include a subsection on notice that (1) refers to §§423.120(b) and (2) requires plan sponsors to develop a notice that explains the exceptions process, the situations in which someone may seek an exception, and the information that is required to support an exception request, which the pharmacy will give to an enrollee who requests coverage for a non-formulary drug or requests to be assessed a lower cost-sharing amount.

§423.578 (a)(2).
This subsection fails to meet the statutory requirement that the Secretary establish guidelines for an exception process. The plan statutory language is not permissive; it does not say that plans may establish additional criteria if they wish. It says that the Secretary is to establish criteria and the plans are to abide by them. Plans should have no discretion whatsoever. The fact that they may establish differing tiered structures is not relevant to the statutory right to request an

exception to whatever structure they devise. In fact, the flexibility accorded to plans is why beneficiaries need strong guidelines to protect their interests.

Where the proposed regulations include guidance for criteria, the criteria listed exceed the scope of the statute. The proposed regulations list a "limited number of elements that must be included in any sponsor's exception criteria," but this list includes criteria that do not apply based on the statutory provision that states an exception applies if a physician determines that a preferred drug would not be as effective or would have adverse effects or both.

The proposed rules also fail to provide adequate guidance to physicians concerning whether the standard requiring the doctor to certify that a preferred drug would not be as effective or would cause adverse effects has been met.

The final regulation should require that the lowest co-pay that applies should apply to drugs for which an enrollee has won an exception to the tiered cost-sharing structure. That's the whole point of this process - to infuse some equity upon a showing that none of the other medications covered are as effective or may cause harm.

The final rule should also include the following omitted criteria: regulations permitting continued access to a drug at given price when there is a mid-year formulary change, and regulations requiring sponsors to give enrollees an opportunity to request exceptions to a plan's tiered cost-sharing structure other than on a case-by-case basis.

§423.578(b) Request for exceptions involving a nonformulary drug.
This subsection fails to meet the statutory requirement that the Secretary establish guidelines for an exception process. In the preamble, CMS states that "[r]equiring sponsors to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied" and will help ensure these formularies "are based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs ." However, the proposed regulations give drug plans complete discretion in determining the criteria they will use to determine exceptions requests. In addition, independent review entities "would not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." By failing to adequately define the criteria plans may use to consider exceptions requests or provide any meaningful oversight over these criteria, these proposed regulations would not ensure that formularies are based on scientific evidence and would not establish a transparent process. The regulations as written subvert CMS's stated goals.

The proposed rules set an impossibly high bar for receiving an exception by requiring prescribing physicians to produce clinical evidence and medical and scientific evidence to demonstrate that the on-formulary drug is likely to be ineffective or have adverse effects on the beneficiary. Clinical trials generally do not include older people, people with disabilities and people with co-morbidities. While some such evidence does exist, it has not been developed for all drugs and conditions. However, a physician may have extensive experience treating these kinds of patients with the condition or illness at issue and this experience should be given at least

equal weight in making such determinations. In fact, the statutory standard requires deference to the doctor's determination that all on-formulary medications would not be effective or cause adverse consequences. This required deference is not reflected in the proposed rules. It is also important that the final rules recognize the existence of individual differences in reactions to the same drug and that exceptions be available to someone who can not tolerate or who does not benefit from a drug even though that drug is beneficial to most people.

The NPRM proposes to authorize plans to require a long list of information in the written certification from the prescribing physician that an off-formulary drug is needed. This list is overly long and repetitive and may encourage drug plans to establish burdensome paperwork requirements as a hurdle to prevent physicians and consumers from following through on an exceptions request. Moreover, this proposed rule also leaves the required contents entirely up to the plan's discretion by including the catch-all phrase - "any other information reasonably necessary". The requirements for this written certification should be standardized to facilitate use of the exceptions process by providers and consumers. These standards would also help achieve CMS's stated goal of establishing a transparent process.

An important provision was left out of the requirements for receiving a dosing exception. The proposed rule states that in order to receive an exception, the physician must demonstrate that the number of doses available is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. This rule must also allow exceptions if the prescribing physician demonstrates that the number of doses available would cause an adverse reaction or harm to the enrollee - as provided in the proposed rules for other kinds of exceptions requests.

The final regulation should clarify that formulary use includes not just dose restriction, but the format of the dosage (liquid vs capsule, etc.) and packaging, such as bubble wraps for long-term care facility residents.

§423.578(c)(2) When a sponsor does not make a timely decision.
The regulation provides for a one month's supply of a drug, but only if the plan does not act timely on an exceptions determination. If the request for an exception is not given expedited treatment, the sponsor can take two weeks to issue a decision, meaning the enrollee would wait two weeks before getting the supply of medicine. Even if the exception is treated as a request for expedited review, the enrollee would still have to wait 72 hours (unless s/he could show the decision needed to be made more quickly because of her/his condition.) Most people wait to the last minute to refill a prescription, often because of drug plan and pharmacy restrictions.

It is also unclear how an enrollee knows about these rights when a sponsor does not make a timely decision.

The enrollee should be entitled to a one month's supply upon presenting the request for a refill and upon presenting a new prescription for a non-formulary drug. Plans should be required to make exception determinations and notify the enrollee in 24 hours as required under Medicaid for prior authorization determinations. 42 U.S.C. §1386r-8(d)(5)(A).

We cannot overemphasize the importance of drug coverage and ensuring no gaps in the intake of medication. In mental health and HIV/AIDS, for example, it is essential that medications be available quickly and without interruption. In the HIV/AIDS sector, for example, consistent research proves that the risk of drug resistance and resulting treatment failure significantly increases with each missed dose of therapy.

423.578(c)(3), When an exception request is approved.
The lowest coinsurance amount should apply anytime an enrollee wins an exception through this process because the drug at issues has been determined medically necessary with no on-formulary drug as a suitable alternative. The exception for the non-formulary drug thus meets the criteria for an exception to the tiered cost-sharing structure as well.

The regulation needs to clearly set forth the requirement that notice be provided when a decision is made on an exception request. The notice should explain that the decision is a coverage determination and explain the appeal rights that are available.

We commend CMS for specifying that, once an exception request is granted, a plan sponsor may not require the enrollee to keep requesting exceptions in order to continue receiving the drug. However, we are concerned that the "exception" to this protection which allows the plan to discontinue a drug if safety considerations arise, is too broad. The final regulation should be revised to permit reversal of a previously granted exception only if the FDA determines that the drug is no longer safe for treating the enrollee's disease or medical condition.

We are concerned that the timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed provisions raise similar concerns. It is extremely unfair to require longer time frames if a beneficiary has paid out of pocket for a needed medication when their alternative would be to wait two weeks to a month for a determination or an emergency one-month supply of the needed drug. Beneficiaries' health and safety may well be at risk if they are forced to forego other necessities because of the added, and most likely very significant, expense of paying out of pocket for their medicines. Although the proposed regulations include some provisions for an emergency supply of medications while a plan is considering an exceptions request, it is unreasonable and bad health policy to make beneficiaries wait two to four weeks before the drug plan must provide an emergency supply. In addition, plans should be required to demonstrate that an extension of the standard time frame for exceptions determinations is in the best interest of the enrollee and the final rule must charge independent review entities with exercising oversight over these extensions. Plans should be required to make determinations regarding exceptions requests and notify the enrollee of these determinations in 24 hours as required under Medicaid for determinations regarding prior authorization requests (42 U.S.C. 1396r-8(d)(5)(A)).

§423.580 Right to a redetermination
The proposed regulations only authorize an enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) to request a redetermination or an expedited redetermination. The enrollee's authorized representative must also be allowed to request a redetermination and an expedited redetermination. Since the proposed regulations would allow an enrollee's authorized

representative to file a request for Determinations and Exceptions, it does not make sense to not allow an enrollee's representative to pursue a claim further through the redetermination, reconsideration, and higher levels of appeal. In fact, the proposed regulations define an authorized representative as an individual authorized to act on behalf of an enrollee "in dealing with any of the levels of the appeals process".

§423.584 Expediting certain re-determinations.
The regulations need to describe in detail the notice responsibilities for both standard and expedited re-determinations, including what must be provided in the notice. This is crucial, given that the next level of review to the IRE is not automatic, as it is with Medicare Advantage plans. The notice should explain the reason for the denial, including the medical and scientific evidence relied upon, the right to request review, or expedited review, to the IRE, including timeframes and the right to submit evidence in person and orally.

§423.584(a) Who may request an expedited redetermination.
See §423.580 regarding allowing an individual's authorized representative to request an expedited re-determination.

§423.584(d)(2).
The information in the letter should also be provided orally. The enrollee should not have to wait three days for this information.

§423.586 Opportunity to submit evidence.
The regulations should establish clear criteria for informing the enrollee and the physician that they can submit evidence in person, as well as clear procedures for in-person review.

§423.590 Timeframes and responsibility for making redeterminations.
The regulation should be amended so that a plan can only extend the timeframe for a re-determination if requested to do so by the enrollee, or if the plan can demonstrate that the extension is in the best interest of the enrollee (for example, the plan needs to obtain additional information to support the enrollee's request). As previously stated, all re-determination requests, and particularly those involving exceptions, should be treated as expedited, and plans should not be given more time to resolve re-determination requests involving payment requests.

§§423.590(c) Effect of failure to meet timeframe for standard redetermination and (e) Failure to meet timeframe for expedited redetermination.
Again, how does enrollee know this and know what to do?

§423.600 Reconsideration by an independent review entity (IRE).
CMS needs to clarify in the final regulations that the role of the IRE is to provide independent, de novo review, especially in regard to the exceptions process. The preamble states that "…The IRE's review would focus on whether the PDP had properly applied its formulary exceptions criteria for the individual in question…..the IRE will not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." If the IRE does not review all the

evidence and issue a reconsideration decision based on its own analysis, then enrollees will be denied independent review, and the requirements of due process will not have been met.

Further, because, as noted above, CMS is required by the statute to set standards for the exceptions process, the IRE must have authority to determine whether the PDP's exceptions criteria comply with the statute. Otherwise, enrollees will have no mechanism for review of arbitrary and improper standards.

Since the Part D process is supposed to follow the MA process, the regulations should follow the MA regulations and require that denials automatically be sent to the IRE for reconsideration. The regulations as written create a barrier to the first level of independent review for enrollees who have difficulty following the complicated process. We dispute CMS's statement in the preamble that many of the drug appeals will involve small monetary amounts. Rather, most will involve medications for chronic conditions that enrollees take on an on-going basis; the yearly sum of the cost-sharing will be quite substantial, especially considering the income level of most people with Medicare. In addition, by requiring the enrollee to file a request for ALJ review, the first truly independent review available, CMS can satisfy the statutory requirement that the enrollee files the appeal.

If the final regulations continue to place the burden of requesting a reconsideration on the enrollee, they need to clarify that an authorized representative can act on the enrollee's behalf. Again, without such clarification, enrollees who lack the capacity to file a reconsideration request will be denied their due process rights. In addition, the prescribing doctor should also be permitted to request a reconsideration, especially since the enrollee needs the doctor's statement in order to request IRE review of an unfavorable exception request.

Finally, the enrollee should be allowed to request a reconsideration orally, especially where the request is for an expedited review.

§423.600(b).
We are pleased that CMS is requiring the IRE to solicit the view of the treating physician. We believe the IRE should also be required to solicit the view of the enrollee. However, because in our experience the MA independent contractor is often reluctant and unwilling to accept the views of and evidence from the beneficiary, the final regulation needs to be more specific. The regulation needs to specify how this will occur, including contact by telephone, email, or face-to-face meeting.

§§423.600(d).
The regulations need to establish a set timeframe by which the IRE must issue its decision in order for this process to be transparent. Enrollees will have no knowledge of the contract between CMS and the IRE and thus will not know how long they will have to wait for a reconsideration decision. Also, if contractual, the time frame can change with each new contract, putting enrollees at greater risk of adverse health consequences from being denied needed medicines. The regulation should also state that an enrollee may appeal to an ALJ if the IRE fails to act within the regulatory time frame and how the enrollee will be apprised of this right.

§423.602 Notice of reconsideration determination by the independent review entity.
The language concerning what the notice must entail is ambiguous. The notice must "inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under 423.610." Does this mean that the notice tells you that you can go to an ALJ, but only if your claim is large enough? Or does this mean the IRE only has to tell you about your right to an ALJ hearing if your claim meets the threshold amount? The latter interpretation is problematic for several reasons, including the fact that you can aggregate claims. The final regulation should state that the notice must inform the enrollee of his or her right to an ALJ hearing, and the procedure for requesting such a hearing, including the dollar amount required to request a hearing.

§423.610 Right to an ALJ Hearing.
Congress recognized the special needs of the low income, and how even small copayment amounts can cause many lower income individuals to forgo filling prescriptions. We urge CMS to provide exceptions to the ALJ threshold requirements for those receiving the Medicare subsidy. For example, the amount at controversy for a lower-income individual could be deemed to be the amount that would be at controversy if the individual were a non-subsidy eligible individual receiving the standard benefit.

It is unclear what §423.610(c) intends when it says, "Two or more appeals may be aggregated by the enrollee… if (I) the appeals have previously been reconsidered by an IRE…" Does this mean that an enrollee will have to file a new appeal each month for a prescription to treat an on-going chronic condition? Such a requirement would be unduly burdensome for enrollees, drug plans, the IRE, and the ALJs. The final regulation needs to clarify that when the plan denies coverage, in order to satisfy the jurisdictional amount an enrollee should be able to add up the cost of the medicine for a year, if the medicine treats an on-going chronic condition, or for the number of refills authorized if the underlying condition is not chronic.

Subsection (ii) says the request for the hearing must list all of the appeals to be aggregated and must be filed within 60 days after all of the IRE reconsideration determinations being appealed have been received. If you are consolidating appeals, and the first denial is in April and the last one you need to get to the jurisdictional amount is in August, will you still be timely? Or does it have to be 60 days from the first denial in April?

§423.612 Request for an ALJ Hearing.
The regulation should specify that, if an appeal is filed with the PDP, the PDP must submit the file to the IRE within 24 hours of receipt of the request, and the IRE must transmit the file to the ALJ within 24 hours. Our experience is that, without set time frames, some current reviewing entities take long periods of time, adding to the delay in the processing and resolution of ALJ appeals.

The regulations also need to require the IRE to include all of the information in the file, such as doctor's statements, statements by the enrollee, and any other evidence submitted by the enrollee, including information not relied upon in making its decision. It has been our experience that

contracting entities, including MA plans, often omit evidence submitted by the enrollee when transferring a file to the ALJ or other level of review.

§§423.634, Reopening and revising determinations and decisions and 423.638 How a PDP sponsor must effectuate expedited redeterminations or reconsidered redeterminations.
Subsection (c) in both of these draft regulations allows the PDP to take up to 60 days to implement a reversal by the IRE, an ALJ, or higher. That's totally unacceptable, since further delays may cause increased health consequences to people who have foregone medication pending appeal. Favorable decisions should be implemented in the same 72 hour time period as reversals at earlier levels of review.

Subpart P - Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§432.772 Definitions.
"Family size." We support defining family members as relatives in the household receiving at least half of their support from the applicant or applicant's spouse. In order to minimize burdens on beneficiaries, the regulations should specify that applicants will be able to self-attest to the status of dependents, without providing further documentation.

"Full subsidy eligible individuals." The definition should refer to the language of §§423.773(b) and(c), in order to avoid ambiguity.

"Income." The definition should make clear that income not actually owned by the applicant, even if his or her name is on the check, should not be counted.

"Institutionalized individual." The definition should include those individuals eligible for home and community based services under a Medicaid waiver (see, e.g., definition of "institutionalized spouse" at 42 U.S.C. § 1396r-5(h)(1)(A)), since those individuals must meet the acuity standards for Medicaid coverage in a nursing facility, and should include individuals in ICF-MRs and individuals in any institution in which they are entitled to a personal needs allowance.

The definition should not include the language "for whom payment is made by Medicaid throughout the month" since an individual could conceivably be a full benefit dual eligible recently returned from a hospital stay whose nursing facility stay would be paid for by Medicare Part A for the entire month. Even though in that month all their drugs are likely to be paid for by Medicare Part A, as a practical matter, for continuity and minimum disruption, they should not lose their status as an "institutionalized individual." The same reasoning should apply to a full benefit dual eligible individual who might be hospitalized during an entire month, during which their entire stay would also be paid for by Medicare Part A.

"Personal representative." The portion of the definition that permits an individual "acting responsibly" on behalf of an applicant needs further clarification as to who would determine that the individual is acting responsibly and what circumstances would constitute a per se conflict of interest.

"Resources." We support the limitation of countable resources to liquid assets. However the definitions of liquid assets and what it means to be able to be converted into cash in 20 days need to be clarified. The final rule should include a specific list of countable resources to promote clarity for state and beneficiaries. Resources should not include burial plots, burial funds or life insurance of any value, nor should it include any officially designated retirement account, such as an IRA, 401(k), 403(b) etc. Alternatively, the respective exclusions for the value of life insurance and burial funds should be increased to a reasonable amount, such as $10,000 per asset. Most potential low-income beneficiaries have assets below this level.

Excluding these resources will ease the application process for consumers and eligibility workers, as well as reduce administrative costs by reducing the time and effort required to verify assets. This is consistent with both Congress's and CMS's intent. Resource assessments should not include any consideration of transferred assets, as would otherwise be required under SSI rules.

We note that a current draft of the SSA application for the low-income subsidy inquires whether an applicant has life insurance with a face value of $1,500 or more. CMS must ensure that any proposed SSA application is harmonized with these rules on assets and income. As noted above, life insurance should not count towards assets, and this question should be eliminated.

§423.773 Requirements for eligibility.
We support the proposal to make dual eligibles (both full dual eligibles and those in Medicare Savings Programs (MSPs)) automatically eligible for the low-income subsidy. As we explain below, however, we believe a great deal more specificity is needed in this section. We are particularly concerned that the proposed rule leaves room for ambiguity regarding these beneficiaries' status. We believe that the proposed eligibility rules for partial dual eligibles will result in inequities and confusion. In addition, the draft regulations do not adequately explain how low-income beneficiaries are to be notified about their eligibility, nor do they explain how prescription drug plans are to determine which beneficiaries are enrolled in the low-income subsidy. The proposed rules also do not adequately protect low-income beneficiaries whose enrollment is delayed or is processed erroneously.

§423.773(a) Subsidy eligible individual.
Although the statute defines a subsidy eligible individual as one enrolled in a Part D plan, the requirement in Subpart S that states take applications for the low-income subsidy beginning July 1, 2005, before Part D plans are available to be enrolled in makes it clear that CMS believes people should be able to apply for the low-income subsidy without being enrolled in a Part D plan. This is actually imperative, as otherwise, an individual would be forced to pay a plan premium that the subsidy, in fact, pays for them. The subsidy eligibility determination would be done "conditionally" - conditioned upon the individual enrolling in a Part D plan. The regulations should reflect this reality and clearly direct both SSA and state Medicaid programs determining eligibility that the individual can both apply and be determined subsidy eligible before she or he has enrolled in a plan

§423.773(b) Full subsidy eligible individual.

The indexing of resources should indicate that rounding is always up to the next multiple of $10.

§423.773(c) Individuals treated as full subsidy eligible.
This section should conform to Subpart S § 423.904(c)(3) which requires states to notify all deemed subsidy eligible individuals of their subsidy eligibility. It should specify that the notice must be given by July 1, 2005 for those individuals eligible at that time. For those who subsequently become eligible, notice should be given at the same time the individual is notified of their eligibility for the benefit that qualifies them to be treated as a full subsidy individual. The notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. For those who will lose Medicaid coverage January 1, 2006, the notice should explain their appeal rights as well. Individuals should also be told of their right to appeal the level of subsidy to which they are entitled.

Section 209(b) states and non-1634 states must coordinate with the Social Security Administration to determine how to provide notice to SSI recipients who are not receiving Medicaid and who therefore do not appear on the state's Medicaid rolls.

§423.773 states that both full benefit dual eligibles and MSP beneficiaries are eligible for the low income subsidy, but it does not explicitly state that these beneficiaries are automatically enrolled in the subsidy program. The regulations should be absolutely clear that an individual treated as full subsidy does not have to take any further action with respect to the subsidy (i.e., make application or in any other way verify their status), but only to enroll in a Part D plan. This will help smooth the transition from Medicaid drug coverage for dual eligibles, and should improve participation for others.

§423.773(c)(3).
We support the decision reflected in this proposed subsection to deem MSP beneficiaries automatically eligible for the low-income subsidy. We are concerned, however, that inequities and confusion among beneficiaries may result because SSA will not apply the more generous income and asset MSP eligibility rules in place in some states (for example, Alabama, Arizona, Delaware, and Mississippi, which have eliminated consideration of assets for MSPs). Eligibility requirements should be the same for all subsidy-eligible individuals in a state, regardless of where and how they apply. Under the proposed regulations, in states that have adopted less restrictive income and asset methodology, people whose assets or income are slightly above the limits set in § 423.773 would be enrolled in a less generous subsidy, or have their application rejected entirely, if they apply directly through SSA, because SSA will apply the national guidelines proposed in §423.773. However, the same people would have their application accepted if they applied through their states' Medicaid offices, were screened and then enrolled in an MSP, and were then automatically eligible for the low-income subsidy.

To resolve this problem, we propose that SSA apply state-specific income and asset eligibility rules in determining eligibility for the low-income subsidy, an option discussed, though rejected, in the preamble. This means that for applicants from states that have eliminated the asset test or

increased disregards under §1902®)(2) for MSP eligibility, SSA should apply the state's rules to determine eligibility. This option is permitted under §1860D-14(a)(3)(E)(iv) of the statute.

Alternatively, the regulations should provide that subsidy applicants who appear to have excess assets or incomes would either be screened by SSA for eligibility in an MSP program, or have their applications forwarded to the state Medicaid agency to be screened for MSP eligibility. States would be precluded from requiring beneficiaries to resubmit information, such as income and asset levels, that they have already provided to SSA. Applicants would be enrolled in the appropriate MSP program, and then be enrolled in the appropriate low-income subsidy under proposed § 423.773(c). Adopting this policy, which is not precluded by statute, will ensure that all subsidy applicants are treated equitably, as well as increase participation in MSPs.

As part of this alternative policy, the low-income subsidy application should allow an applicant to opt out of screening and enrollment for an MSP, as some applicants may not wish to participate in an MSP. Under §1860D-14(a)(3)(v)(II) of the statute, beneficiaries who are determined eligible for MSPs may be enrolled in the low-income subsidy. There is no requirement that beneficiaries actually enroll in an MSP. Therefore, applicants who meet eligibility requirements for an MSP, but who decline to enroll in the program, should still be automatically eligible for the low-income subsidy.

Because enrollment in an MSP can affect the amount of assistance a beneficiary may receive through other public assistance program, such as Section 8 housing vouchers or food stamps, there will be a profound need for beneficiary counseling during the enrollment process. We recommend that CMS plan for this need by making funds available to local agencies, including state health insurance assistance programs (SHIPs), and other community-based organizations.

This draft regulation states that a state Medicaid agency must notify full benefit dual eligibles that they are eligible for the low-income subsidy and should enroll in a Part D plan. The regulations do not state, however, when this notice should be issued, or what the notice should say. Consistent with our comments above and those accompanying 423.904(c)(3), the notification should be sent to beneficiaries on or near July 1, 2005, when states will have made the automatic eligibility determinations.

We also suggest that CMS develop model notices based on input from beneficiaries, which would explain the purpose of new subsidy simply and clearly. The notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. It should also explain as simply as possible what level of subsidy the beneficiary will receive, and the beneficiary's appeal rights if she believes the subsidy level is in error.

The draft regulation fails to address eligibility issues for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) state. These beneficiaries should be informed of their likely eligibility for a low-income Medicare subsidy and given an opportunity to enroll. When they have met their spenddown, they should be informed of their entitlement to a lower co-payment, if applicable, as a deemed subsidy eligible.

Our recommendations for redeterminations of these beneficiaries are discussed below, in §423.774.

§423.773(d) Other subsidy eligible individuals.
The indexing of resources should indicate that rounding is always up to the next multiple of $10.

§423.774 Eligibility determinations, redeterminations, and applications.

§423.774(a) Determinations of whether an individual is a subsidy eligible individual.
This subsection provides that determinations of eligibility for the subsidy are to be made by state Medicaid agencies or by SSA, depending on where an individual applies. We believe that in order to ensure prompt enrollment in both the subsidy and ultimately in a plan, the regulations should specify that a determination notice must be sent to the applicant no later than 30 days after the application is filed. Because determinations for the low-income subsidy should be a simple process, very little time should be required to render a decision. Both SSA and states should be required to notify CMS with 24 hours of a individual being determined eligible for the subsidy.

§423.774(b) Effective date of initial eligibility determination.
In order to avoid delays in the ability of beneficiaries to use their subsidy benefits while their application is pending, the final rule should offer beneficiaries the option of applying through a presumptive eligibility system. Such a system would be especially helpful to beneficiaries who have enrolled in a Part D plan but are not yet receiving the low-income subsidy. Applicants can complete a short form at a provider's office or other location in which they declare their family size, income and assets. If their income and assets are below the relevant eligibility levels, they are found presumptively eligible. Applicants may still be required to complete a full application within a prescribed period of time (typically 30 to 60 days) if additional information is required. In the meantime, however, beneficiaries are given temporary cards that they can present to health care providers and receive services immediately. Experience has shown that the error rate for these enrollment systems is very low. In the rare cases where beneficiaries are later found ineligible, they and their providers are held harmless for the benefits they receive during the presumptive eligibility period.

Applicants for the low-income subsidy could be found presumptively eligible at state Medicaid offices, SSA offices, pharmacies, or other providers. If the low-income subsidy application form is simple enough, applicants could complete the form itself and self-attest to their income and assets. If they appear to be eligible, they would be enrolled in the appropriate subsidy while their application is processed. They would receive some form of temporary certification stating that they have been presumptively enrolled, which their pharmacy would accept while their application is processed. Such a system would encourage beneficiaries to apply, as they would be able to see the benefits of the system immediately.

§423.774(c) Redetermination and appeals of low-income subsidy eligibility.
There should be a provision for prompt reconsideration of a subsidy eligibility determination, for beneficiaries who believe they have either been erroneously denied eligibility or approved for the

wrong subsidy category. The provisions applying the appeal rules of state Medicaid plans or SSA do not provide for a prompt reconsideration process. Because obtaining prescription drugs is so vital, and especially because low-income beneficiaries are unable to pay the costs of their prescription drugs out of their own pockets, a quick reconsideration process is essential.

The draft regulation refers to redeterminations and appeals under the state Medicaid plan. This is inadequate, as frequent redeterminations in place in some states will cause some beneficiaries to drop out of the program. To maximize enrollment, the rule should establish that all determinations are for one year, per the Secretary's authority under the statute. We also urge CMS to adopt an annual, passive, and simple redetermination for all beneficiaries, whether they have enrolled through SSA or states. Should it be necessary, the Secretary should direct the Commissioner of SSA to create such a system. Under a passive redetermination system, beneficiaries would be sent a statement of the relevant information on file and asked to respond only if any of that information had changed over the year. If they do not respond, their coverage would continue unchanged for another year.

If states are not required to adopt passive redeterminations, we urge that redeterminations be made as they are under the state's MSP programs, or under the most passive, simplified redetermination process used for any category of coverage under the state plan.

§423.774(d), Application requirements.
This section should make clear to both states and SSA that no documents should be required of the individual as long as the applicant authorizes the agency to verify information from financial and other institutions. Documentation production should be only the absolute last resort.

Also, as we mentioned in our comments to §423.773 above, the proposed rule does not address eligibility determinations and recertification periods for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) state. Once beneficiaries become deemed subsidy eligible individuals by completing their spenddown, they should retain that status for a full year, until their next redetermination for the low-income subsidy, regardless of whether they go off Medicaid. Otherwise, individuals who go in and out of medically needy status, depending on the length of their state's budget period, will have extremely confusing changes regarding their Medicare low-income drug subsidy.

§423.800 Administration of Subsidy.

§423.800(a), Notification of eligibility for low-income subsidy.
We are concerned that there is no provision in §423.800(a) specifying a time period by which CMS must notify a plan that an enrollee is eligible for a subsidy. This is an essential step in the process, because without the subsidy, prohibitive costs will prevent low-income beneficiaries from using their Part D benefits. We propose that CMS be required to inform Part D plans of beneficiaries' enrollment in the subsidy no later than 24 hours after the application for the subsidy is approved. As this will likely be an electronic notification, it should not be burdensome. It is vital that plans know which beneficiaries are enrolled in the subsidy, so that these low-income beneficiaries do not have to pay the full cost of their prescriptions while their subsidy application is process.

§23.800(e), Reimbursement for cost sharing paid before notification of eligibility for low-income subsidy.
The draft reimbursement provisions are inadequate to protect low-income beneficiaries. The proposed regulation would require plans to reimburse low-income beneficiaries for excess copayment and premium amounts made after the effective date of the subsidy application. This is not a realistic solution to the problem facing beneficiaries who have prescription drug needs before their Part D plans are notified that the beneficiaries are subsidy-eligible and need to have their records adjusted accordingly. Low-income beneficiaries will not be able to afford to pay these costs out of their own pockets with the expectation of being reimbursed later. Instead, these beneficiaries will forego prescription drug coverage until their plan processes their subsidy, making the first month or more of their subsidy period meaningless.

Adoption of a presumptive eligibility system recommended above would alleviate this problem. As an additional alternative, the regulations should provide that beneficiaries may present their notice of approval for the subsidy to their pharmacy when they seek prescription drugs. Pharmacies should accept this notice as adequate to relieve the beneficiary from making a co-payment, and instead seek reimbursement for the beneficiary's plan.

Subpart S - Special Rules for States - Eligibility Determinations for Subsidies and General Payment Provisions

§423.904 Eligibility determinations for low-income subsidies.

§423.904(a) General Rule.
This subsection should cross reference the entire Subpart P, or, at a minimum the definitions included in §423.772.

§423.904(b) Notification to CMS.
The rule should direct states to notify CMS of eligibility determinations within 24 hours of making them, as we previously recommended with respect to SSA determinations.

§423.904(c) Screening for eligibility for Medicare cost-sharing and enrollment under the State plan.
The proposed regulation regarding states' obligations to screen subsidy applicants and offer them enrollment in Medicare Savings Programs ("MSPs") are inadequate. In particular, the regulation should specify what "offer enrollment" means. We believe an applicant must be offered the opportunity to enroll during the same visit or contact (in office, by phone, or by mail), without providing any further documentation or completing any additional forms. Only if enrollment is easy and convenient will Congress's intent of increasing participation in MSPs be accomplished. Furthermore, because under the current rules, enrollment in an MSP may be the only entry into the subsidy for some beneficiaries, a quick and easy application for MSP programs is essential. As written, the regulation would permit states to say they have "offered enrollment" simply if they tell applicants that they might be eligible for an MSP and may return another time to complete another application form if they wish to apply. Such an outcome would defeat the

purpose of the screen and enroll provision included in the new §1935(a)(3) established in §103(a) of the statute. Instead, as proposed in our comments to Subpart P, the low-income subsidy application should include an "opt-out" provision, under which qualified applicants would be enrolled in an MSP unless they affirmatively decline to do so. This provision would explain that enrollment in an MSP may be another way to qualify for the low-income subsidy.

As we explained in our comments to Subpart P, because enrollment in an MSP may affect receipt of other public benefits, there is a tremendous need for good quality counseling of beneficiaries. In addition, in order to ensure that enrollment requirements between MSPs and the low-income subsidy are aligned, states should not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective and can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP.

In the interest of further aligning eligibility rules for MSPs and the low-income subsidy and easing administrative burdens, we suggest that CMS direct states to apply the definitions of resources used in Subpart P, §423.772, in making their resource determinations for MSP applicants.

In addition, should CMS adopt a policy, as has been discussed publicly, under which most subsidy applications to state Medicaid agencies would be forwarded to SSA for the actual eligibility determination, the regulations should be clear that the screening for MSP eligibility must take place prior to the processing of the applications to SSA. Potential beneficiaries should not have to wait to be screened and offered enrollment in MSPs. Furthermore, an individual cannot be told, by either SSA or the state that she or he is ineligible for the low-income subsidy until MSP eligibility has been determined (if the individual wishes). It would be incredibly confusing for an individual to receive a notice from SSA that she is ineligible for a subsidy, have her MSP eligibility determined by the state, then receive a notice from the state that she is eligible for both MSP and the subsidy. Whatever the mechanics, the individual must be told that MSPs are a route to subsidy eligibility.

Finally, as we discussed in our comments to §423.773, SSA should also screen subsidy applicants for eligibility in MSPs as well, and develop a system with states to enroll eligible beneficiaries. Applicants should not miss out on the opportunity to enroll in MSPs because they apply through SSA rather than state Medicaid offices. The same concerns about beneficiary education and estate recovery discussed above apply to enrollment through SSA.

The regulations should also ensure that beneficiaries are screened for eligibility for full Medicaid and offered enrollment if they qualify, consistent with 42 C.F.R. §435.404. Ideally, all subsidy applicants would be screened for Medicaid, and offered enrollment if they qualify. Because the importance of maintaining a simple application process for the subsidy is paramount, CMS may wish to consider using a simple screening process based on information obtained through the subsidy application. This screening would trigger a follow-up with applicants who appear to be eligible for full Medicaid.

Many Medicare beneficiaries who are eligible for a low-income subsidy under the Part D Program will also be eligible for other important benefits. Some of these benefits, such as food stamps, are also administered by states and have eligibility rules that very closely correspond with the new eligibility rules for the Part D subsidies. Historically participation by seniors and people with disabilities in these programs has been low, despite the fact that the benefits that low-income Medicare beneficiaries would be able to receive could help them struggle less to make ends meet every month. The Part D enrollment process offers an historic opportunity to connect Medicare beneficiaries to these other programs.

Beyond saying that applications may be filed either with a State's Medicaid program or with SSA, the proposed rule has very little detail about how the application process is likely to work. We urge CMS to specify that the new eligibility process should dovetail with other programs so that low-income Medicare beneficiaries can be enrolled as seamlessly as possible in all the state- or SSA-administered benefits for which they qualify

423.904(d)(3)(ii), Cost-effectiveness of information verification.
This section should be modified to permit states to use the verification process established by the Social Security Administration to verify the income and assets of people who apply for a Part D subsidy through a state Medicaid agency.

PART 403-SPECIAL PROGRAMS AND PROJECTS

Subpart B-Medicare Supplemental Policies

Disclosure notices advising consumers of their statutory rights must be short, simple, easy to understand, and address as few issues as possible. The proposed disclosure notice concerning Medigap policies H, I, and J included in the Preamble is too long, provides unnecessary information, and includes information that may not be accurate for all beneficiaries. We suggest that the letter be modified as follows:

Delete the information about Medicare Part D at the beginning of the disclosure notice;
Delete statements about the value of Part D benefits, which are irrelevant to the issue of changes to Medigap;
Delete the second statement about the need to notify the Medigap issuer if a person later enrolls in Medicare Part D. This information is repetitive; and

Delete the information concerning enrollment issues about Medicare Part D which is unrelated to whether a Medigap policy provides creditable coverage.

In addition, we encourage CMS to develop a different notice for people who will have creditable coverage as their options will be different from those of people whose Medigap policies are not deemed to provided creditable coverage. The specific information this group of beneficiaries will need about their creditable coverage, and any required action, will vary depending on whether their coverage is employer sponsored retiree coverage, a Medigap Plan J, a pre-standard Medigap plan, or a Medigap with a rider or an innovative benefit.

The discussion in the Preamble to the Regulation beginning with Subpart T 4(c)(iii) references the difficulty of determining creditable coverage and the inability to even make that determination in advance of a final rule to implement Part D. We expect there will be confusion on this issue and that mistakes may be made by issuers in applying an actuarial test to groups of policies issued all over the country. We expect additional confusion due to the proposal to modify the definition of Medicare Supplement (Medigap) policies in §403.205 to include riders and freestanding benefits for prescription drugs. We are requesting two remedies for Medicare beneficiaries who are initially notified of creditable coverage when the coverage is no longer or never was creditable: a Special Enrollment Period in Part D and a guaranteed issue right to a Medigap policy without prescription drug benefits. We are also requesting the extension of the right to a guaranteed issue policy to Dual Eligibles who lose their eligibility to Medicaid benefits.

Thank you for the opportunity to submit comments on the proposed rule. We hope that this will not be the final opportunity to do so.

Very truly yours,

Diane F Paulson
Senior Attorney
Medicare Advocacy Project, Greater Boston Legal Services

Linda Landry
Disability Law Center

Deborah Thomson
Massachusetts Law Reform Institute

CMS-4068-P-1258

Submitter : Dr. Eddie Rowe **Date & Time:** 10/04/2004 08:10:27

Organization : Rowe's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

BENEFICIARY ACCESS TO COMMUNITY RETAIL PHARMACIES:
I am concerned about the proposed rul regarding the pharmacy access standard. Under the proposed regulation, each prescription drug benefit plan is allowed to apply the Department of Defense's TRICARE standards on the local (37664)level rather than 'on average' in a regional service area.

To address the situation where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level (no pharmacy in the zip code), the regulation should require that the access standard be the greater of the TRICARE standard or the access equal to that available to a member of the general public living in that zip code.

Requiring plans to meet the standard on a local level is the only way to ensure patients equal and convenient access to their chosen pharmacies.

PROPOSED REGULATION CREATES NETWORKS SMALLER THAN TRICARE:
The proposed regulation also allows plans to create 'preferred' pharmacies and 'non-preferred' pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one 'preferred' pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only 'preferred ' pharmacies shoud count when evaluation whether a plan has met the required TRICARE access standards. The Dept. of Defense network of pharmacies meets the Tricare access standards and has uniform cost sharing for all these network pharmacies. CMS shoould require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan's standards terms should be allowed to provide the same copays to the patient population.

EQUAL ACCESS TO RETAIL AND MAIL ORDER PHARMACIES FOR MEDICARE BENEFICIARIES:
I believe it was the intent of Congress to assure Medicare beneficiaries are able to obtain covered prescriptions drugs and medication therapy management services from the pharmacy provider of their coice. As such, plans must permit beneficiaries to obtain covered outpatient drugs and medication therapy management services at any community retail pharmacy in the plan's network, in the same amount, scope, and duration that the plan offers through mail order pharmacies. According to the proposed regulation, the only difference a beneficiary would have to pay between retail and mail order prescriptions should be directly related to the difference in the service costs, not the cost of the drug product. Under Medicare Part D, all rebates, discounts or other price concessions shoould be credited equally to reduce the cost of prescription drugs no matter where they are dispensed. The benefits from these arrangements shoould be required to be used to directly benefit the Medicare beneficiary in terms of lower cost prescriptions.

Pharmacists are also the ideal health care professionals to provide Medication Therapy Management Program and determine which services each beneficiary needs.

I, also, know that the local pharmacist is the most accessible healthcare provider a Medicare beneficiary has. I have even gone to patients homes to help them with their medications because they couldn't understand the physician's instructions, so how could they possibly understand a mail-order pharmacist on the telephone.

In conclusion, I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.

Sincerely,
Eddie Rowe, DPh.
Rowe's Pharmacy

2416 Memorial Blvd
Kingsport, TN 37664
423-245-5191
rowespharmacy@earthlink.net

CMS-4068-P-1259

Submitter : Mr. Michael Starkowski **Date & Time:** 10/04/2004 08:10:44

Organization : State of Ct. DSS

Category : State Government

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

The state of Ct is submitting comments on the entire range of issues not just sections 1-10.

CMS-4068-P-1259-Attach-1.doc

STATE OF CONNECTICUT

File Code: CMS-4068-P

October 4, 2004

Dr. Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) is historic legislation that presents opportunities and challenges for Connecticut. As a state with representation on the State Pharmaceutical Assistance Transition Commission (SPATC) authorized by that law, we are pleased to have been a part of the communication process between the Centers for Medicare and Medicaid Services and certain states that will be impacted by the new Medicare pharmaceutical benefit. We have not repeated all of the recommendations made by the Commission in these comments. However, we want to note that the State of Connecticut supports all of the recommendations outlined by the Commission.

While the SPATC process was certainly a helpful forum for presenting comments of importance to Connecticut, the impact of the Medicare Modernization Act extends beyond the interests of state pharmaceutical assistance programs to include issues relevant to the Medicaid program and to state retirees. The State of Connecticut believes that there are important threshold issues in the rule related to SPAPs. Therefore, we have repeated some of the SPATC comments here to underline the critical nature of these areas.

Accordingly, attached please find comments from the State of Connecticut regarding CMS's proposed rule for implementing the Medicare prescription drug benefit. If you have any questions about our comments, please contact Paul Potamianos at 860-418-6272 (paul.potamianos@po.state.ct.us) or David Parrella at 860-424-5116 (david.parrella@po.state.ct.us).

Sincerely,

Marc S. Ryan
Secretary
Office of Policy and Management

Patricia A. Wilson-Coker, JD, MSW
Commissioner
Department of Social Services

Attachment

A. General Provisions

Section 423.4. Definitions. *PDP Sponsor.* Section 1860D-41(13) of the Act defines a PDP sponsor as a "nongovernmental entity," which is operationalized at Section 423.4 of the proposed rule (p. 46810). We ask that CMS be flexible in its interpretation of the Act and its definition of nongovernmental entity so that states can comply with the law while at the same time allowing for creation of state-sponsored nongovernmental entities or selection of one entity as PDP sponsor for our Medicaid dual-eligible and SPAP populations. Not only would this approach minimize client confusion and ensure continuity of care (since we are familiar with both the medical and pharmaceutical histories of our clients), but it would resolve issues of data-sharing, client notification and client enrollment.

Section 423.6 (p. 46636 of the preamble). Cost-Sharing in beneficiary education and enrollment. It is unclear whether PDPs or MA-PD plans can pass along education and information costs in the form of user fees to states. To the extent that there are education and information costs, these should be borne by CMS and/or PDPs or MA-PD plans, not states.

Section 423.112 (p. 46636 of the preamble). Establishment of prescription drug plan service areas. Because the MMA allows for up to 50 state regions, and because Connecticut is an SPAP state, we believe that CMS should establish PDP regions in a way that allows Connecticut to be its own region. This is of importance to Connecticut because of the need to coordinate between our SPAP and the PDP or MA-PD plans. The needs and concerns of smaller states (especially states with SPAPs) could be subsumed by larger states with different integration needs. Allowing Connecticut to be its own region will help ensure that all PDPs or MA-PD plans will be responsive to meeting Connecticut's needs, and will help maintain continuity of care for Connecticut's vulnerable populations.

Section 423.34(d) (pp. 46638-46640 of the preamble). Enrollment process. *Enrollment requirement for full benefit dual eligibles.* The preamble proposes that full benefit dual eligibles be given until May 15, 2006, to establish initial enrollment before the auto-enrollment process begins. Under this proposal, some full benefit dual eligibles will not be covered by Part D until after May 15, 2006, which would mean either that those individuals have no prescription coverage or that states will be forced to continue coverage through their Medicaid programs for that time period, but without receiving FFP for those Medicaid costs. Indeed, states will incur costs for full benefit duals who do not enroll until May 15, 2006, even beyond that date, since we do not have the administrative and programmatic ability to ensure that those individuals are immediately enrolled in a Part D plan and are accessing Part D prescription drug benefits. States should not be penalized by the fact that many full benefit dual eligibles will likely not be enrolled prior to January 1, 2006; rather, states should be able to receive FFP for prescription costs for duals until initial enrollment is accomplished and individuals are able to access their Part D benefits.

To best address this situation, we believe CMS should implement an auto-enrollment process whereby full benefit dual eligibles are automatically enrolled in a default plan effective January

1, 2006, unless the individual elects to enroll in a different plan prior to that date. In addition, in order for states to implement the most effective, best integrated wrap around program, and to minimize disruption to clients, states should be able to auto-enroll dual eligibles into a preferred PDP (similar to the drug discount card).

Under the rule, a full benefit dual who fails to enroll would be automatically enrolled in a PDP that has a monthly beneficiary premium equal to or below the subsidy amount for low income beneficiaries. While the regulation is clear that states can wrap around for beneficiaries, it is not clear whether a state can elect to enroll a dual (or perhaps SPAP recipient) in a higher premium plan if the state paid the difference and determined it to be cost effective compared to what the state's wrap around cost would otherwise be. In contrast, if a dual elects a higher premium plan as the regulation allows, the beneficiary would cover the cost of the difference (see page 46639 of the preamble). CMS should clarify that there is no obligation for states to cover the differential for duals who enroll in a plan with a premium higher than the premium subsidy benchmark level.

The proposed regulation provides for auto-enrollment for any dual eligible who has not enrolled in a Part D PDP by the end of the individual's enrollment period or upon becoming dual eligible after an initial enrollment period. While the preamble states that full benefit dual eligibles may choose to change enrollment, we believe that they should not be able to disenroll from one plan and enroll in another in a way that would create a break in coverage since this could potentially result in no prescription coverage at all or, for those states that choose to wrap around, it could force states to cover prescription costs through Medicaid at 100% state cost. Such scenarios conflict with CMS's stated rationale for auto-enrollment, which is to ensure that full-benefit dual eligibles receive outpatient drug coverage under Part D (see p. 46638 of the preamble).

If CMS does allow for a break in Part D coverage, protocols need to be in place for the coordination of and payment for drug benefits for any time period that a Medicaid dual eligible is not actually enrolled in a PDP or MA-PD plan. In addition, states need to be notified whenever a dual eligible disenrolls so that state Medicaid programs will know that the individual is no longer covered under Part D. The exposure to state Medicaid programs and SPAPs is significant as many states that choose to wrap around dual eligibles' Part D coverage will find themselves covering 100% of the prescription costs for those dual eligibles that decline enrollment or disenroll from a Part D plan.

Section 423.34 (p. 46639 of the preamble). Enrollment process. CMS is requesting comments on the most appropriate method and entity to perform auto-enrollment of dual eligibles. If the state assumes responsibility for the auto-enrollment of dual eligibles, then the rule should be amended to include an FFP provision. Since Medicare is a federal benefit, we believe that states should be fully reimbursed at 100% of their costs.

B. Eligibility and Enrollment

Section 423.36(a) (p. 46639 of the preamble). Enrollment periods. *Initial Enrollment Period for Part D—Basic Rule*. States with large SPAPs need time to develop and implement a

wraparound. Indeed efforts in this regard are complicated by the fact that many states with SPAPs will also be seeking to integrate their dual eligible populations into their programs to wraparound a dual eligible's minimal Part D costs. In effect, this creates a need to administer two wraparounds. To the degree that CMS will not announce PDP and MA-PD plans until late 2005 and with enrollment not expected until the beginning of November 2005, it is unlikely that all SPAPs will be ready to integrate their programs with the new Part D benefit. In addition, with the late rollout of Part D, there will be little time to educate consumers and help them understand the Part D benefit and its impact on them. If individual SPAPs are not ready to wrap around the federally subsidized drug benefits, SPAP states should have the option to obtain a lump sum transitional payment in FFY 2006 for SPAP recipients or elect to continue under the drug discount card program for SPAP recipients. It is assumed that non-SPAP residents would be enrolled in the nationwide program.

Left open in the preamble (see page 46727) is who will enroll beneficiaries into the Part D benefit. Section 423.774 (page 46855) of the regulation indicates that states may play a role in determining subsidy eligibility for Medicaid duals, but it is unclear if states will be required to or have the flexibility to assume the eligibility and enrollment for both Medicaid duals and SPAP beneficiaries in Part D. Many states would argue that this is the most efficacious way of enrolling beneficiaries. The regulation also leaves open the prospect that states may be the best entities to handle auto enrollment issues for duals that do not enroll in Part D voluntarily. It is noted that states could provide the best and most timely and accurate Medicaid data for determination in these instances.

But, if states are to assume the exclusive role or part of the role in the eligibility and enrollment process, states should be compensated for that cost. States should be offered the opportunity to count all administrative costs, including the costs of determining eligibility and enrollment in Part D plans as eligible Medicaid expenses, whether the beneficiary is enrolled in Medicaid or an SPAP. Consideration should be given to an enhanced reimbursement rate common to all states.

Section 423.48 (p. 46642 of the preamble). Information about Part D. CMS intends to provide information to beneficiaries in advance of initial and annual enrollment periods that would help promote informed beneficiary decisions. However, it could be very confusing for beneficiaries to receive a notice from CMS about monthly premiums and cost sharing requirements, for example, if the beneficiary is also covered by an SPAP or an employer sponsored plan that elects to wrap around the Part D coverage. Connecticut's intention is to ensure that there is no change in benefits or costs to clients of our SPAP or state retirees as a result of Part D, so a notice from CMS about cost-sharing or premiums that the state intends to cover will generate a great deal of confusion on the part of this elderly and disabled population. As an alternative, we believe that notices to beneficiaries covered by SPAPs or covered by a state employee health plan should be coordinated with states so that beneficiary confusion is minimized.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections

Section 423.100 (p. 46646 of the preamble). Definitions. *Covered Part D drug.* It is unclear whether an over-the-counter (OTC) drug currently covered under Medicaid is still subject to FFP

once Part D is implemented. The rule suggests that covered Part D drugs are prescription-only with minor exceptions and must be Medicaid-covered. We believe that dual eligibles should still be able to get non-prescription drug coverage through Medicaid (with associated FFP to the state) because these items are not covered under Part D. It is not a good use of public dollars to have Medicare pay for a more expensive product plus a dispensing fee when a cheaper product is available and is something the client wants. Such a policy could result in doctors prescribing a prescription medication instead of an OTC product so that the client can have it paid for by Medicare.

Section 423.100 (pp. 46648 – 46649 of the preamble). Definitions. *Long-term care facility.* CMS requests comments on how long-term care facilities should be defined in this section and, specifically, whether intermediate care facilities for the mentally retarded should be designated as long-term care facilities. Currently, the rule suggests that the only entities to be defined as long-term care facilities would be skilled nursing or nursing facilities. The CMS justification is that only those facilities are bound to Medicare conditions of participation that result in exclusive contracts with long-term care pharmacies. CMS appears to be willing to reconsider its position on ICF/MRs if evidence is provided that such facilities have pharmacy contracts like long-term care facilities. While ICF/MRs generally may not contract with long-term care pharmacies, it is the case that many state-run ICF/MRs tend to have separate and distinct contracts with pharmacies that are sensitive to the unique needs of these residents. As well, the preamble notes that Medicare does have special coverage related to mentally retarded individuals and that these individuals will need to be assured access to Part D drugs.

We believe ICF/MRs should be designated long-term care facilities for the following reasons:

- Many of these clients have similar health conditions as those in skilled nursing facilities.
- Contracting arrangements are similar to long-term care facilities to respond to residents' unique needs.
- The special coverage in Medicare for the mentally retarded may be better protected through this designation.
- CMS has indicated that it may exempt special needs populations from cost-sharing and formulary restrictions. Residence in a designated long-term care facility would be an appropriate criterion for inclusion in a special needs group, as discussed elsewhere in our comments. Therefore, it is important to define long-term care facilities to include all facilities where individuals live due to health related reasons and also face barriers to their access to pharmacies and drugs due to their living circumstances.

In addition to ICF/MRs, we believe that the regulation should also include group homes under a 1915(c) home and community-based waiver as long-term care facilities for the reasons outlined above. The populations in these facilities are substantially similar to those in ICF/MRs and often are included in state contracts for pharmacy services for ICF/MRs.

Section 423.100 (p. 46651 of the preamble). Definitions. *Incurred costs.* For persons eligible for both ADAP and Medicare, we believe that ADAP expenditures or, alternatively, at least state expenditures for prescription assistance to persons with HIV/AIDS, should count as "creditable"

coverage and should be added to the list of forms of "creditable" coverage under Section 423.56 of the proposed rule (p. 46644 of the preamble). Contrary to the assertion by CMS in the preamble at pages 46650-46651, state funds used to provide prescription assistance to individuals with HIV/AIDS are no different from SPAP expenditures and should count toward that beneficiary's out of pocket costs. We believe that 1860D-24 of the Act gives the Secretary the discretion to define "insurance or otherwise" as described in 1860D-2 in a way that is consistent with our recommendation. The definition of "incurred costs" in Section 423.100 of the proposed rule should therefore be revised accordingly.

Section 423.100. Definitions, or Section 423.104. Requirements related to qualified prescription drug coverage. Since plans can define a one month supply differently (e.g., 30, 31 or 32 days), the proposed rule should establish a consistent definition of supply limits. Without such a definition, one payor may reject a claim saying the refill is too soon, when another would pay. Ensuring a consistent definition will minimize the impact on SPAPs and employer sponsored wrap-around plans, which are likely at risk for covering any charges for early refills.

Section 423.104(h)(1) (p. 46654 of the preamble). Requirements related to qualified prescription drug coverage. *Access to negotiated prices.* The general understanding, based on the language in this section, is that, for a formulary drug, the negotiated PDP or MA-PD plan price will hold through the "donut hole" period and for a non-formulary drug, the SPAP will pay under their pricing structure. Thus, even though it is the SPAP not the PDP or MA-PD plan covering the expense of a formulary drug, the rebate would go to the PDP or MA-PD plan since it is their negotiated rate that is being used and which was most likely developed based on a claims volume that includes the "donut hole" period. By forcing the SPAPs to integrate their programs with all of the plans (see page 46697 of the preamble), there is a disincentive for the states to wraparound. In addition, states lose any bargaining power with manufacturers with regard to rebates if states can no longer guarantee a certain volume or as large a volume. In effect, SPAP costs could now increase during the "donut hole" for a given client as the state no longer has the ability to reduce ultimate costs through significant rebates from a drug manufacturer as the rebate is already being paid to a PDP or MA-PD plan even though the PDP or MA-PD plan is not covering the actual costs of the drugs during the "donut hole." The law and regulation are clear that PDPs and MA-PD plans have to make the discounted price available to beneficiaries even during the "donut hole" period. We recommend that, for states that need the volume to maintain rebates, they be allowed the option of covering prescription costs under their own arrangements (i.e., under existing reimbursement policies and manufacturer rebate agreements), during the "donut hole" period. While a PDP or MA-PD plan may lose some volume discount, states need the leverage.

Section 423.104(h)(3) (p. 46654 of the preamble). Requirements related to qualified prescription drug coverage. *Negotiated prices. Disclosure.* States must have access to the price concession data that CMS says will be required reporting from the PDPs and MA-PD plans despite confidentiality issues. Because states are at risk of losing discounts in both Medicaid and SPAPs, this data will help states determine the financial impact of wrapping around Part D for these populations.

Section 423.112 (p. 46655 of the preamble). Establishment of prescription drug plan service areas. Because the MMA allows for up to 50 state regions, and because Connecticut is an SPAP state, we believe that CMS should establish PDP regions in a way that allows Connecticut to be its own region. This is of importance to Connecticut because of the need to coordinate between our SPAP and the PDP or MA-PD plans. The needs and concerns of smaller states (especially states with SPAPs) could be subsumed by larger states with different integration needs. Allowing Connecticut to be its own region will help ensure that any PDP or MA-PD plans will be responsive to meeting Connecticut's needs, and maintaining continuity of care for Connecticut's vulnerable populations.

Section 423.120(a) (pp. 46658 - 46659 of the preamble). Access to covered Part D drugs. *Assuring pharmacy access.* The proposed rule distinguishes between preferred and non-preferred network pharmacies, where a non-preferred pharmacy is a network pharmacy that offers Part D enrollees higher cost-sharing for covered Part D drugs than a preferred pharmacy. As noted in the preamble, cost sharing can vary not only based on the type of drug or formulary tier, but also on a particular pharmacy's status within the plan's pharmacy network. This adds yet another level of complexity to the plan, especially as SPAPs or employer sponsored plans try to wrap around and coordinate with multiple PDPs and MA-PD plans. Further, while the proposed rule appears to guarantee beneficiaries wide access to pharmacies, a PDP or MA-PD plan could still meet these access requirements but in effect have a very small preferred network that discourages enrollment of certain populations as well as enrollment from certain geographic areas. On page 46659 of the preamble, CMS says it will review the design of proposed plans to ensure that such plans do not "substantially discourage" enrollment. This is important as the current rule does not ensure adequate access to preferred pharmacies and could be used by PDPs or MA-PD plans to shift certain costs back to SPAPs or employer sponsored plans that choose to wrap around the Part D benefit. To maximize access, CMS should establish clear guidelines to ensure the broadest network of preferred pharmacies throughout a PDP's or MA-PD plan's coverage area. We believe this could best be achieved by requiring plans to meet network access standards using preferred pharmacies. In addition, the rule should mandate that CMS approve changes to a PDP's or MA-PD plan's network annually, as well as any substantive midyear changes in plan networks.

Section 423.120. Access to covered Part D drugs. The MMA does not appear to address the issue of continuity of benefits with respect to dual eligibles. Since the existing provisions in Title XIX have not been repealed, CMS will need to clarify whether state Medicaid programs continue to be bound by the requirement to provide non-formulary drugs as dual eligibles transition to Medicare Part D. Similarly, if there is an appeal of a formulary decision, we believe that Medicare should pay for the cost of the requested prescription pending resolution of the appeal, so that Medicaid is not responsible for continuing coverage at 100% state cost.

Section 423.120 (p. 46661 of the preamble). Access to covered Part D drugs. CMS is requesting comments on special needs populations and any special treatment needed for such populations as it relates to flexibility and cost containment in the program. The preamble recognizes the unique health needs of such populations and notes that open formularies are the norm for clients in long-term care facilities. Section 423.782(a)(2)(ii) also exempts individuals in long-term care facilities from cost-sharing.

Skilled nursing facility residents and residents of ICF/MRs appear to be deemed institutionalized under the Act and would be free of cost-sharing requirements. That may not be the case for residents of 1915(c) waiver group homes and other similar facilities for persons with mental illness or mental retardation. Because these special needs populations have substantially similar financial status and health needs as residents of skilled nursing facilities and ICF/MRs, we believe that all of these populations should be treated equally.

While residents of ICF/MRs and group homes and other facilities may have some income disregarded (those in nursing homes do not), their income is still extremely limited. The personal needs allowances (PNAs) in skilled nursing facilities are generally well below $100 in most states, and need only be $30 per month according to federal Medicaid law. These PNAs must cover personal incidentals as well as co-pays and non-formulary drugs. If not deemed institutionalized or otherwise freed of cost-sharing, a medically fragile individual subject to cost-sharing and with multiple prescriptions could not afford even the minor cost-sharing under Part D.

The financial wherewithal of all special needs populations, including those in skilled nursing facilities and ICF/MRs otherwise free of cost-sharing, may not be able to afford their medications or have true access to them if formulary restrictions apply. Formulary restrictions could force such special needs individuals to utilize the majority or all of their monthly income on medications if a needed drug is not on a formulary, and must be purchased out-of-pocket while pursuing an appeal. Indeed, in some cases, their PNA would not be adequate to cover the out-of-pocket cost, resulting in a break in therapy. Furthermore, few of these individuals have the cognitive abilities to deal with appealing a formulary denial and it would be an enormous burden for their group home or case manager to have to navigate the appeals process on behalf of numerous clients.

CMS clearly recognizes in the preamble that such populations may need special treatment because they are more sensitive to and less tolerant of many medications. Also noted is that most long-term care pharmacies have open formularies to respond to this fact. In general, the existence of any formulary restrictions and cost-sharing could easily lead to greater medical costs for non-drug benefits for these exceedingly medically fragile populations. Research published by the Center for Health System Change has documented that barriers to access for drugs for the Medicaid population, including co-payments and prior authorization, have led to reduced adherence to medically necessary drug regimens. Failure to properly comply with medication therapy results in exacerbations of chronic and acute illnesses that, at a minimum, bring these patients back to the physician and, at worst, puts them in a hospital or other institutional setting.

We believe strongly that all special needs populations must be exempt from formulary restrictions and cost-sharing. Formulary exceptions and exemptions from cost-sharing are important for the following groups:

- Residents of skilled nursing facilities and other like entities.
- Residents of ICF/MR facilities.
- Residents of 1915(c) waiver group homes.

- Residents of state-run group homes that operate similarly to 1915(c) waiver group homes but have not technically met federal Medicaid qualifications.
- Those with chronic mental illness, whether they qualified for federal SSI or not. These individuals often are required to have less-than-30-day supplies of prescription drugs because of suicidal tendencies or the need for close monitoring. Formularies and cost-sharing for this population would complicate the already major challenge of drug adherence for many of these individuals, whose very illnesses make it difficult to adapt to change. Furthermore, paying out of pocket for denied drugs would force these individuals to exhaust the vast majority of their income each month. States that have implemented even nominal co-pays on Medicaid recipients have at least anecdotally found that such co-pays have dissuaded the mentally ill from filling prescriptions. This was the case even when Medicaid beneficiaries were told that federal law dictated that the drug could not be withheld due to lack of payment of co-pays. Thus, we know that financial barriers for this population result in under-treatment and consequently larger costs for non-drug services.
- Those with other chronic health conditions, such as HIV/AIDS. These beneficiaries often have multiple prescriptions due to the complex nature of their conditions. As such, they would be unable to afford cost-sharing or the additional financial implications of being subjected to a restrictive formulary.
- Beneficiaries who are otherwise on Medicaid community-based waivers (to avoid institutionalization) and therefore have very limited incomes should also be considered to be free of cost-sharing and certain formulary restrictions. This would apply to individuals on home and community-based waivers for the elderly and disabled or those on Katie Beckett waivers.

Section 423.120 (see also section 423.124) (p. 46657 of the preamble). Access to covered Part D drugs. CMS is seeking comments regarding whether plans should be required to contract with long-term care pharmacies. Section 1860D-4(b)(1)(C)(iv) of the law gives the Secretary discretion to require plans to contract with long-term care pharmacies. We would recommend that section 423.120 of the rule be modified to include access to all long-term care pharmacies.

Section 423.120 (p. 46659 of the preamble). Access to covered Part D drugs. The proposed regulation provides for fairly stringent rules to ensure that beneficiaries have access to medically necessary drugs. While section 1860D-4(b)(3)(A) of the Act requires that the formulary be "developed and reviewed" by a P&T committee, it is CMS' interpretation that the P&T committee may establish and change drugs on a formulary and that the committee's decision is binding on the plan. Section 423.120 of the regulation, however, requires only that a PDP's and MA-PD plan's formulary be reviewed by a P&T committee. The regulation should be amended to adopt CMS' intent about the binding nature of the P&T committee's decisions.

Section 423.120(a)(6) (p. 46649 of the preamble). Access to covered Part D drugs. *Level playing field between mail-order, and network pharmacies.* The proposed rule provides that those who choose an extended supply of a Part D drug through a retail pharmacy would be responsible for the differential between the retail pharmacy's negotiated price and the network's mail-order

negotiated price. We are concerned about this policy because, if that amount is greater than the amount the SPAPs or employer sponsored wrap-around plans would have paid for the extended supply, then costs are being shifted to the states.

CMS is seeking comments on their proposal that this price differential be counted as an incurred cost against the annual out-of-pocket threshold. We support this position and recommend that the rule clearly state that this differential counts towards out-of-pocket expenditures.

Section 423.120(b)(2) (p. 46660 of the preamble). Access to covered Part D drugs. *Inclusion of drugs in all therapeutic categories and classes.* There is a requirement that PDPs and MA-PD plans have at least two drugs in each class as well as have generics available. The regulations are not clear, however, whether generics can be one of the two drugs. We believe two brands plus a generic (when available) should be the minimum requirement.

Section 423.120(b)(5) (p. 46819 of the preamble). Access to covered Part D drugs. *Provision of notice regarding formulary changes.* Section 1860D-4(b)(3)(E) of the Act states: "Any removal of a covered Part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists." Of concern is that CMS has interpreted "appropriate notice" to mean 30 days. Specifically, section 423.120 (page 46819) of the proposed rule reads: "A PDP sponsor or MA organization offering an MA–PD plan must provide at least 30 days notice to CMS, affected enrollees, authorized prescribers, pharmacies, and pharmacists prior to removing a covered Part D drug from its plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug." CMS may maintain that any arbitrary change is unlikely as it has a requirement for all formulary changes to go through a P&T committee that meets specifications and the approval of CMS. The issue is not that changes might be made arbitrarily, but it simply does not allow enough time for the SPAPs to respond to or integrate the formulary change in their programs. Therefore we recommend that, at a minimum, PDPs be required to grandfather-in coverage of a deleted drug for anyone who was taking the medication prior to the deletion, unless the deletion is due to the new availability of a generic substitute or due to the FDA's removal of the drug from the market due to safety reasons. This should not be construed as prohibiting a PDP from asking physicians to voluntarily switch their patients to less costly drugs, in a therapeutic substitution initiative. In the alternative, we believe that any formulary change should require 90 day notice to all beneficiaries as well as SPAPs and state retiree plans.

Section 423.120(b)(5) (p. 46661 of the preamble). Access to covered Part D drugs. *Provision of notice regarding formulary changes.* CMS proposes that PDPs and MA-PD plans only inform those taking a drug affected by a formulary change of such a change. We believe that all beneficiaries and all parties, including SPAPs and state retiree plans, should be notified of formulary changes.

Section 423.124 (p. 46662 of the preamble). Special rules for access to covered Part D drugs at out-of-network pharmacies. In the preamble, CMS details four scenarios where out of network access would be guaranteed. A fifth scenario for out-of-network access should be added that specifically identifies those retirees who reside in different parts of the country during the year

("snowbirds") and are outside of the service area, (e.g., they reside for several months at a time in Connecticut and in Florida). Regional plans may not be sufficient for snowbirds. Even if a plan's service area does cover both areas of the country where the snowbird resides, the plan may not use the same contracting pharmacies in the dual locations, thereby subjecting the retiree to pay higher costs from out-of-network pharmacies during a portion of the year. This is an important consideration for employers who currently have (or are required to have per union agreements or otherwise) prescription drug coverage that is nationwide or covers entire regions of the country and are deciding whether to switch to a plan that has Medicare Part D as the primary payer for prescription coverage.

D. Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

Section 423.153 (p. 46667 of the preamble). Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste. CMS requests comments regarding a proposed requirement that cost-savings strategies be under the direction and oversight of a Pharmacy and Therapeutics Committee. We support this proposal.

Section 423.153 (p. 46670 of the preamble). Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste. For states to run successful disease management programs, it is important that they retain the ability to access prescription history for dual eligibles. In addition, in order to minimize prescription abuse by clients who are in lock-in status, states need the ability to continue to track a client's prescription history. The exchange of data between PDPs / MA-PD plans and states is critical. Limiting the number of plans (see our comments in Subpart J) would facilitate integration and allow the state to better coordinate care.

Section 423.153(c). Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste. *Data Sharing/ Quality Assurance.* To ensure an effective drug benefit program, quality assurance and evaluation are essential. In particular, SPAPs and state retiree plans must have access to data to evaluate program performance. As a result, we believe CMS should share Medicare evaluation data with SPAPs and state retiree plans to allow states to make decisions regarding ongoing quality improvements. We also believe CMS should issue an annual report assessing the effectiveness of the Part D drug benefit program. The report should include detailed information on claim denials; exceptions and appeals and their outcomes; the turnaround times for PDP processing of prior authorization requests, exception requests, and re-determination requests; and, the percent of the total negotiated drug costs paid by the PDP versus the beneficiary, SPAP, or state retiree plan.

F. Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation

Sections 423.104 and 423.272 (p. 46681 of the preamble). Review and negotiation of bid and approval of plans submitted by potential PDP sponsors or MA organizations planning to offer MA–PD plans. The general understanding, based on section 423.104 of the proposed rule and page 46654 of the preamble, is that, for a formulary drug, the negotiated PDP or MA-PD plan price will hold through the "donut hole" period and for a non-formulary drug, the SPAP will pay under their pricing structure. Thus, even though it is the SPAP not the PDP or MA-PD plan covering the expense of a formulary drug, the rebate would go to the PDP or MA-PD plan since it is their negotiated rate that is being used and which was most likely developed based on a claims volume that includes the "donut hole" period. By forcing the SPAPs to integrate their programs with all of the plans (see page 46697 of the preamble), there is a disincentive for the states to wraparound. In addition, states lose any bargaining power with manufacturers with regard to rebates if states can no longer guarantee a certain volume or as large a volume. In effect, SPAP costs could now increase during the "donut hole" for a given client as the state no longer has the ability to reduce ultimate costs through significant rebates from a drug manufacturer as the rebate is already being paid to a PDP or MA-PD plan even though the PDP or MA-PD plan is not covering the actual costs of the drugs during the "donut hole." The law and regulation are clear that PDPs and MA-PD plans have to make the discounted price available to beneficiaries even during the "donut hole" period. We recommend that, for states that need the volume to maintain rebates, they be allowed the option of covering prescription costs under their own arrangements (i.e., under existing reimbursement policies and manufacturer rebate agreements), during the "donut hole" period. While a PDP or MA-PD plan may lose some volume discount, states need the leverage.

Section 423.272 (p. 46681 of the preamble). Review and negotiation of bid and approval of plans submitted by potential PDP sponsors or MA organizations planning to offer MA–PD plans. This section allows CMS to reject any bid if it finds that it will "substantially discourage enrollment by certain Part D eligible individuals." In the preamble, CMS asks for comments on how to evaluate the proposed formularies in bid proposals. We believe a reasonable formulary should assure that 90% of patients with any particular diagnosis could find their medication on the formulary. CMS should therefore establish a formulary evaluation criterion that would trigger a much more detailed evaluation of the adequacy of the formulary if a drug plan failed to offer enough medication choices to assure that 90% of the beneficiaries will be able to continue on their current therapies. A formulary that requires vast numbers of elderly to switch or appeal will result in the potential for numerous interruptions in drug therapy that result in other medical cost and quality problems. It will also result in significant costs for SPAPs that will wrap around Part D by picking up the costs of drugs that are denied as non-formulary drugs.

Section 423.293(a) (p. 46685 of the preamble). Collection of monthly beneficiary premiums. *General rule.* The regulation allows for payment of premiums directly to PDPs or MA-PD plans. Because CMS will have the most up-to-date information about which plan a beneficiary is enrolled in, SPAPs should pay premiums directly to CMS. One mechanism that could be used is to parallel the existing programs whereby states pay QMB and SLMB cost-sharing to the federal government through Medicaid reimbursement withholds.

The regulation also allows for the collection of beneficiary premiums through withholding from Social Security checks. However, in the case where an SPAP state wishes to wrap its SPAP

benefit around the Part D benefit, such withholding is inappropriate. Once again, we want the option of paying premiums directly to CMS. Such payments could be made similar to the way Medicare buy-in payments are made for dual eligibles. With state payment of premiums, we would want to ensure that there are beneficiary protections to prevent disenrollment of the beneficiary if a federal-state payment dispute arises.

G. Payments to PDP Sponsors and MA Organizations Offering MA-PD Plans for All Medicare Beneficiaries for Qualifies Prescription Drug Coverage

Section 423.336 (p. 46693 of the preamble). Risk-sharing Arrangements. *Plan spending below target*. In the preamble, CMS writes "if plan spending fell below the target, plans would share the savings with the government." Because states are contributing toward the cost of running the Part D program through the clawback, any savings that accrue to "the government" should be shared with states.

I. Organization Compliance With State Law and Preemption by Federal Law

No comments.

J. Coordination Under Part D Plans With Other Prescription Drug Coverage

Section 423.464(a) (p. 46700 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *General rule*. This section addresses the data sharing that should occur with SPAPs as to coordination of benefits, calculation of out-of-pocket requirements, etc. In our view, the regulation is weak with respect to safeguarding states' needs for coordination because it says that PDPs "must permit" SPAPs to coordinate with PDPs. We believe that the rule should be modified to read that PDPs and MA-PD plans "are required to coordinate with SPAPs." We also believe that, once the initial coordination is in place, language requiring ongoing coordination needs to be added to the rule. In addition, we believe explicit language in the contracts of PDPs and MA-PD plans (see section 423.505 of the rule) must be included to ensure the proper data sharing and coordination, especially if PDPs and MA-PD plans are responsible for TrOOP calculation, as opposed to a separate vendor contracted by CMS. We have offered additional comments under Subpart K, below, regarding contractual language that would help effectuate the requirement for PDPs and MA-PD plans to coordinate with SPAPs.

Section 423.464(a). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *General rule*. While this section of the regulation requires PDPs and MA-PD plans to permit SPAPs to coordinate with plans, the detail is insufficient to address the significant continuity of care concerns raised by SPAP plans on behalf of their beneficiaries. The regulation needs to be stronger on the requirements of PDPs and MA-PD plans to share data and enter into agreements regarding continuity of care and coordination of such things as prior authorization, generic substitution and formulary changes. The regulation should make clear that PDPs and MA-PD plans are required to work with SPAPs and give some deference to the controls,

processes, and limitations (e.g., preferred drug list, prior authorization and generic substitution decisions) already established by SPAPs. We recommend that state rules addressing patient access to drugs should govern PDPs and MA-PD plans. To protect continuity of care, procedures should be put in place before the January 2006 start date to mandate dialogue concerning SPAP clients that have already been prior authorized for certain brand drugs.

Section 423.464(e)(ii) (p. 46697 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Non-discrimination.* Section 1860D-3 of the Act requires the Secretary to ensure that each Part D eligible individual has a choice of at least two qualifying plans or, if necessary, the opportunity to enroll in a fallback prescription drug plan. Section 1860D-23(b)(2) prohibits SPAPs from working with a subset of plans available in the region (the so-called "anti-discrimination" requirement), which means that SPAPs must coordinate with multiple plans. Section 426.464(e)(1)(ii) operationalizes the Act by requiring SPAPs to provide assistance "to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls." Section J of the preamble (page 46697) states:

> "We are interpreting the nondiscrimination language to mean that SPAPs, if they offer premium assistance or supplemental assistance on Part D cost sharing, must offer equal assistance by all PDPs or MA–PD plans available in the State and may not steer beneficiaries to one plan or another through benefit design or otherwise. State programs cannot, for example, use the threat of withholding SPAP enrollees to negotiate coverage, premium or formulary changes with PDPs or MA–PD plans. Violations of the non-discrimination rule will jeopardize the program's special status with respect to true out-of-pocket costs. That is, a State program that discriminates does not qualify under the definition of an SPAP, and consequently, its contributions to cost sharing do not count toward the out-of-pocket limit."

CMS indicated in an 8/4/04 conference call that the actual operational details were not yet defined. For administrative ease, efficiency and cost effectiveness, states need the ability to limit the number of PDPs with which they need to coordinate to one or two. The states need to have ways to ratchet down their costs, especially in light of no guarantee of reimbursement for ongoing administrative costs, the strong likelihood of a loss of drug rebate dollars in SPAP and Medicaid programs, and the ongoing "donut hole" costs to states. More to the point, continuity of care can be maximized (and costs to the state and federal governments minimized) if states have the ability to work with one or two preferred PDPs. Further, many SPAPs will be providing some form of wrap around coverage or will be subsidizing a plan's premiums. As a result, it is essential that SPAPs be given the opportunity to steer their beneficiaries away from those PDPs requiring disproportionately high premiums without providing any clear benefits to their enrollees. The language in section 423.464 of the regulations should be broadened to allow states to contract with one or two PDPs as long as the contracts are competitively bid and limiting the number of PDPs would be in the best interest of state SPAP clients because the state clearly defined what it was looking for during the bidding process. We believe that states would still be able to meet the anti-discrimination test with this process. As an alternative, states should be allowed to design a wrap around and limit enrollment of its SPAP and dual-eligible clients in those plans that agree to the state's contractual requirements. As a further alternative, states should have the right to auto-enroll any SPAP clients who are required as a condition of enrollment in an SPAP to enroll in Part D but fail to do so (or duals that either refuse to enroll voluntarily or disenroll from Part D) in a state's preferred PDP vendor(s). Indeed, section 423.34

of the regulation refers to states potentially doing an automatic and random enrollment function with regard to duals that do not voluntarily enroll. We believe that allowing states to enroll SPAP clients and dual eligibles in default plans, but then allowing those enrollees to choose another PDP if they do not want to be in the default plan, will meet the test of anti-discrimination.

Section 423.464(f)(3) (pp. 46696-46700 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Imposition of fees.* While SPAPs are not required to coordinate with PDPs (see page 46701 of the preamble), section 423.464(a) of the regulation says PDPs "must permit" SPAPs to coordinate with PDPs and MA-PD plans. The rule allows Part D plans to impose fees on SPAPs for required coordination, including enrollment, claims processing, payment of premiums, and administrative processes (see page 46700 of the preamble). Because no funding is provided to states for this coordination, such fees should not be imposed on the states. While 1860D-11(j) of the Act says that fees unrelated to the cost of coordination are not to be imposed, we believe that CMS has the authority to interpret this language to prevent unnecessary and unreasonable fees from being charged at all. Instead, CMS should establish a baseline requirement of coordination that is applicable nationwide, with any costs related to that coordination factored into a plan's bid and paid by CMS. Only extraordinary costs related to a state's unique situation that are beyond the scope of normal, reasonable national-standard coordination requirements should be borne by the state, and even then we seek the ability to negotiate such costs in concert with CMS before plan contracts are executed. Additionally, it is important that the regulations and the PDP and MA-PD plan contracts signed with CMS be clear and specific on the level of coordination that PDPs and MA-PD plans must have with SPAPs, and that any state-specific requirements be included in the contracts executed by CMS and the plans. Without these protections, there is absolutely no incentive for plans to negotiate in good faith with states, and states could be subjected to unreasonable and excessive fees as a result of needing to coordinate SPAP and retiree coverage with the plans. (We have made related comments on contract protections in Subpart K.)

Section 423.464(f)(ii) (pp. 46698 – 46699 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Employer Options*. If employers pick an option that requires their retirees to enroll in Part D with Medicare as the primary payer, the final rule should contain special access and financial protections to safeguard those employers with significant numbers of "snowbird" retirees. As discussed in our comments on Subpart C, above, this segment of the retiree population has access issues that must be addressed. This is particularly important because there is still uncertainty over how many plans that currently offer nationwide drug discount cards will participate in Part D due to the notion of presumed risk.

Section 423.464(d) (p. 46701 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Cost Management Tools.* Section 423.464(d) of the proposed rule and section 1860D-24(c)(1) of the Act allow PDPs and MA-PD plans to continue to use cost-containment strategies even as they relate to SPAPs or other drug plans providing wrap-around or supplemental coverage. CMS seeks comments in the preamble on how CMS "can ensure that wrap-around coverage offered by SPAPs and other insurers does not undermine or eliminate the cost management tools established by Part D plans." The greater concern may be how to ensure that Part D plans are not incentivized to cost shift to SPAPs and state retiree plans. If states are

paying for coverage for SPAP enrollees who are also Medicare Part D beneficiaries (regardless of whether the PDP or MA-PD plan is directly providing the additional benefits under contract with the SPAP or whether the SPAP is coordinating such wrap around coverage with the PDP or MA-PD plan), we believe CMS should help support state laws and policies regarding SPAP coverage. States are as interested in cost management as CMS—but we are also mindful of the impact on vulnerable populations and the need to ensure continuity of care. The rule makes no attempt to prevent PDPs and MA-PD plans from controlling or overruling SPAP decision-making when coverage is paid for by SPAPs, particularly in the "donut hole." Section 423.464(d) of the rule should be modified to require that PDPs and MA-PD plans accede to SPAP rules where SPAPs are paying for beneficiary coverage.

Section 423.464(e)(2) (p. 46702 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Special treatment under out of pocket rule*. CMS indicates it is interested in comments on whether SPAPs should be required to provide feedback on how much TrOOP they have paid. Because PDPs know how much of the claim they have paid and because beneficiary and SPAP expenditures both count as TrOOP costs, it is irrelevant how much of that claim is SPAP related. There are enough administrative and coordination requirements in MMA without imposing more. The rule should be modified by deleting the phrase "collect information on and" from Section 423.464(e)(2). PDPs should count any non-PDP costs for SPAP enrollees as out of pocket for purposes of TrOOP calculation.

Section 423.464(e)(2) (pp. 46706 and 46789 of the preamble). Coordination of Benefits With Other Providers of Prescription Drug Coverage. *Tracking TrOOP*. CMS seeks comments on whether a single, central entity or multiple PDPs are best suited to tracking TrOOP. Because of coordination requirements with SPAPs, we recommend that one central entity (CMS) maintain a data system rather than having multiple PDPs maintaining separate systems.

K. Proposed Application Procedures and Contracts With PDP Sponsors

Section 423.505. Contract Provisions. (cross reference Section 423.464. Coordination of Benefits). Section 423.464 of the rule and page 46700 of the preamble address the data sharing that will occur with SPAPs as to coordination of benefits, calculation of out-of-pocket requirements, etc. See our comments under Subpart J, above, regarding strengthening the rule by requiring PDPs to coordinate with SPAPs. CMS has proposed no specific contractual language for PDPs and MA-PD plans that would describe the required coordination. Section 423.505 of the proposed regulation only states that PDPs would need to "comply with the coordination requirements…in subpart J". In order to implement this requirement, we believe explicit language in section 423.505 of the rule as well as in the contracts of PDPs and MA-PD plans must be included to ensure the proper data sharing and coordination, especially if PDPs and MA-PD plans are responsible as opposed to a separate vendor contracted by CMS.

Section 423.505. Contract Provisions. (cross reference Section 423.464. Coordination of Benefits). *Fees*. CMS has proposed no specific contractual language for PDPs and MA-PD plans that would prevent unreasonable or excessive fees from being imposed (see comments to Section 423.464 under Subpart J). Section 423.505 of the proposed regulation only states that

PDPs would need to "comply with the coordination requirements…in subpart J". Because no funding is provided to states for coordination, such fees should not be imposed on the states. While 1860D-11(j) of the Act says that fees unrelated to the cost of coordination are not to be imposed, we believe that CMS has the authority to interpret this language to prevent fees from being charged at all, or at a minimum the imposition of unnecessary and unreasonable fees. Instead, CMS should establish a baseline requirement of coordination that is applicable nationwide, with any costs related to that coordination factored into a plan's bid and paid by CMS. Only extraordinary costs related to a state's unique situation that are beyond the scope of normal, reasonable, national-standard coordination requirements should be borne by the state, and even then we seek the ability to negotiate such costs in concert with CMS before plan contracts are executed. Additionally, it is important that the regulations and the PDP and MA-PD plan contracts signed with CMS be clear and specific on the level of coordination that PDPs and MA-PD plans must have with SPAPs, and that any state-specific requirements be included in the contracts executed by CMS and the plans. Without these protections, there is absolutely no incentive for plans to negotiate in good faith with states, and states could be subjected to unreasonable and excessive fees as a result of needing to coordinate SPAP and retiree coverage with the plans. (We have made related comments on contract protections in Subpart J.)

Sections 423.509 and 423.510. Termination of contract by PDP or CMS. Currently, SPAPs are not among the parties specifically delineated as requiring notification by either PDPs or CMS. Given the significant impact Part D plans will have on SPAPs and state retirees, states must be included as parties to be notified of the termination of PDP contracts. At a minimum, SPAPs should be allowed greater notice than to the public in order to coordinate coverage as well as current and future enrollment. Sections 423.507 through 423.510 of the proposed rule should be amended to include timely notification to SPAPs and state retiree plans of termination of a PDP contract. (Similar notification requirements should be imposed by CMS on MA-PD plans.)

L. Effect of Change of Ownership or Leasing of Facilities During Term of Contract

Sections 423.551(c) and 423.552(a)(1) (pp. 46716-46717 of the preamble). Advance Notice Requirement. Currently, states are not among the parties specifically delineated as requiring notification by either PDPs or CMS. Given the significant impact Part D plans will have on SPAPs and state retirees, states must be included as parties to be notified of changes in ownership. To ensure continuity of care and minimize disruption of coordinated benefits, the advanced notification requirements in sections 423.551 and 423.552 of the proposed rule should be amended to include states, especially SPAP states.

M. Grievances, Coverage, Reconsiderations, and Appeals

Section 423.562. General Provisions. (cross-reference Section 423.44 (p, 46641 of the preamble). Disenrollment by the PDP). Section 423.44 of the proposed rule allows for the disenrollment of beneficiaries whose behavior is "disruptive, unruly, abusive, uncooperative or threatening." Because of the special needs of the dual eligibles, as well as the elderly and disabled served under our SPAP, an adequate appeals process needs to be established as well as

provisions to ensure that there will be no lapse in coverage since lack of coverage would threaten their health needs.

Sections 423.560 to 423.638. To protect continuity of care, procedures should be put in place before the January 2006 start date to mandate dialogue between states and PDPs and MA-PD plans concerning SPAP clients that have already been prior authorized for certain brand drugs. In Connecticut, atypical antipsychotic drugs are exempt from prior authorization for clients currently on them – only newly prescribed atypical antipsychotics that have at least three A-rated generics available for substitution are required to get prior authorization, and then for initial scripts only. The regulation should be modified to ensure that PDPs honor the existing prior authorization and generic substitution decisions made by SPAPs. This will help maintain continuity of care.

Section 423.560. Definitions, and Section 423.562. General Provisions. *SPAPs as Authorized Representatives, and Data Sharing*. While the definition of an authorized representative under section 423.560 could be interpreted to include an SPAP acting on behalf of an SPAP client, the regulation should be clarified. For both administrative and programmatic reasons, it is important that SPAPs be allowed to be the authorized representatives for SPAP clients.

For example, regarding step therapy, SPAPs may have claims history to show that the PDPs and MA-PD plans preferred drug was previously tried. PDPs and MA-PD plans should be required to coordinate with SPAPs and share claims history because SPAPs may have the longest and most complete clinical history. This is especially important because people may change PDPs and MA-PD plans every year, but the SPAP will remain consistent.

SPAPs and PDPs / MA-PD plans need to coordinate or at least share clinical criteria for prior authorization and also generic substitution. It is important both to avoid having two entities undertake prior authorization but also to protect continuity of care.

It will be confusing for SPAPs that have full benefit plans to know whether they should pay under their wrap-around when a PDP or MA-PD plan denies coverage. For example, when denials occur for a DUR reason, how will an SPAP know not to pay for a contraindicated drug? Certainly, SPAPs will want to continue with their own DUR programs to both protect their clients as well as prevent unnecessary costs. This will be challenging if the PDP or MA-PD plan and SPAP DUR programs don't have the same system edits.

Again, the rule must be clarified to ensure that the definition of "authorized representative" includes SPAPs and retiree plans acting on behalf of a beneficiary. We also recommend that CMS add requirements to Section 423.562 to ensure that PDPs are required to share data with SPAPs, at no cost to SPAPs, to ensure coverage is coordinated to promote continuity of care.

Section 423.566 (pp. 46718-46721 of the preamble). Coverage determinations. A phase-in period for formulary denials by PDPs and MA-PD plans for new enrollees is needed. This would ensure that new enrollees don't first discover that they aren't covered for a drug when they have run out and are seeking a refill – leaving them no time to pursue a switch or to appeal. This is especially important for individuals taking multiple drugs who may discover that more

than one medication needs to be switched. Good clinical practice calls for not switching multiple drugs at once, but rather doing them one at a time, so that it is clear which drug is causing side effects, if any show up. An exception should automatically be granted any time an individual is running into more than one denial for non-formulary drugs. Otherwise, SPAPs and employer sponsored wrap-around plans will wind up paying for all of these denials.

Section 423.568(a). Standard timeframe and notice requirements for coverage determinations. The proposed rule allows PDPs up to 14 days to issue a decision on the request for an exception. This timeframe, however, is far too lengthy and is inconsistent with current industry practice as well as Medicaid standards. If adopted, this standard could put vulnerable populations, particularly those with chronic illnesses, at significant risk. PDPs should be required to render a decision on a request for an exception within 48 to 72 hours. While an exception request is pending, the beneficiary should receive the requested prescription (at a minimum, a 3-day supply if a 48-72 hour timeframe for PDP review of exception requests is adopted).

Section 423.578. Exceptions process. We have a number of recommendations regarding the proposed exceptions process. First, the final regulation must ensure that exceptions processes dovetail with SPAP prior authorization processes. Second, SPAPs must be allowed to be authorized representatives for the individual during the exception appeal. Third, while an exception is pending for dual eligibles, Medicare should pick up the full cost of the requested prescription until a decision is rendered so that states are not forced to pick up the costs as a potential Medicaid and SPAP continuity of care issue. This is particularly important because of restrictions on limiting Medicaid state plan services for the dual eligible population. Fourth, PDPs should be required to grandfather-in coverage of a deleted drug for anyone who was taking the medication prior to the deletion, unless the deletion is due to the new availability of a generic substitute or due to the FDA's removal of the drug from the market due to safety reasons. This should not be construed, however, as prohibiting a PDP from asking physicians to voluntarily switch their patients to less costly drugs as part of a therapeutic substitution initiative. Finally, we urge inclusion of language to guarantee access to lower co-pays when midyear increases are made by the PDPs.

Section 423.600 (p. 46722 of the preamble). Reconsideration by an Independent review entity (IRE). Connecticut supports the proposal for establishing an independent review entity for reconsideration of PDP redeterminations.

Sections 423.560 to 423.638. Grievances, Coverage Determinations, and Appeals. As an alternative to the dispute resolution framework presented in the proposed rule, we offer a potential retrospective dispute settlement framework. Under this alternative, a drug is authorized in favor of continuity of care while the dispute resolution process takes place. The system could be modeled after several Medicare demonstration programs operating in states dealing with home care coverage in the Medicare and Medicaid programs.

N. Medicare Contract Determinations and Appeals

No comments.

O. Intermediate Sanctions

No comments.

P. Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Section 423.772 (pp. 46725-46726 of the preamble). Definitions. *Family Size.* In addition to applicant and his/her spouse, the household includes "individuals who are related to the applicant or applicants…and who are dependent on the applicant or the applicant's spouse for at least one-half of their financial support." As the preamble indicates, this rule is dissimilar to the SSI as well as eligibility determination rules for Transitional Assistance under the current drug discount card program. By requiring the consideration of a household member other than a spouse, complexity is added to the process, increasing the administrative burden on states performing eligibility determinations for low income subsidy individuals. It is also very different than how eligibility is determined for our SPAP, and as such, it increases the administrative burden involved in wrapping around the Part D benefit. The rule should be changed to have greater consistency with existing government programs.

Section 423.772. Definitions. *Resources*. The proposed rule at Section 423.773 includes resource limits (also known commonly as "asset limits") for "full subsidy eligible" and "other low-income subsidy" eligible individuals. The definition for resources under Section 423.772 of "other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act" is problematic because it is vague. It is not clear how this 20-day liquidation rule should be interpreted. The regulation should provide a specific list of instruments and asset types that are excluded. For example, cash surrender value of life insurance should be totally excluded. Providing a clear list of excluded "non-liquid" resources will foster uniform eligibility determination and ease the administrative burden for SPAPs.

Section 423.772. Definitions. *Institutionalized individual.* (cross reference Section 423.782. Cost-sharing subsidy.) While institutionalized persons have no cost sharing for covered Part D drugs covered under their PDP or MA-PD plans, the definition of "institutionalized" is problematic. Individuals in residential care homes, group homes, etc. are vulnerable populations and their care is typically paid for or subsidized by states and the federal government. The imposition of cost-sharing on these individuals could have the unintended effect of encouraging institutionalization in order to provide prescription coverage under Part D. The incentive should be for the client to choose the community option, not the institutional option. Community settings such as residential care homes and group homes should be included in the definition of "institutionalized individual."

Section 423.782(a)(2)(ii) (p. 46729). Cost-sharing subsidy. *Full subsidy eligible individuals.* Consistent with the MMA statute, this section rules out any cost-sharing for institutionalized beneficiaries, although page 46729 of the preamble may not completely comport with the outlined section. The preamble refers to 1902(q)(1)(B) of the Social Security Act:

(B) In this subsection, the term "institutionalized individual or couple" means an individual or married couple—

(i) who is an inpatient (or who are inpatients) in a medical institution or nursing facility for which payments are made under this title throughout a month, and

(ii) who is or are determined to be eligible for medical assistance under the State plan.

It would appear that the SSA section above does define ICF/MRs as institutions, so those clients would not be subject to cost sharing. It is less clear whether individuals in 1915(c) waiver group homes, assisted living facilities, residential care homes, boarding homes and other such entities would be defined also as "medical institutions." For the reasons outlined in our comments on special needs populations (section 423.120), we strongly believe that all of these individuals need to be exempt from cost-sharing. Thus, the proposed rule should be clarified to include in the definition of "institutionalized beneficiary" all individuals in 1915(c) waiver group homes, assisted living facilities, residential care homes, boarding homes and other such therapeutic residential facilities.

Q. Guaranteeing Access to a Choice of Coverage (Qualifying Plans and Fallback Plans)

See our comments under Subpart J regarding nondiscrimination and use of preferred plans.

Section 423.855 (p. 46638 of the preamble). Definitions. *Eligible Fallback Entity or Fallback Entity*. If the fallback option must be implemented because not enough PDPs or MA-PD plans express interest in serving in a state, the definition of an eligible fallback entity should be modified so that an SPAP can serve as the fallback plan for SPAP clients (and all others would go to the Part D fallback provider).

R. Payments to Sponsors of Retiree Prescription Drug Plans

Section 423.884 (pp. 46741 – 46743 of the preamble). Requirements for qualified retiree prescription drug plans. *Definition of Actuarial Equivalence.* CMS' concern over windfalls, though justifiable, could drive sponsors from participating in the subsidy or worse yet drive them to drop their employer-sponsored drug coverage completely. CMS is so concerned that employers could impose the full cost of the benefit package on employees through employee premiums or contribute a smaller amount toward the financing of the package and still be eligible for subsidy, that they don't realize their proposed requirements to qualify for the subsidy are too stringent for most employers.

Three tests for actuarial equivalency have been proposed. Option 1 is the creditable coverage gross test or one prong approach. Option 2 proposes to limit the amount of the retiree drug subsidy so that it could not exceed the amount paid by plan sponsors on behalf of their retirees. Option 3 proposes a two- prong gross and net test that employers must satisfy. We do not support the proposals under Options 2 and 3 as they contradict the intent of the MMA to slow the decline in employer-sponsored retiree insurance. In addition, CMS stated in the preamble that, "we have questions about the adequacy of the legal basis" for the proposed policies in Options 2 and 3. If

a limit on the subsidy is imposed, there is no incentive for employers that offer a retiree drug benefit that exceeds the proposed Part D coverage to continue to provide high-quality prescription drug coverage to their Medicare eligible retirees. The two-prong approach under Option 3 places an undue burden on employers by requiring them to meet both tests in order to qualify for the subsidy. The unnecessary burden of meeting the net test may force employers to not apply for the subsidy, discontinue its coverage and make Medicare Part D the primary payer for its retiree drug costs.

For all these reasons stated above, we believe the gross test for actuarial equivalency proposed as Option 1 is more than sufficient. It meets the policy goal established by Congress in that it will minimize the administrative burdens on employers. By minimizing the administrative burdens, more employers will retain their sponsored drug coverage for its retirees and thereby fulfill two other goals of Congress to maximize the number of retirees retaining employer-sponsored drug coverage and minimize the costs to the government of providing retiree drug subsidies.

Section 423.888 (pp. 46745 – 46746 of the preamble). Payment methods, including provision of necessary information. *Plan Year versus Coverage Year Issues.* Cost threshold and cost limits are calculated for plan years that end in 2006 yet the subsidy amount for a qualifying covered retiree is based on coverage year (calendar year). Connecticut is a state that has a July 1 through June 30 plan year. As such we would encounter the situation identified where for the plan year July 1, 2006 through June 30, 2007, our actuarial attestation would be due on April 1, 2006. However, the cost threshold and cost limit for 2007 would most likely not be calculated. This is a major issue for employers. How can employers provide evidence of actuarial equivalency without knowing the cost limit and cost threshold that will be in place during the plan year? It is unreasonable and unrealistic to expect that this can be done.

A second aspect of this issue is specific to the first year of implementation. How should CMS handle plan years that begin in 2005 with respect to the subsidy payment? The options are to: 1) start counting gross costs for prescriptions filled after January 1, 2006; 2) determine a subsidy amount as if the sponsor were authorized to receive subsidy payments for the entire plan year and then prorate this amount based on the number of plan year months that fall in 2006; or 3) determine subsidy amounts on a monthly basis as if the sponsor were authorized to receive subsidy payments for the entire plan year but would then pay only the amounts for the plan year months that fall in 2006. Of the three options presented the preference is for either Option 1 or Option 3. Because our plan year begins July 1, 2005, the same results would be achieved under either scenario.

Section 423.888 (pp. 46746 – 46748 of the preamble). Payment methods, including provision of necessary information. *Payment Methodology.* The proposal is for CMS to make monthly payments with adjustments for over/under payments to subsequent periodic payments and a final reconciliation 45 days after the end of the calendar year. This requires plan sponsors to certify by the 15th of the following month the total amount by which actual drug spending exceeds the cost threshold and yet remains below the cost limit. CMS based this method on the assumption that plan sponsors use PBMs and PBMs routinely adjudicate claims on a real-time basis with very limited claims or payment lags. This may be true, but what does a sponsor do if it can't get the data in a timely fashion from the plan? The State of Connecticut utilizes the services of one PBM

for the collection of prescription claims data for all employees, including retirees. The prescription benefits are on a fully insured basis with employees contributing a set dollar amount for a co-payment. The state has encountered problems with respect to receiving timely information from the PBM. The expectation to require sponsors to certify the prior month's amounts by the 15th is idealistic and is a goal that the state would be unlikely to meet. A more realistic goal would be to allow sponsors to certify within the range of 45 – 60 days after the end of the month.

Section 423.888 (p. 46748 of the preamble). Payment methods, including provision of necessary information. *Data Collection*. Of the options proposed, we recommend the first option that requires the sponsor (or group health plan designated by the sponsor) to submit the aggregate total of all allowable drug costs of all of the qualifying covered retirees in the plan for the time period in question. This choice does not place excessive burdens on the employer and is the most protective of the retiree's privacy. CMS states that this option may be the most problematic in terms of assuring the accuracy of the subsidy payment but we disagree. Even though the aggregate cost submitted to CMS would not be broken down to each qualifying retiree, the sponsor (or group health plan) must maintain the claims data to support and verify its submission for audit purposes for at least six years after the end of the plan year.

The remaining options require a sponsor (or group health plan) to submit the aggregate allowable costs for each qualifying covered retiree. Even if this data is required for only the first two years as proposed in one option, there are still privacy issues. Therefore the remaining options are not recommended as they impinge on a retiree's privacy. This infringement is to the point where the submission of costs broken down to each retiree does not appear to comply with the government's own HIPAA requirements.

S. Special Rules for States—Eligibility Determinations for Low-Income Subsidies, and General Payment Provisions

Section 423.904 (p. 46751 of the preamble). Eligibility determinations for low-income subsidies. (See also Section 423.744 (p. 46727 of the preamble)). We request clarification of the language on page 46751 of the preamble regarding eligibility determinations for low-income subsidies being conducted "consistent with the manner and frequency" that Medicaid determinations and redeterminations are conducted. While Section 1860D-14(a)(3) of the Act and the proposed rule at Section 423.774(a) say that eligibility determinations for low-income subsidies are made "by the State under its State plan under title XIX if the individual applies with the Medicaid agency," this is inconsistent with the language on page 46751 of the preamble. Also, if a state were to consider using a contractor for the eligibility determination and redetermination process, we would want costs associated with the contractor to be eligible for FFP.

The state is seeking clarification as to whether CMS would approve a State Plan Amendment that eliminates prescription drugs as a covered benefit for full duals (because of the availability of the Part D benefit), without violating equal amount, scope and duration requirements. In other words, can states limit pharmaceutical coverage in Medicaid to non-duals? Without this ability, states will be faced with providing prescription drug coverage for dual eligible Medicaid

recipients who decline enrollment or disenroll at 100% state cost. If CMS will not approve such an amendment, the state will be open to coverage at 100% state cost of Part D non-formulary drugs pending the outcome of an appeal.

Section 423.906(a) (p. 46751 of the preamble). General payment provisions. *Regular Federal matching*. The proposed rule indicates that states could receive the regular federal match for administrative costs in determining subsidy eligibility and for notification. However, the preamble also indicates that states would be responsible for periodic redeterminations. We therefore believe that the rule should be modified to clarify that FFP for redeterminations is permitted.

In addition, ongoing financial support should be provided for states' operational and administrative costs once transitional grants end in/after FFY 06. Specifically, in addition to the provision that allows states to gain federal financial participation on their administrative costs associated with determining a dual eligible's subsidy, states and SPAPs should be eligible to count the following as eligible reimbursement costs in the Medicaid program: costs of enrolling dual eligibles in the Part D program; enrollment and eligibility costs of SPAP recipients in the part D program; and all administrative costs associated with administering a wraparound for both dual eligible and SPAP recipients.

Section 423.910. Requirements. If Connecticut determines that it is in their best interest – from both a financial and continuity of care standpoint – to run their own prescription drug program for their dual eligibles at 100% state cost (e.g., through our SPAP), can we waive the auto-enrollment process for dual eligibles? It appears that under this scenario, the state would not be subject to the phase-down state contributions provisions.

Section 423.910(b)(1) (p. 46752 of the preamble). Requirements. *State contribution payment. Calculation of payment*. The 2003 base year is artificially high because it fails to account for changes in utilization and pricing that were implemented through Connecticut law to bring down pharmacy costs in the Medicaid program for dual eligibles (e.g., MAC pricing, prior authorization, generic substitution, dispensing fee changes, preferred drug list and supplemental rebates). We believe that the law (Section 1935(b), page 2157 of MMA) gives the Secretary the discretion to make adjustments to the 2003 base. In determining the gross per capita Medicaid expenditures for prescription drugs, the Secretary shall "use data from the Medicaid Statistical Information System (MSIS) and other available data" (emphasis added). We believe the Secretary could use actuarial analyses or other data to evaluate the changes to state drug expenditures (as described above) to consider adjustments to the 2003 baseline. We ask that you consider this and adjust the proposed rule accordingly.

Section 423.910(b)(2) (p. 46752 of the preamble). Requirements. *State contribution payment. Method of payment.* The rule specifies that state payments for the "phased-down state contribution" would be made in a manner similar to the mechanism by which states pay Medicare Part B premiums for dual eligibles. If Connecticut can make its contribution in the same manner as we are currently doing for our dual eligibles, this methodology is acceptable. If the Secretary were to require that we submit a check or make an electronic transfer payment,

there would be significant implications for Connecticut's constitutional and statutory expenditure cap.

T. Part D Provisions Affecting Physician Self-Referral, Cost-Based HMO, PACE, and Medigap Requirements

No comments.

CMS-4068-P-1260

Submitter : Ms. c c **Date & Time:** 10/04/2004 08:10:46

Organization : c

Category : Individual

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

lkjkl kjllkj lkjlkj lkjlkjlkj

Submitter : Dr. Paul Wettengel **Date & Time:** 10/04/2004 08:10:00

Organization : FirstChoice Healthcare

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Thank you for your attention to this matter.

CMS-4068-P-1261-Attach-1.rtf

To CMS Officials,

FirstChoice Healthcare is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

FirstChoice Healthcare is licensed to provide home health care nursing, palliative care and I.V. therapy services in 25 Central and Eastern Nebraska counties as well as a wide geographic area in Western Iowa. Approximately 20% of referred infusion therapy patients return home to their local community to finish their prescribed intravenous regimen.

As FirstChoice Healthcare provides a complete range of intravenous therapies, enteral therapies, home health services and palliative care services, demographics are quite diverse: pediatric, adult, geriatric, surgical oncology, AIDS, infectious diseases, OB/GYN, the terminally ill, cardiology, immuno-compromised, pulmonary, and the solid organ and bone marrow transplantation population.

FirstChoice Healthcare appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD

community, his new coverage under Part B *has not resulted in additional access to home IVIG under Medicare.* We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm .

CMS should establish **specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies** to ensure adequate enrollee access to home infusion therapy under Part D.

CMS should require **specific standards for home infusion pharmacies** under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

CMS should adopt the **X12N 837 P billing format** for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

CMS should **mandate that prescription drug plans maintain open formularies for infusion drugs** to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Paul J. Wettengel, PharmD
President/CEO
FirstChoice Healthcare
8710 F Street, Suite 118
Omaha, NE 68127-1532

CMS-4068-P-1262

Submitter : Mr. Randall Binning **Date & Time:** 10/04/2004 08:10:38

Organization : Mr. Randall Binning

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS,

I write this comment in hopes that you will consider the role pharmacists can play in the improvement of healthcare given to the clients covered by medicare and medicaid.

Pharmacists are in an important position to manage medication therapy for patients who need to take chronic medications. Pharmacists are highly accessible, as well as most patients pick up medications monthly.

Currently pharmacists get paid to dispense medications regardless of the amount of time or information that is given to the patient. FOr the most part there is little incentive for pharmacists to make sure patients are using their medications properly. If pharmacists are given reimbursement for their services, patients with chronic conditions could be monitored on a monthly, or some other regular basis that would improve the medication therapy.

In the new CMS bill, I believe there needs to be a definition of what pharmacy management of medication therapy is and it must not be left up to the pharmacy benefit managers (PBM) to determine what this reimbursement is.

This medication management is already in place but could be vastly improved if reimbursement for it was appropriate.

It is also important that all pharmacists would be elligible to receive reimbursement if medication therapy management is given. Please do not allow the PBMs to dictate which pharmacist can give the management.

In closing, pharmacies can be an integral component of the new Medicare benefit. Medicare recipients often rely on their pharmacist for advice and counsel. Pharmacists will be able to assist in making this new benefit successful or they will speak out against it. Medicare must make specific requirements of the plan sponsors otherwise many of the nation?s foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacists must be allowed to participate equally and fully. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program.

Thank you for your consideration.

Sincerly,

Randall Binning PharmD (graduated 2004)
Pharmacy Resident

CMS-4068-P-1263

Submitter : Mr. John Bynon **Date & Time:** 10/04/2004 08:10:48

Organization : TVA Retirees Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attached letter.

CMS-4068-P-1263-Attach-1.doc

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8014

Re: File Code CMS-4068-P
Comments to Proposed Rules for Medicare Prescription Drug Benefit

Dear Sir or Madam:

The following are the comments of the Tennessee Valley Authority Retirees Association on the proposed rules to implement the new Medicare Prescription Drug Benefit. We appreciate the opportunity to provide comments on these important issues.

The TVA Retirees Association seeks to represent the views of retirees of TVA, who are not eligible for coverage in the Federal Employees Health Benefits Program, but who instead are covered by medical plans sponsored by TVA.

For the most part, TVA retirees pay for their TVA-sponsored retiree medical benefits out of a TVA-funded pension supplement provided by the TVA Retirement System and not directly by TVA. This unique way of providing employer assistance for retiree medical benefits was adopted in part to assure that retirees would continue to receive an employer-funded vested benefit, which the retirees could choose to use for the retiree medical benefits of their choice.

According to the proposed rules, employers will have several options available to them, one of which is to continue to sponsor retiree prescription drug coverage that is actuarially equivalent to Medicare Part D benefits while accepting a retiree drug subsidy (the "Primary Coverage Option"). It is our understanding that CMS is leaning toward the "two-prong" test for determining actuarial equivalence. Based on the unique way in which a portion of the TVA plan premiums may be paid with the use of retiree pension subsidies, TVA is concerned that the TVA plan may not satisfy the second "net value" prong as currently proposed. In light of the Medicare Part D program, the inability to qualify for the Primary Coverage Option would be a disincentive to TVA to continue providing the TVA plan as primary coverage to its Medicare-eligible retirees. Such a result would be contrary to CMS's express goals of maximizing the number of retirees retaining employer-based drug coverage while minimizing the administrative burdens on beneficiaries and employers.

The TVA Retirees Association supports adoption of a final rule which would give TVA the flexibility to adopt the Primary Coverage Option if such an option is desired by and beneficial to TVA's Medicare-eligible retirees and achieves CMS's goals with respect to employer-based drug coverage. We request that CMS draft the final rules to allow employers like TVA, which have retiree drug plans with benefits at least as equivalent to the Part D benefit but which are financed in unique ways such as with pension subsidies, to satisfy the actuarial equivalence test

or to provide the flexibility to work with CMS in order to qualify for the Primary Coverage Option.

Sincerely,

John S. Bynon, Sr.
Chairman, Insurance Committee
TVA Retirees Association
224 West Hills Road
Knoxville, TN 37909

CMS-4068-P-1264

Submitter : Mr. Timothy Schuerch **Date & Time:** 10/04/2004 08:10:51

Organization : Alaska Native Tribal Health Consortium

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please find enclosed MS Word document containing comments applicable to a number of provisions of the proposed Part D regulations; dd

CMS-4068-P-1264-Attach-1.doc

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM
Administrative Offices 4141 Ambassador Drive
Anchorage, Alaska 99508
Telephone: 907-729-1900
Facsimile: 907-729-1901

FILE CODE: CMS-4068-P

Comments To Proposed Medicare Part D Regulations

I. INTRODUCTION: The Alaska Native Tribal Health Consortium

The Alaska Native Tribal Health Consortium (ANTHC) is the largest privately operated Indian health program in America, managing over $125 million annually in IHS program and project funds, and with total revenues in excess of $300 million per year, all of which is devoted exclusively to providing health services to Alaska's 100,000+ Alaska Natives.

We are organized under the Alaska Non-profit Code, and enjoy tax-exempt status under Section 501(c)(3) of the Internal Revenue Code. Our three primary sources of revenue are (1) compacted IHS funds; (2) third party reimbursements, including private insurance, Medicare and Medicaid; and (3) federal grant funds. Our vision is *"a unified Native health system, working with our people, achieving the highest health status in the world."*

Pursuant to our charitable public health mission, we employ over 1,600 staff, including over 600 Indian Health Service (IHS) employees assigned to us under the Intergovernmental Personnel Act (IPA), and over 100 Commissioned Officers of the Public Health Service assigned to us under 42 USC 2004b in accord with 42 USC 215(d).

Our services encompass the Alaska Native Medical Center (ANMC), a JCAHO-accredited 150-bed acute care hospital in Anchorage, which we operate in cooperation with the Southcentral Foundation under the authority of Section 325 of P.L 105-83.

The ANMC Pharmacy is a large I/T/U pharmacy providing an array of services to our customer-owners, including Medicaid covered services, Medicare Part A covered services, Medicare Part B covered services, and Medicare Part D covered services. The ANMC Pharmacy serves many thousands of Medicare Part D eligible AI/AN, a significant percentage of which are subsidy eligible AI/AN.

Thus the treatment of AI/AN under the Medicare Part D regulations, especially AI/AN receiving services from I/T/U pharmacies, will have a significant impact on our third party reimbursements, which we heavily rely upon to support the provision of services to our AI/AN customer-owners.

II. KEY POLICY CONSIDERATIONS

(1) Aligning Part D regulations, as permitted by statute, with the Departmental AI/AN policy goal of narrowing the American Indian/Alaska Native health disparities gap, e.g., by lowering AI/AN barriers to access to pharmacy services.

(2) Consistent with Departmental AI/AN policy goals, and as permitted by statute, maximizing participation of Part D eligible AI/AN in the Part D program by ensuring that AI/AN, and the I/T/U pharmacies serving AI/AN, are consistently and uniformly treated in a manner that reflects Departmental AI/AN policy goals.

(3) Consistent with Departmental AI/AN policy goals, and as permitted by statute, maximizing participation of Part D eligible AI/AN by tailoring the regulations to prospectively avoid Secretarial findings for AI/AN under 42 USC 1860D-11(e)(2)(D)(i), with regard to any PDP, that "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan."

(4) Consistent with Departmental AI/AN policy goals, and as permitted by statute, mitigating the financial burden on I/T/U pharmacies and States resulting from transition of payment for Part D covered services for subsidy eligible AI/AN from 100% FMAP-paid State agencies to the Medicare Part D system, which allocates costs for subsidy eligible AI/AN between I/T/U pharmacies, CMS and States.

(5) Consistent with Departmental AI/AN policy goals, and as permitted by statute, avoiding penalization of I/T/U pharmacies for providing services to AI/AN on an IHS-prepaid basis, without charge to the patient (per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)).

III. COMMENTS

SUBPART A—GENERAL PROVISIONS

(NO COMMENTS)

SUBPART B—ELIGIBILITY AND ENROLLMENT

COMMENT WITH REGARD TO THE SUBPART AS A WHOLE: In order to ensure maximum participation of AI/AN in Part D; in order to ensure that the Part D regulations treat AI/AN and the national network of I/T/U pharmacies serving AI/AN in a uniform manner that is consistent with Departmental AI/AN policy goals; and in order to minimize the likelihood of Secretarial findings for AI/AN under 42 USC 1860D-11(e)(2)(D)(i), with regard to any PDP or MA-PD, that, "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan," **ANTHC feels the Secretary should consider amending the provisions of Subpart B of the proposed regulations to reflect the following comprehensive statutory approach to access and enrollment of AI/AN in PDPs and MA-PDs:**

(1) The Secretary should exercise his statutory discretion under 42 USC §1860D-1(b) and 42 USC §1395w-21(b)(1)(A) to waive, in the case of AI/AN, the requirement that Part D eligible individuals may only enroll in a plan that encompasses that PDP's or MA-PD's geographic region;

(2) Through the bidding and approval processes of 42 USC §1860D-11 (PDPs) and §1854(a) (MA-PDs), the Secretary should establish a small number of PDPs and/or MA-PDs that, in addition to providing coverage for all Part D eligible individuals in their respective PDP or MA-PD area(s) who choose to enroll in that plan, would also provides coverage for AI/AN on a national basis for all Part D eligible AI/AN who choose to enroll in each such plan, as permitted by 42 USC §1860D-11(a)(3).

(3) In preparation for PDP and MA-PD bidding processes, the Secretary should develop and publicize, in close consultation with the CMS Tribal Technical Advisory Group (CMS TTAG), an **AI/AN supplemental information packet**. The packet would solicit PDP sponsors and MA-PD organizations to consider including in their bids one or more plans that would provide coverage for Part D eligible AI/AN on a national basis. It would contain information on Part D eligible AI/AN and the national network of I/T/U pharmacies serving AI/AN, in sufficient detail to allow bidders to fairly assess whether they should include in their bids the information required under 42 USC §1860D-11(b)(2), with regard to any plan(s) in the bid proposing to provide coverage for Part D eligible AI/AN on a national basis. The packet would also set forth any "additional information" that the Secretary (in close consultation with the CMS TTAG) would require to be included in bids containing one or more plans to provide national coverage to Part D eligible AI/AN, as permitted under 42 USC §1860D-11(b)(2)(F). Specific types

of information that the Secretary might consider including in the **AI/AN supplemental information packet** might include general information on AI/AN and AI/AN health issues, as carefully and compellingly set forth in **the National Indian Health Board comments to these regulations.** Consideration should also be given to describing in detail the national network of I/T/U pharmacies serving AI/AN, including:

- who they serve (AI/AN, per 25 USC §1680c);
- the basis on which services are provided (IHS-prepaid without charge to the AI/AN);
- where they are located (in I/T/U facilities near the AI/AN served);
- the way they buy drugs (FSS or 340B programs);
- the way they dispense drugs (with much more patient consultation than in the private sector due to the high risk of culture and/or language barriers impeding instructions);
- the information system used track drug and reimbursement information (RPMS);
- the charitable mission served (providing pharmacy services to a population group and in geographic areas characterized by failure of competitive market dynamics); and
- the way Medicare reimbursements are processed (via a nationally centralized system).

(4) In reviewing and negotiating bids (under 42 USC §1860D-11(d)) that contain one or more plans proposing to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such review and negotiation is conducted in a manner consistent with Departmental AI/AN policy goals.

(5) In approving or disapproving any plan (under 42 USC §1860D-11(e)) that proposes to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such approval or disapproval is made in a manner consistent with Departmental AI/AN policy goals, especially with regard to the requirement of 42 USC §1860D-11(e)(2)(D) that the Secretary approve a plan only if he "does not find that the design of the plan and its benefits (including any formulary or tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan."

(6) The Secretary has already successfully adopted a centralized national model similar to that proposed above for processing Medicare Part A and Part B payments to I/T/U facilities, through the use of a single Carrier for I/T/U providers nationwide. With I/T/U facilities already possessing the capacity to be reimbursed for Part A-covered drugs, and on the verge of gaining the capacity to be reimbursed for Medicare Part B-covered drugs and biologicals under §630 of the MMA, the Secretary may wish to consider the efficiencies and improved coordination of benefits in the administration of the various Medicare drug programs as they apply to I/T/U providers that would likely result from adopting a similarly centralized, national system for processing Part D drug benefit payments to I/T/U facilities. For example, Trailblazer LLC has done a fair job of coordinating Part A and Part B payments to I/T/U facilities since the passage of the BIPA. Organizations like Trailblazer might prove to be efficient and effective sponsors of

PDP or MA-PD plans providing Part D coverage to Part D eligible AI/AN on a national basis.

(Additional Comments to SUBPART B, ELIGIBILITY AND ENROLLMENT):

42 CFR 423.44 DISENROLLMENT BY THE PDP

COMMENT: Because I/T/U pharmacies provide services to AI/AN on an IHS-prepaid basis without charge to the AI/AN, per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)), the financial burden of disenrollment of a Part D eligible AI/AN receiving services from an I/T/U pharmacy will fall squarely on the I/T/U pharmacy, rather than the AI/AN. Moreover, the cost and expense of reenrollment of the Part D eligible, including payment of some or all of the premiums that may be owing, will also fall on the I/T/U pharmacy. Thus ANTHC feels the Secretary should consider adding a new subsection to 42 CFR 423.44 to clarify that in the case AI/AN, the Secretary reserves the discretion to waive or amend the disenrollment and reenrollment provisions of the section.

42 CFR 423.48 INFORMATION ABOUT PART D

COMMENT: This section requires each PDP and MA-PD plan to provide to CMS on an annual basis "the information necessary to enable CMS to provide current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage." For PDP or MA-PD plans providing coverage for Part D eligible AI/AN on a national basis, the Secretary should require this information to also be provided to the CMS TTAG and the IHS for distribution to AI/AN through the national network of I/T/U pharmacies.

42 CFR 423.50 APPROVAL OF MARKETING MATERIALS AND ENROLLMENT FORMS

COMMENT: CMS should consult closely with the CMS TTAG and the IHS in carrying out its review and approval of the marketing materials and enrollment forms of PDP and MA-PD plans providing coverage for Part D eligible AI/AN on a national basis.

42 CFR 423.56 PROCEDURES TO DETERMINE AND DOCUMENT CREDITABLE STATUS OF PRESCRIPTION DRUG COVERAGE

COMMENT: Subsection (a)(9) properly includes as creditable prescription drug coverage "coverage provided by the medical care program of the IHS, Tribe or tribal organization, or urban Indian organization (I/T/U)." However, we feel there are significant administrative burdens and inefficiencies with the approach of the proposed regulations to require, before coverage provided by I/T/U providers may be considered creditable prescription drug coverage, that coverage provided by I/T/U providers must meet the general requirement of subsection (a) that "the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles…." Because I/T/U pharmacies uniformly provide services to AI/AN on an IHS-

prepaid basis, without charge to the AI/AN, and uniformly only scale back services as a last resort when funding falls short, it is highly likely that coverage provided by I/T/U providers will nearly always equal or exceed the actuarial value of standard Medicare Part D prescription drug coverage. And, in those few instances when it may not, it will likely nearly always be because program funding was inadequate, in which case the I/T/U provider providing coverage would especially not be in no position to divert scarce resources away from direct services in order to pay for expensive actuarial analyses. Thus we believe significant public health policy interests weigh in favor of amending this section to waive the actuarial equivalence requirements in the case of coverage provided by I/T/U providers.

SUBPART C—BENEFITS AND BENEFICIARY PROTECTIONS

42 CFR 423.100 DEFINITIONS

Definitions of "INCURRED COSTS" and "INSURANCE OR OTHERWISE:

COMMENT: A bona fide question of statutory interpretation exists with regard to whether (1) amounts up to the annual deductible limit paid by an I/T/U pharmacy on behalf of non-subsidy eligible AI/AN, (2) cost-sharing expenses above the annual deductible limit up to the initial coverage limit waived or absorbed an I/T/U pharmacy on behalf of a non-subsidy eligible AI/AN, and (3) amounts exceeding the initial coverage limit paid by an I/T/U pharmacy on behalf of a non-subsidy eligible AI/AN, should be treated as *"incurred costs"* under 42 USC §1860D-2(b)(4)(C)(ii), and thus be counted by CMS towards the non-subsidy eligible AI/AN Part D enrollee's annual out-of-pocket threshold, which in 2006 will be $3,600.

It is fairly clear that under the preceding subsection at 42 USC §1860D-2(b)(4)(C)(i), all three of these cost categories must be treated consistently, i.e., either all three are "incurred costs" in cases where an I/T/U pharmacy pays or waives them on behalf of a non-subsidy eligible Part D AI/AN enrollee, and thus counted towards the AI/AN's annual out-of-pocket threshold, or all three are "insurance or otherwise," and not counted towards the AI/AN's out-of-pocket threshold.

Given his statutory discretion in this matter, the Secretary may wish to consider the likely, reasonably foreseeable outcomes of the latter, more restrictive of the two interpretations, and determine whether those outcomes are consistent with Departmental AI/AN policy goals.

If in 2006, an I/T/U pharmacy were to provide services to a non-subsidy eligible AI/AN Part D enrollee on an IHS-prepaid basis, without charge to the AI/AN, per its charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)), it would likely want to calculate the costs vs. benefits of paying the $250 deductible on behalf of the AI/AN.

If the AI/AN were to use up $1,250 worth of covered drug benefit in the year, then the I/T/U pharmacy might well decide to pay the $250 deductible, because after it was paid, the PDP or MA-PD would pay 75% of the remaining $1,000 ($750) with the I/T/U pharmacy paying the

remaining 25% ($250). In other words, between the deductible payment and its 25% cost-sharing obligation, the I/T/U pharmacy would pay or waive a total of $500 on behalf of the AI/AN, in return for which it would receive $750 from the PDP or MA-PD, or 60% of the AI/AN's total covered drug costs for the year.

If the AI/AN were to use up $2,250 worth of covered drug benefit in the year, topping out but not exceeding the initial coverage limit for the AI/AN in the year, then the I/T/U pharmacy would get a slightly better deal: it would pay $250 for the deductible, plus waive 25% of the remaining $2,000, for a total cost of $750. In return, it would receive from the PDP or MA-PD 75% of the $2,000 of drug costs in excess of the deductible, or $1,500, or 66.67% of the AI/AN/s total covered Part D drug costs for the year.

If the AI/AN were to use up $3,250 worth of covered drug benefit in the year, then the I/T/U pharmacy's benefit received from the PDP or MA-PD, as a percentage of payment for the AI/AN's total costs for covered Part D drugs for the year, would fall significantly: The I/T/U pharmacy would pay $250 for the deductible ($250), plus bear the cost of waiving the 25% cost-share for next $2,000 worth of covered drug benefit usage ($500), plus bear 100% of the cost of the remaining $1,000, because that is the amount by which the AI/AN's covered drug benefit costs for the year exceed his/her initial coverage limit ($1,000), for a total cost to the I/T/U pharmacy of $1,750, in return for which it would receive from the PDP or MA-PD 75% of the $2,000 ($1,500) of covered drug costs exceeding the deductible amount but less than the initial coverage limit, or 46.15%.

And, to the degree the AI/AN were to use up ever higher amounts of covered drug benefit in the year, the I/T/U pharmacy's benefit received from the PDP or MA-PD, expressed as a percentage of payment for the AI/AN's total costs for covered Part D drugs for the year, would continue to decline ad infinitum, since neither the deductible amounts paid by the I/T/U pharmacy, nor the cost-sharing amounts waived by the I/T/U pharmacy, nor the payment by the I/T/U pharmacy on behalf of the AI/AN of costs in excess of the initial coverage limit would be counted as "incurred costs" for purposes of calculating when that AI/AN's out-of-pocket threshold for that year. In other words, the out-of-pocket threshold amount for that year for that AI/AN would never be reached, nor could the out-of-pocket threshold ever be reached in any year for non-subsidy eligible AI/AN Part D enrollees.

Thus the reasonably foreseeable net effect of treating I/T/U pharmacy payment and waiver amounts as "insurance or otherwise," and not as "incurred costs," is a modest benefit if the AI/AN uses up no more than a few thousand dollars per year in covered Part D drug benefit, but a complete absence of any additional benefit for amounts exceeding the initial coverage limit, which in 2006 will be $2,250. The stop-gap benefits that would normally come into play for amounts of the covered Part D drug benefits in excess of the annual out-of-pocket limit, $3,600 in 2006, would be completely eliminated. In other words, with regard to the significant stop-gap benefits that would otherwise be available to non-AI/AN non-subsidy eligible Part D enrollees, AI/AN non-subsidy eligible Part D enrollees, and the I/T/U pharmacies that serve them, are severely penalized precisely because the I/T/U pharmacy providing services to that AI/AN does

so on an IHS-prepaid basis, without charge to the patient (per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)). **In other words, the proposed regulations, as written, subject AI/AN and the I/T/U pharmacies that serve AI/AN to severe financial penalties in comparison to non-AI/AN and non-I/T/U pharmacies precisely for doing nothing more than fulfilling their public health mission and carrying out the Departmental policy objective of narrowing the AI/AN health disparities gap via, e.g., lowering AI/AN barriers to access to pharmacy services.**

We also agree with and incorporate by reference into these comments the excellent, well-thought-out public health policy discussion regarding these definitions in **the National Indian Health Board comments** to the definitions of "incurred costs" and "insurance or otherwise" in 42 CFR 423.100 of the proposed regulations.

42 CFR 423.100 DEFINITIONS (continued)

Definition of "Network Pharmacy:"

COMMENT: ANTHC feels consideration should be given to amending this definition, or otherwise clarifying in regulation, policy, PDP or MA-PD contract, and/or in "additional information" the Secretary might require of certain plans in their bid documents, that PDP or MA-PD plans that provide coverage for Part D eligible AI/AN on a national basis be required to include as "network pharmacies" all pharmacies in the national I/T/U pharmacy network.

Definition of "Person:"

COMMENT: ANTHC strongly urges the Secretary to amend this definition by adding an additional sentence that affirmatively assures the inclusion of all I/T/U pharmacies, regardless of whether operated by the IHS, a Tribe or tribal organization, or an urban Indian organization. The significance of this definition is that it would clarify that costs paid or waived by I/T/U pharmacies on behalf of AI/AN are "incurred costs" for purposes of calculating the annual out-of-pocket limit for all AI/AN Part D enrollees under 42 USC §1860D-2(b)(4)(B)(ii), including non-subsidy eligible AI/AN.

Definition of "Preferred Pharmacy:"

COMMENT: ANTHC feels consideration should be given to amending this definition, or otherwise clarifying in regulation, policy, PDP or MA-PD contract, and/or in "additional information" the Secretary might require of certain plans in their bid documents, that PDP or MA-PD plans that provide coverage for Part D eligible AI/AN on a national basis be required to treat all I/T/U pharmacies as "preferred pharmacies."

42 CFR 423.112 ESTABLISHMENT OF PRESCRIPTION DRUG PLAN SERVICE AREAS

(NO COMMENTS)

42 CFR 423.120 ACCESS TO COVERED PART D DRUGS

Subsections (a)(1) and (3):

COMMENT: We feel consideration should be given to creating an additional waiver under subsection (a)(3) of the pharmacy access requirements of subsection (a)(1) in the case of the national I/T/U pharmacy network. The national I/T/U pharmacy network has been established by the IHS, Tribes and tribal organizations, and urban Indian organizations for the express purpose of maximizing AI/AN pharmacy access within the constraints of the limited resources available to I/T/U pharmacies. To impose the generally applicable access requirements of (a)(1) on I/T/U pharmacies would be inequitable, costly, and have the effect of penalizing the more remote and underfunded I/T/U pharmacies by creating incentives for PDP and MA-PD plans to de-select them and otherwise attempt to exclude them from their respective networks. In other words, it is precisely because I/T/U pharmacies tend to serve populations and geographic areas characterized by failure that what would normally be generally applicable market assumptions implicit in subsection (a)(1) would not hold true. Again, without such a waiver, PDPs and MA-PDs will in many cases avoid dealing with I/T/U pharmacies, which in turn will result in sub-optimized participation of AI/AN, particularly those in remote or impoverished areas, in the Medicare Part D benefit, contrary to Departmental AI/AN policy goals.

Subsection (a)(5), Discounts for Preferred Pharmacies:

COMMENT: We feel consideration should be given to amending this subsection to clarify that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis must treat all I/T/U pharmacies as "preferred pharmacies," to ensure that in all cases, I/T/U pharmacies will receive the best negotiated PDP or MA-PD reimbursement available, assuring that IHS-funded I/T/U pharmacies, and thus taxpayers, will in all cases be able to take advantage of the financial benefits of the MMA's competition-assurance provisions, as well as assuring that the Department policy goal of narrowing the AI/AN health disparities via lowering AI/AN barriers to access to pharmacy services is well-served.

Subsection (b)(1), Formulary Requirements—Development and Revision By a Pharmacy and Therapeutic Committee:

COMMENT: This provision requires that a PDP sponsor's or MA organization's formulary "must be reviewed by a pharmacy and therapeutic committee" that meets certain requirements. We feel consideration should be given to amending this subsection to require that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis must include on their respective pharmacy and therapeutic committees at least one pharmacist or physician selected by the IHS; at least one pharmacist or

physician selected by Tribes and tribal health organizations; and at least one pharmacist or physician selected by urban Indian organizations.

Subsections (b)(4), (5), and (7), Periodic Evaluation of Protocols; Provisions of Notice Regarding Formulary Changes; Provider and Patient Education:

COMMENT: We feel consideration should be given to clarifying in the regulatory language or in Secretarial policy that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis be required to engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies in the protocol evaluation requirement of subsection (b)(4); the provisions of notice regarding formulary changes requirement of subsection (b)(5); and the provider and patient education requirement of (b)(7).

Subsection (c) Use of Standardized Technology:

COMMENT: We feel consideration should be given to clarifying in the regulatory language or in Secretarial policy that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis be required to engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies in the technology standardization requirements of this subsection.

42 CFR 423.128 DISSEMINATION OF PLAN INFORMATION

COMMENT: We feel consideration should be given to clarifying in the regulatory language or in Secretarial policy that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis be required to engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies regarding the plan information dissemination requirements of this section.

42 CFR 423.132. PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS

COMMENT: We strongly urge the Secretary to consider amending this section to provide an exception from this requirement in the case of I/T/U pharmacies. I/T/U pharmacies provide services to AI/AN on an IHS-prepaid basis, without charge to the patient, per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)). Thus it is the I/T/U pharmacies, and not the AI/AN receiving services, that bear the cost of PDP or MA-PD formulary choices, obviating the need for AI/AN receiving services from I/T/U pharmacies to have such price-comparison information.

SUBPART D: …

(NO COMMENTS)

SUBPART F: SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL

COMMENT: COMMENT WITH REGARD TO THE SUBPART AS A WHOLE: In order to ensure maximum participation of AI/AN in Part D; in order to ensure that the Part D regulations treat AI/AN and the national network of I/T/U pharmacies serving AI/AN in a uniform manner that is consistent with Departmental AI/AN policy goals; and in order to minimize the likelihood of Secretarial findings for AI/AN under 42 USC 1860D-11(e)(2)(D)(i), with regard to any PDP or MA-PD, that, "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan," **ANTHC feels the Secretary should consider amending the provisions of Subpart F of the proposed regulations to reflect the following comprehensive statutory approach to access and enrollment of AI/AN in PDPs and MA-PDs:**

(7) The Secretary should exercise his statutory discretion under 42 USC §1860D-1(b) and 42 USC §1395w-21(b)(1)(A) to waive, in the case of AI/AN, the requirement that Part D eligible individuals may only enroll in a plan that encompasses that PDP's or MA-PD's geographic region;

(8) Through the bidding and approval processes of 42 USC §1860D-11 (PDPs) and §1854(a) (MA-PDs), the Secretary should establish a small number of PDPs and/or MA-PDs that, in addition to providing coverage for all Part D eligible individuals in their respective PDP or MA-PD area(s) who choose to enroll in that plan, would also provides coverage for AI/AN on a national basis for all Part D eligible AI/AN who choose to enroll in each such plan, as permitted by 42 USC §1860D-11(a)(3).

(9) In preparation for PDP and MA-PD bidding processes, the Secretary should develop and publicize, in close consultation with the CMS Tribal Technical Advisory Group (CMS TTAG), an **AI/AN supplemental information packet**. The packet would solicit PDP sponsors and MA-PD organizations to consider including in their bids one or more plans that would provide coverage for Part D eligible AI/AN on a national basis. It would contain information on Part D eligible AI/AN and the national network of I/T/U pharmacies serving AI/AN, in sufficient detail to allow bidders to fairly assess whether they should include in their bids the information required under 42 USC §1860D-11(b)(2), with regard to any plan(s) in the bid proposing to provide coverage for Part D eligible AI/AN on a national basis. The packet would also set forth any "additional information" that the Secretary (in close consultation with the CMS TTAG) would require to be included in bids containing one or more plans to provide national coverage to Part D eligible AI/AN, as permitted under 42 USC §1860D-11(b)(2)(F). Specific types of information that the Secretary might consider including in the **AI/AN supplemental information packet** might include general information on AI/AN and AI/AN health issues, as carefully and compellingly set forth in **the National Indian Health Board comments to these regulations.** Consideration should also be given to describing in detail the national network of I/T/U pharmacies serving AI/AN, including:

- who they serve (AI/AN, per 25 USC §1680c);
- the basis on which services are provided (IHS-prepaid without charge to the AI/AN);
- where they are located (in I/T/U facilities near the AI/AN served);
- the way they buy drugs (FSS or 340B programs);
- the way they dispense drugs (with much more patient consultation than in the private sector due to the high risk of culture and/or language barriers impeding instructions);
- the information system used track drug and reimbursement information (RPMS);
- the charitable mission served (providing pharmacy services to a population group and in geographic areas characterized by failure of competitive market dynamics); and
- the way Medicare reimbursements are processed (via a nationally centralized system).

(10) In reviewing and negotiating bids (under 42 USC §1860D-11(d)) that contain one or more plans proposing to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such review and negotiation is conducted in a manner consistent with Departmental AI/AN policy goals.

(11) In approving or disapproving any plan (under 42 USC §1860D-11(e)) that proposes to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such approval or disapproval is made in a manner consistent with Departmental AI/AN policy goals, especially with regard to the requirement of 42 USC §1860D-11(e)(2)(D) that the Secretary approve a plan only if he "does not find that the design of the plan and its benefits (including any formulary or tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan."

The Secretary has already successfully adopted a centralized national model similar to that proposed above for processing Medicare Part A and Part B payments to I/T/U facilities, through the use of a single Carrier for I/T/U providers nationwide. With I/T/U facilities already possessing the capacity to be reimbursed for Part A-covered drugs, and on the verge of gaining the capacity to be reimbursed for Medicare Part B-covered drugs and biologicals under §630 of the MMA, the Secretary may wish to consider the efficiencies and improved coordination of benefits in the administration of the various Medicare drug programs as they apply to I/T/U providers that would likely result from adopting a similarly centralized, national system for processing Part D drug benefit payments to I/T/U facilities. For example, Trailblazer LLC has done a fair job of coordinating Part A and Part B payments to I/T/U facilities since the passage of the BIPA.

SUBPART G: PAYMENT TO PDP SPONSOR AND MA ORGANIZATIONS OFFERING MA-PD PLANS FOR ALL MEDICARE BENEFICIARIES FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

42 CFR §423.329 DETERMINATION OF PAYMENT

Subsection (b), Health Status Risk Adjustment:

COMMENT: We feel that for PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis, the Secretary should engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies in the establishment of risk adjustment factors, data collection of risk adjustment factors, development of methodologies to measure risk adjustment factors, and publication of risk adjustment factors as required under this section.

…

SUBPART P: PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

42 CFR 423.772 DEFINITIONS

Definition of "Resources:"

COMMENT: Many AI/AN hold interests in real property that is held in one or more types of trust status by the U.S. Government. Given the statutory restrictions that these real property interests are subject to by definition, we feel consideration should be given to amending this definition to make clear that real property interests of AI/AN individuals held in some form of trust status by the U.S. Government are excluded from this term. **We incorporate by reference the excellent, well-researched National Indian Health Board comments on this definition**.

Definition of "Income:"

COMMENT: Under the MMA, the Secretary has the option to permit a State to make subsidy eligibility determinations using the methodology set out at section 1905(p) of the Act if the Secretary determines that this would not result in any significant difference in the number of individuals who are made eligible for the subsidy. This in turn would permit a State to use the same resource methodologies that it uses to determine Medicaid eligibility for QMBs, SLMBs, and QIs if the Secretary determines that the use of those methodologies would not result in any significant differences in the number of individuals who are made eligible for a subsidy. This includes the less restrictive methodologies a State may use under section 1902(r)(2) of the Act to determine eligibility for QMBs, SLMBs and QIs.

The Secretary has proposed not to exercise this option at all under the proposed regulations, for two reasons: First, allowing States this greater flexibility to establish their own income determination standards would detract from the policy objective of achieving uniformity in the low-income subsidy determination process. Second, allowing States this flexibility would result in significant administrative burdens and complexity in administering the Medicare Part D low-income subsidy eligibility determination process.

Given the Departmental policy goal lowering barriers to access to services to narrow the AN/AI health disparities gap, and given the well-documented barriers of poverty, distance, high incidence of disease experienced by many Medicare-eligible AN/AI, and given the scarce resources and escalating costs experienced by all I/T/U pharmacies, we feel significant public health policy considerations weigh heavily in favor of the Secretary exercising his statutory discretion granted to him at under 42 USC §1860D-14(a)(3)(C)(iv) of the Act to amend this proposed regulatory definition of "income" in a way that would allow States to employ the less restrictive methodologies of 1902(r)(2) in making subsidy eligibility determinations for AI/AN.

The policy interest of maintaining uniformity would still be well-served, because the exception to the rule that would be created would be miniscule in comparison to the entire Part D program; the exception would only apply to a very defined population group; and in creating their own income determination standards under 1902(r)(2), States would still be constrained by the limits inherent in 1902(r)(2) and related statutes.

The policy interests of assuring economy and efficiency and avoiding unnecessary complexity and administrative burdens in carrying out the Part D program would also be well-served because State programs are already quite familiar with AI/AN populations; the I/T/U pharmacies that serve them; and are quite capable of working closely with I/T/U pharmacies to identify AI/AN beneficiaries and appropriately calculate their income for purposes of subsidy eligibility determination in a way that balances the need to control health care costs with the Departmental policy objective of lowering barriers to health services for AI/AN.

It should also be noted that should the Secretary choose to exercise his statutory discretion under the MMA to allow States 1902(r)(2) flexibility with regard to calculation of AI/AN income for purposes of subsidy eligibility determination, that approach would be consistent with the Secretary's exercise of statutory discretion in similar situations, e.g., such as in 2002, when the Secretary exercised his discretion to not subject I/T/U providers to the Medicaid 100% upper payment limit requirements of 42 CFR 447.272.

42 CFR 423.773 REQUIREMENTS FOR ELIGIBILITY

Under Subsection (c)(3), a State agency must notify individuals treated as full benefit dual eligible individuals that they are eligible for a full subsidy of Part D premiums and deductibles. Individuals to receive such notification would include QMBs, SLMBs, and QIs. We feel consideration should be given to providing such notification to the I/T/U pharmacy serving such subsidy-eligible individuals as well.

AI/AN receiving services at an I/T/U pharmacy are likely to include many individuals who are to be treated as full subsidy eligible individuals, all of whom would be receiving care from such

I/T/U pharmacies on an IHS-prepaid basis, with no charges to the individual, pursuant to the public health mission of I/T/U pharmacies.

In these cases, it is the I/T/U pharmacy, rather than the full-subsidy AI/AN that would bear financial responsibility for the payments and waivers that would apply if there were no subsidy. Therefore, we feel consideration should be given to amending subsection (c)(3) to require that in the case of AI/AN served by an I/T/U pharmacy, notice also be given to the I/T/U pharmacy.

42 CFR 423.780 PREMIUM SUBSIDY

Subsections (a) and (b):

I/T/U pharmacies provide services to AI/AN on an IHS-prepaid basis, at no charge to the AI/AN, pursuant to the Departmental public health policy goal of lowering barriers to health services for AI/AN. For this reason, we feel consideration should be given to amending these subsections to expressly clarify that I/T/U pharmacies may pay Part D premium amounts on behalf of the AI/AN that might not be fully covered by the premium subsidy available to full subsidy eligible AI/AN or other low-income subsidy eligible AI/AN. In addition to this, we feel consideration should be given to amending these subsections to make clear that for AI/AN receiving services from I/T/U pharmacies, the I/T/U pharmacies may pay any other unsubsidized premium amounts on behalf of other low-income subsidy eligible AI/AN, as well as on behalf of unsubsidized AI/AN Part D beneficiaries.

We feel this approach would have a significant positive impact on the participation of AI/AN in the Medicare Part D drug benefit.

It should be noted, however, that we feel strongly that such charitable, public health-oriented premium payment amounts (as well as cost-sharing amounts) by I/T/U pharmacies on behalf of AI/AN MUST be counted as "incurred costs," as defined in the proposed regulations at 42 CFR 423.100, as noted at length above in our comments addressed to that section.

42 CFR 423.800 COST-SHARING SUBSIDY:

Subsections (a) and (e):

I/T/U pharmacies provide covered services to low-income subsidy eligible individuals on a IHS-funded, pre-paid basis, with no out-of-pocket charges to the low-income subsidy eligible AI/AN, pursuant to the public health mission of I/T/U pharmacies of reducing barriers to health services for AI/AN, in furtherance of the Departmental AI/AN policy goals.

The Congress has expressly approved this practice in the MMA itself, at Section 101, Part D, Subpart 5, by amending 42 USC 1320a-7b(b)(3) to permit, in the form of a statutory exception to the federal anti-kickback statute,

> "…(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under Part D of Title XVIII, if the conditions described in clauses (i) through (iii) of section 1128A(i)(6)(A) are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1860D-14(a)(3), section 1128A(i)(6)(A) shall be applied without regard to clauses (ii) and (iii) of that section)."

In light of this very recent, unmistakeably clear statutory expression of the Congress, and in light of the compelling public health mission served by I/T/U pharmacies in lowering barriers to access for AI/AN by providing covered Part D drugs to AI/AN on an IHS-funded, pre-paid basis, we believe consideration should be given to amending subsections (a) and (e) to require that in all cases in which an I/T/U pharmacy waives or reduces cost-sharing amounts that would otherwise have been paid as out-of-pocket costs by a low-income subsidy eligible individual, the reimbursement that would otherwise be paid by the individual shall be paid to the I/T/U pharmacy.

42 CFR 423.800 ADMINISTRATION OF SUBSIDY PROGRAM:

Subsections (c) and (d):

Payment to a PDP sponsor or MA organization for cost-sharing subsidies made on a capitated basis may be inappropriate with regard to payments made on behalf of AI/AN to PDP sponsors or MA organizations for PDPs or MA-PDs primarily serving I/T/U pharmacy beneficiaries. Although such a capitated payment system may work well for the private sector, we believe such a payment system inappropriately creates incentives for PDP sponsors or MA organizations to attempt to maximize profits at the expense of reducing the scarce resources necessary for I/T/U pharmacies to carry out the Secretary's stated goal of narrowing the AI/AN health disparities gap.

We would ask that consideration be given to amending these subsections to reflect that PDP sponsors or MA organizations with PDPs or MA-PDs that serve a significant number of AI/AN would not have available to them the option of having the cost-sharing subsidies reimbursed to them on a capitated basis.

SUBPART P: SPECIAL RULES FOR STATES IN MAKING ELIGIBILITY DETERMINATIONS FOR SUBSIDIES

423.902 DEFINITIONS

Definitions of "STATE MEDICAL ASSISTANCE PERCENTAGE," and "PHASED-DOWN STATE CONTRIBUTION PAYMENT"

The proposed regulatory definition of State medical assistance percentage is identical to the statutory definition at section 1935 of the Act: "The proportion equal to 100% minus the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs."

This definition requires the Secretary, in determining each State's medical assistance percentage to first determine "the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs."

Unfortunately, under the Act's FMAP provisions at 42 USC 1396d(b), a State's FMAP can vary.

On the one hand, a State's FMAP for a given fiscal year could be calculated using the default FMAP formula set out in the first paragraph of subsection (b).

On the other hand, the plain language of the 1935 reference to 1396d(b), under well-established principles of statutory interpretation, ould be read more broadly to include ALL of subsection (b), including (b)(1), (b)(2), (b)(3) and (b)(4).

We feel that the correct reading of §1935 should follow well-established principles of statutory interpretation, and in a manner that weighs in favor of achieving the Departmental AI/AN policy goal of narrowing the AI/AN health disparities gap by lowering AI/AN barriers to access to covered Part D drugs, by allowing States to calculate their SMAP for purposes of §1935 by factoring in the 100% FMAP reimbursement amounts received for the applicable year, weighted in proportion equal to that State's overall proportion of 100% FMAP-paid reimbursement in comparison to the overall reimbursement amounts received in that year at otherwise-applicable FMAP percentages.

For example, if New Mexico's established FMAP percentage for a given year were 50%, but 20% of the total value of Medicaid reimbursements paid by the Secretary to New Mexico for that year were paid at 100% FMAP (due to those reimbursements being made for services provided to AI/AN), then 80% of the total value of paid Medicaid claims for that year were reimbursed at 50% FMAP, and 20% of the total value of paid Medicaid claims for that year were reimbursed at 100% FMAP.

So if New Mexico's total value of paid Medicaid claims in a given year were $1 billion, the actual FMAP experienced by New Mexico would be ($800 million x 50% FMAP) = **$400 million + $200 million** ($200 million x 100% FMAP) = $600 million, or 60%, rather than the published FMAP rate of 50%.

This difference, in turn, significantly impacts the amount of New Mexico's phased-down State contribution payment to the Secretary under the statutory formula.

Under the formula, New Mexico's monthly contribution amount is equal to 1/12 of the product of the base year (2003) Medicaid per capital expenditures for covered Part D prescription drugs

for full-benefit dual eligible individuals, multiplied by the State medical assistance percentage (which is the inverse percentage amount of the FMAP percentage), the applicable growth factor, the number of the State's full-benefit dual eligible individuals that month, and the phased-down state contribution factor.

We feel consideration should be given to accepting the plain language of section 1935 on its face, and to assign an FMAP value to each State for each fiscal year using State's FMAP value

As is pointed out in the General Provisions accompanying the proposed regulations at 69 FR 46638, 3rd column:

> "General principles of statutory interpretation require us to reconcile two seemingly conflicting statutory provisions whenever possible, rather than allowing one provision to effectively nullify the other provision. Consequently, when a statutory provision may reasonably interpreted in two ways, we have an obligation to adopt the interpretation that harmonizes and gives full effect to competing provisions of the statute."

****

(END OF ANTHC COMMENTS TO PROPOSED PART D REGULATIONS)

Submitter : Ms. Jennifer Dripps **Date & Time:** 10/04/2004 08:10:01

Organization : UNC School of Pharmacy

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

I believe patients should be able to choose the pharmacy and pharmacists they prefer. Limiting medicare patients to preferred pharmacies takes away there freedom to choose!

CMS-4068-P-1266

Submitter : Mr. William von Oehsen **Date & Time:** 10/04/2004 08:10:18

Organization : Public Hospital Pharmacy Coalition

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

PHPC wishes to submit the attached comments. If you have questions, please contact William von Oehsen or Ted Slafsky at (202) 466-6550.

CMS-4068-P-1266-Attach-1.pdf

PHPC
Public Hospital Pharmacy Coalition
www.phpcrx.org
(A Coalition of the National Association of Public Hospitals and Health Systems)

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4068–P
P.O. Box 8014
Baltimore, MD 21244–8014

Re: Comments to Proposed Medicare Prescription Drug Benefit; Docket ID CMS–4068–P

Dear Dr. McClellan:

The Public Hospital Pharmacy Coalition (PHPC) would like to take this opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the proposed Medicare Prescription Drug Benefit. PHPC is an organization of over 200 safety net hospitals and health systems that participate in an outpatient drug discount program established under Section 340B of the Public Health Service Act. The Coalition was formed to increase the affordability and accessibility of pharmaceutical care for the nation's poor and underserved populations. PHPC submits these comments for three reasons. First, it wants to ensure that prescription drug plans (PDPs) and Medicare Advantage (MA) organizations do not discriminate against or otherwise obstruct participation of pharmacies that are based in 340B providers, such as disproportionate share hospitals (DSHs) and federally-qualified health centers (FQHCs). Second, PHPC recommends that CMS actively encourage PDPs and MA plans to include 340B provider pharmacies in their pharmacy networks, especially in connection with any medication therapy management program that the plans choose to offer. Third, we seek assurance that PDPs and MA plans are permitted to offer separate co-branded drug benefit programs to beneficiaries who are existing patients of a 340B provider and are therefore eligible to receive 340B-discounted pricing. This alternative model for offering and financing a Medicare prescription drug benefit should improve both the affordability and continuity of pharmaceutical care for low-income Medicare patients. These three recommendations are discussed in greater detail below.

BACKGROUND

Established by Congress and signed into law by President George H.W. Bush in 1992, the Public Health Service 340B program was designed to assist federally-funded safety net providers and programs expand access to pharmaceutical care by giving them access to deeply discounted pharmaceuticals. 340B discounts are approximately half of average wholesale prices. In addition to eleven categories of federal grantees and sub-grantees, a number of disproportionate share hospitals that provide large volumes of indigent care are eligible to participate in the 340B program. These hospitals are either owned by state or local government or have a contractual relationship with state or local government to provide care to low-income populations. There are currently over 200 DSH hospitals participating in the 340B program and most of them are teaching facilities.

Although 340B hospitals constitute less than 5 percent of all hospitals in the United States, they provide over 25 percent of the uncompensated health care for Americans. Participating DSH hospitals also provide an enormous volume of care to Medicare beneficiaries, particularly low-income beneficiaries who often lack pharmaceutical coverage. Close to two million Medicare patients are treated at 340B hospitals each year and 340B hospital pharmacies are responsible for almost all of the pharmaceutical care for these patients. Due to the existing relationships between 340B hospital pharmacists and their patients, these professionals are in a unique position to monitor drug utilization, provide culturally sensitive pharmacy counseling services, and ensure compliance with drug regimens. Yet, 340B hospitals face ever-increasing budgetary constraints which, when coupled with significant increases in pharmaceutical costs, have forced many of them to consider limiting access to medically necessary drugs for the indigent and vulnerable populations that they serve.

COMMENTS

The intersection of the 340B program and the new Medicare Part D drug benefit both raises concerns and creates opportunities which are the subject of PHPC's comments below. For each comment, we have identified the relevant proposed regulation and quoted the applicable language therein.

Section 423.120(a)(4)

Pharmacy network contracting requirements. In establishing its contracted pharmacy network, a PDP sponsor or MA organization offering qualified prescription drug coverage—

> (i) Must contract with any pharmacy that meets the prescription drug plan's or MA–PD plan's terms and conditions; and
>
> (ii) May not require a pharmacy to accept insurance risk as a condition of participation in the PDP plan's or MA–PD plan's network.

Comment:

340B hospitals have historically faced barriers to being included in pharmacy networks established by pharmacy benefit mangers (PBMs) and managed care plans. The refusal of manufacturers to give rebates to PBMs and managed care plans for drugs that have already been deeply discounted under the 340B program creates a disincentive for these sponsors to offer participation agreements to 340B hospitals and other covered entities. PHPC has received reports from some members that they have encountered similar barriers to signing up for the Medicare drug discount card program. Because the new Part D benefit will be administered in large part by PBMs and managed care organizations, we are concerned that the subtle forms of discrimination against 340B pharmacies over the past decade will be perpetuated in the new Part D program. PHPC requests CMS's assistance in addressing this concern.

On its face, Section 423.120(a)(4) appears to protect pharmacies from potential discriminatory conduct by Part D plans. However, plan sponsors can devise certain "terms and conditions" that, whether intentional or not, have the effect of excluding 340B provider pharmacies from plan networks. For example, a condition of participation that the pharmacy serve all plan enrollees would conflict with a covered entity's obligation under the 340B statute not to sell or otherwise transfer its 340B-discounted drugs to anyone other than its own patients. If enrollees who are not patients of the 340B provider are permitted to fill prescriptions at the 340B pharmacy, the 340B provider would be saddled with having to choose between two equally unattractive options: augment the 340B pharmacy's infrastructure to allow it to maintain two inventories of drugs (340B and non-340B) or violate the 340B prohibition against dispensing discounted drugs to non-patients. Price disclosure requirements or billing terms could also be used by PDPs and MA plans to exclude 340B pharmacies. PHPC therefore asks that CMS add to Section 423.120(a)(4) a statement that PDP sponsors and MA organizations be prohibited from developing any terms or conditions that have the effect of discouraging or barring 340B provider pharmacies from participating in the plans' pharmacy networks.

In promoting the Medicare discount card program, CMS has already recognized the vital role that FQHCs, DSH hospitals, and other 340B providers play in caring for low-income seniors and disabled Americans. Indeed, CMS issued specific guidance urging drug card sponsors to reach out to FQHCs and other 340B providers in building their pharmacy networks. These same 340B pharmacists are in a unique position to educate low-income Medicare patients about the new Part D benefit and to help them navigate through the various choices. If 340B pharmacies are excluded from the networks of Medicare Part D plans, continuity of care will be compromised and patients may suffer adverse health consequences which, among other things, could end up increasing costs to the Medicare program. PHPC therefore urges CMS to continue its policy of promoting use of the 340B program by Medicare patients. It can communicate this policy by regulation – in which case Section 423.120(a)(4) appears to be the relevant provision – or it can notify PDP and MA sponsors by less formal means.

Section 423.104(h)(1)

Negotiated prices. (1) *Access to negotiated prices.* Under qualified prescription drug coverage offered by a PDP sponsor or an MA organization, the PDP sponsor or MA organization is required to provide its enrollees with access to negotiated prices for covered Part D drugs included in its plan's formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for covered Part D drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit.

Comment:

Section 423.104(h)(1) states that PDP and MA sponsors must give enrollees access to prices that the sponsors have negotiated. Although PHPC supports this pricing policy, it believes that CMS needs to clarify the regulation with respect to pharmacies participating in the 340B program. The discounts available to the 340B provider will often be larger than the range of discounts negotiated by Part D plans through the use of formularies and market share agreements. To accommodate the lower prices available through the 340B program, PHPC asks that CMS clarify that 340B pharmacies are permitted, but not required, to sell at lower prices than the Part D negotiated prices. Access to lower 340B prices should save money for both the Medicare program and beneficiaries. PHPC's request, therefore, reflects sensible policy.

Section 423.120(a)(5)

Discounts for preferred pharmacies. A PDP sponsor or MA organization offering a prescription drug plan or an MA–PD plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs (relative to the copayments or coinsurance applicable when those covered Part D drugs are obtained through a non-preferred pharmacy) when a Part D eligible individual enrolled in its prescription drug plan or MA–PD plan obtains the covered Part D drug through a preferred pharmacy. If the prescription drug plan or MA–PD plan provides actuarially equivalent standard coverage, the plan must still meet the requirements under §§ 423.104(e)(2) and (5). Any cost-sharing reduction must not increase CMS payments under § 423.329.

Comment:

PHPC supports giving PDP and MA sponsors the flexibility of establishing preferred and non-preferred pharmacies in their Part D pharmacy networks. However, as mentioned in our first comment, we are concerned about potential discrimination against 340B provider pharmacies. The flexibility that Part D plans enjoy under this section could be used to discourage use of 340B pharmacies by relegating them to non-preferred status. We therefore ask that CMS prohibit plans from using criteria to accept pharmacies into preferred networks that are more difficult for 340B providers to satisfy than non-340B pharmacies. We would prefer that an explicit statement to this effect be added to Section 423.120(a)(5).

Section 423.153(d)

(d) *Medication therapy management program.* (1) *General rule.* A medication therapy management program—

(i) Must assure that drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Must, for the targeted beneficiaries described in paragraph (d)(2) of this section, reduce the risk of adverse events, including adverse drug interactions;

(iii) May be furnished by a pharmacist; and

(iv) May distinguish between services in ambulatory and institutional settings.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the medication therapy management program described in paragraph (d)(1) of this section are enrolled Part D eligible individuals who—

(i) Have multiple chronic diseases;

(ii) Are taking multiple covered Part D drugs; and

(iii) Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level that CMS determines.

(3) *Use of experts.* The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program under section 1807 of MMA.

(5) *Considerations in pharmacy fees.* An applicant to become a PDP sponsor or an MA organization wishing to offer an MA–PD plan must—

(i) Describe in its application how it will take into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing medication therapy management services for covered Part D drugs under a prescription drug plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for medication therapy management services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

Comment:

PHPC strongly supports the establishment of a medication therapy management program within the Medicare program. Most 340B hospitals are academic medical centers that rely heavily on clinical pharmacies for identifying and delivering treatment options. Hospital pharmacists are part of the professional team that evaluate and recommend patient-specific therapies. We therefore want to ensure that 340B hospital pharmacies have a fair chance to participate in the new medication therapy management program and are not subject to conditions of participation that directly or indirectly discriminate against them. In addition to the proposed requirement that such medication management therapy programs are developed in cooperation

with licensed and practicing pharmacists and physicians, we also strongly recommend that the regulation require that these programs are under the supervision of a licensed pharmacist and that such a pharmacist is reasonably reimbursed for his or her services.

Section 423.272(b)(2)

Plan design. CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. If the design of the categories and classes within a formulary is consistent with the model guidelines (if any) established by the United States Pharmacopeia, that formulary may not be found to discourage enrollment on the basis of its categories and classes alone.

Comment:

Since the launch of the Medicare drug discount card several months ago, several 340B providers have partnered with discount card sponsors to develop a co-branded discount card giving cardholders access to 340B-discounted pricing. These specialized card programs are built around a 340B provider – typically a DSH hospital, FQHC or a combination of DSHs and FQHCs – that is already serving a large population of low-income Medicare patients. Initial reports suggest that these co-branded care programs have been successful in promoting continuity of care for low-income Medicare patients while lowering the cost of drugs well below the discounts advertised on the CMS website. These co-branded discount card partnerships between 340B providers and card sponsors would like to transition into the Part D program in 2006. PHPC is concerned about application of Section 423.272(b)(2) because access to the co-branded card is limited to the subset of cardholders who are "patients" of the 340B partner within the meaning of the 340B statute and implementing guidelines. The prohibition in Section 423.272(b)(2) against discouraging enrollment by certain Part D eligible individuals could be construed as prohibiting the co-branded partnership model that both 340B providers and prospective PDPs would like to establish in the Part D program.

With respect to discount card programs in which a 340B entity offers a co-branded discount card option, CMS has already endorsed in writing that the card sponsor can limit enrollment into the co-branded card option to only those cardholders who are "patients" of the 340B entity. CMS endorsement of this policy was essential to the success of the 340B-based discount card model because, under the 340B anti-diversion provision, the 340B providers are prohibited from selling or otherwise transferring their discounted drugs to anyone other than their own patients. PHPC simply seeks an extension of this policy to the new Part D benefit so that PDPs can offer special 340B-based drug benefits to enrollees who are patients of 340B providers. There are at least three advantages to this model.

First, if the target Medicare population chooses to sign up with the 340B provider's co-branded drug benefit, patients could continue using the 340B entity's pharmacy during the so-

called donut hole or during other gaps in coverage when the enrollees would otherwise find themselves unable to afford retail pharmacy prices, even at the PDP's discounted rates. In the absence of such a program, many low-income Medicare beneficiaries will have to change pharmacies after their coverage is depleted, returning to their original 340B pharmacy providers, where they are assured of getting their prescriptions filled. Unlike retail pharmacies, DSH and FQHC pharmacies are required by law to serve all patients, regardless of their ability to pay. Allowing patients within this vulnerable population to keep their pharmacy "home" at the 340B provider will avoid the inevitable switching of pharmacies during gaps in coverage. This, in turn, will avoid disruptions in pharmaceutical care, especially since a change in pharmacies may end up forcing patients to change drugs because of the different formularies maintained by the pharmacies.

The second advantage of a DSH- or FQHC-based discount card is that the covered entity's pharmacy will almost always be able to offer prices at or below the discounted prices typically available to low-income Medicare beneficiaries who sign up for the Part D benefit. 340B discounts will likely be deeper than the discounts that non-340B pharmacies will be able to offer to enrollees. Not only would beneficiaries benefit from these deeply discounted rates, manufacturers would not have to pay rebates to help card sponsors make their drugs more affordable. The affordability of the drugs available through the DSH or FQHC benefit would result from their acquisition through the 340B program, not from the use of manufacturer rebates to lower a participating pharmacy's drug costs.

The third reason why CMS should support a 340B-based co-branded benefit program is that it would help strengthen this nation's safety net. DSH hospitals and FQHCs represent the backbone of our country's health care system for the poor. As the number of uninsured Americans climbs and availability of taxpayer revenue to pay for health care shrinks, 340B providers often find themselves at the brink of financial collapse. It is therefore not surprising that these safety net institutions want their Medicare patients to use drug benefit dollars on their own pharmacy services rather than using their coverage elsewhere. Helping to direct this new source of federal revenue to 340B providers would further the mission of safety net institutions in meeting the needs of the underserved, both today and for future generations.

In summary, PHPC asks that CMS clarify Section 423.272(b)(2) in order to facilitate, or at least not hinder, partnerships between approved PDPs and 340B entities so that the 340B drug discount program could be used to fund a specialized co-branded benefit for enrollees who are patients of the 340B entities.

We hope that CMS will work with PHPC in pursuing this exciting model for expanding pharmaceutical access and stretching scarce resources for low-income Medicare beneficiaries.

* * * *

PHPC appreciates this opportunity to submit comments. Please do not hesitate to contact

me at (202) 466-6550 if you have any questions or need additional information.

Sincerely,

William H. von Oehsen
Counsel

Correspondence should be sent to:

William H. von Oehsen
Public Hospital Pharmacy Coalition
1875 Eye Street, N.W.
12th Floor
Washington, D.C. 20006

Submitter : Mr. Nelson Soltman **Date & Time:** 10/04/2004 08:10:46

Organization : Legal Assistance Foundation of Met. Chicago

Category : Individual

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

III. Subpart J: ?423.464(e)(1): Requirements to be a State Pharmaceutical Program.

Many elderly Medicare beneficiaries in Illinois participate in the SeniorCare program for pharmaceutical assistance. Illinois estimates that about 200,000 participants age 65 and over are in SeniorCare, which provides comprehensive prescription drug coverage. Seniors in Illinois with incomes at or below 200% FPL, and who otherwise meet the eligibility standards for Medicaid, may use SeniorCare. Cost sharing is generally minimal with no premiums, $4 copays for brand name drugs and $1 copays for generics for the first $1,750 of drug spending. After $1,750 of drug spending has been reached, a senior pays a coinsurance of 20 percent in addition to the copays.

SeniorCare is more generous than the proposed Part D program, according to estimates by the Illinois Department of Public Aid (IDPA), Illinois? Medicaid agency. CMS should allow for the continuation and renewal of the Senior Care Program, and should not mandate that the Senior Care population switch its coverage to Part D. CMS should provide flexibility for Illinois to modify SeniorCare to coordinate benefits with Medicare Part D to maximize coverage and minimize costs for beneficiaries.

Part D should be implemented to protect and maintain these beneficiaries? current ability to access affordable prescription drugs. The definition of SPAP should be modified to provide for the continuation of Illinois? SeniorCare program, and to assure that SeniorCare participants are not penalized for participation in SeniorCare. The SeniorCare structure has been in operation for several years, and works well for beneficiaries. They should be able to continue to benefit from SeniorCare.

ELIGIBILITY, ELECTION, AND ENROLLMENT

I. Transition of Dual Eligibles: 423.34(d) Enrollment requirement for full benefit
dual eligibles

Transition of the dual eligibles to Part D coverage is a major problem. CMS should eliminate any potential gap in coverage between the time that Part D takes effect (January 1, 2006) and the end of the initial enrollment period, when auto-enrollment would occur (May 15,2006). The Part D dual eligible population does not generally have experience in choosing prescription plans. They will have been on Medicaid, without the need for making such a choice. Some, such as those with cognitive impairments, may find it especially difficult to make such choices.
CMS? proposed delayed timeline for automatic enrollment could expose dual eligibles to a four and half month coverage gap that would cause hardship and could have serious health consequences for this vulnerable population. Creating such a gap will also run the risk of increasing hospital costs nationwide for services provided to beneficiaries hospitalized due to the deterioration of their health resulting from the gap in prescription coverage.

To prevent these consequences for dual eligibles, the transition of drug coverage for dual eligibles should be delayed for at least six months. Dual eligibles will need this long, given their higher prescription use, increased incidence of cognitive impairment, and need for individualized counseling and assistance, to select the most appropriate Part D coverage.

In addition, CMS should fund a comprehensive campaign of individualized counseling and assistance to explain to individuals in advance of their required enrollment what their choices are and how to enroll in a plan; if applicable, to explain how to get benefits under the plan to which they have been auto-assigned; and, if applicable, explain that they can choose a different plan from the one to which they have been auto-assigned and assist in choosing and enrolling in such a plan.
II. Section 423.46: Late enrollment penalty.

CMS should delay implementation of this section for all enrollees for at least one year. Part D is a new and particularly complex program. Many

beneficiaries will be confused about the program, not understand that they must choose a plan and enroll, or not be able to complete the enrollment steps. Many who require prescription drug coverage and are eligible for it do not necessarily know how to access it. For instance, Illinois estimates that almost 360,000 Illinois seniors are eligible for SeniorCare, but only about 200,000 are enrolled.

The people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness. Many Medicare beneficiaries will need more than six months to understand the program, understand how Part D coordinates with other drug coverage they may have, and choose the drug plan that is right for them. Beneficiaries should not be penalized because of the complexity of Part D and its implementation.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

IV. Subpart M: Grievances, Coverage Determinations and Appeals

This subpart should be simplified. The timeframes, required paperwork, and procedures should be simplified into one system, understandable to beneficiaries, that meets the requirements of the Due Process. The current system does not meet that test. The appeals process described in Subpart M does not provide dual eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity to a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes. It should be modified to meet those requirements.

CMS-4068-P-1268

Submitter : Mrs. Gerald Shea **Date & Time:** 10/04/2004 08:10:49

Organization : AFL-CIO

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4068-P-1268-Attach-1.pdf

VIA ELECTRONIC DELIVERY

October 4, 2004

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014
Http://www.cms.hhs.gov/regulations/ecomments

Dear Sirs/Madams:

In response to the notice by the Centers for Medicare and Medicaid Services (CMS) of a proposed rule implementing the new Medicare Prescription Drug Benefit (69 Fed. Reg. 46632), the American Federation of Labor-Congress of Industrial Organizations (AFL-CIO) and the National Education Association (NEA) are submitting the following comments regarding the payment of retiree drug subsidies to sponsors of retiree prescription drug plans and related issues.

The AFL-CIO is a voluntary federation of 60 national and international labor unions, representing approximately 13 million working women and men and more than 3 million retirees of every race and ethnicity and from every walk of life. The mission of the AFL-CIO is to improve the lives of working families—to bring economic justice to the workplace and social justice to our nation. The achievement of a reasonable level of health security in retirement is an important component of economic justice. The NEA is the nation's largest professional employee organization. Its 2.7 million members are represented throughout the field of public education, including elementary and secondary teachers, education support professionals, higher education faculty, and retired educators who belong to 51 state-level affiliates. The NEA believes that "affordable, comprehensive health care, including prescription drug coverage, is the right of every resident."

The law passed by Congress and signed into law by the Administration last year includes a number of serious structural flaws and shortcomings. Too few beneficiaries will receive the help they need, while insurance companies are given an advantage over the traditional fee-for-service Medicare program -- a structure that is sure to undermine the guaranteed Medicare benefits upon which tens of millions of our nation's elderly and disabled have come to depend. In addition, the True Out of Pocket provision discriminates against beneficiaries with retiree health benefits, making it nearly impossible for retirees to qualify for Medicare's catastrophic coverage. In fact, the Congressional Budget Office (CBO) found this inequitable treatment is a significant factor in their estimate that 2.7 million retirees could lose their employer-sponsored prescription drug coverage as a result of the new law. And the additional funds provided for the employer subsidy

in the conference agreement -- $18 billion to make the subsidy tax free – provided absolutely no additional benefit to non-taxable entities such as public sector employees and multiemployer plans that provide retiree health benefits.

Implementation of the retiree drug subsidy provisions of the Medicare Modernization Act (MMA) will have enormous and far-reaching implications for Medicare-eligible retirees with existing prescription drug benefits provided through a former employer. While the statute was prescriptive in certain respects, it also left to the Administration broad authority to implement many of the provisions, particularly with regard to the employer subsidy. Establishing the standards employers must meet to qualify for the subsidy can either exacerbate or mitigate the harmful provisions of the underlying statute – making the number of retirees who are helped rather than hurt relatively better or worse. In order to prevent employers from using the standards as an excuse to significantly reduce the coverage they now provide – even with the financial assistance of the federal subsidy – CMS must adopt and enforce strong retiree protections. In those instances in which the Secretary concludes he lacks the statutory authority to issue adequate protections for retirees, it is incumbent upon him to propose to the Congress specific legislative changes that would give him that authority, or that would otherwise protect retirees.

General Provisions

In the Preamble CMS described Congress's key policy goals for the Medicare retiree drug subsidy program and stated that the new Medicare law gives the Secretary of Health and Human Services the authority to achieve them. According to CMS, these goals are:

- Maximize the number of retirees retaining employer-based drug coverage through the retiree drug subsidy program;
- To not create windfalls, whereby retirees might receive a smaller subsidy from retiree drug plan sponsors than Medicare Part D would provide on their behalf (i.e., the employer would receive a greater subsidy than what it contributes to its retiree drug plan);
- Minimize the administrative burdens on beneficiaries, employers, and unions; and
- Minimize costs to the government of providing retiree drug subsidies and not exceed the budget estimates.[1]

Under the MMA, employers have several options for continuing to provide prescription drug coverage to Medicare-eligible retirees: retain actuarially equivalent coverage and receive a federal subsidy; "wrap around" or supplement the Medicare Part D benefit; or contract with or become a prescription drug plan (PDP) or Medicare Advantage (MA) plan. The primary focus of our comments is on the employer subsidy, and, in particular, what to measure in considering an employer-sponsored prescription drug benefit, what standard that benefit must meet in order to qualify for the subsidy, and how to ensure the subsidy is used to preserve retiree health benefits.

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[1] 69 Fed. Reg. 46741 (August 3, 2004).

I. Determining "Actuarial Equivalence," or Equal Value, for Alternative Coverage through Employer Sponsored Retiree Drug Plans

Under the new Medicare prescription drug law, the federal government will pay a cash subsidy to employers and other plan sponsors[2] that provide retiree prescription drug coverage that is at least equal in value to Medicare's new Part D prescription drug coverage. Coverage under these retiree prescription drug plans is meant as a substitute for coverage under the standard Medicare Part D prescription drug plan. The drug subsidy payable to the employer would be 28 percent of a retiree's total covered drug costs between $250 and $5,000 per year, which translates to a maximum subsidy payment to an employer of $1,330 per retiree.

The standard Part D benefit design enacted by Congress and signed into law by President Bush, while providing for partial government financing of the new benefit, still requires retirees to pay a substantial part of the costs of prescription drugs.[3]

In order to qualify for the federal subsidy, the employer's drug benefit does not have to look exactly like the standard Part D prescription drug benefit; it just has to be of equal or greater value. For example, the employer retiree drug plan might require each retiree to pay a $50 monthly premium (instead of the estimated 2006 $35 Part D premium) but other variations in the benefit design more favorable to retirees could make it of equal or greater value to the standard Part D benefit.

The law defines this test of equal value as one of "actuarial equivalence," which makes it possible to compare the value of different benefit designs. Actuarial equivalence looks at the expected cost of a benefit for a typical person, not how much it will actually cost for any given individual. This is important because a person who has greater health care needs obviously will cost more than one who is healthier.

CMS will have to create a standard for determining whether an employer retiree drug benefit is actuarially equivalent to the standard Part D benefit. It does not do this in the proposed rules.

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[2] Throughout these comments, the term "employer" is used as shorthand for all plan sponsors under the MMA.

[3] The basic features of the standard Part D benefit are as follows;

- Retirees who choose to enroll in a PDP will pay a monthly premium that will be set by the PDP but is estimated to begin in 2006 at $35 per month and increase from that point.
- The PDP will decide which prescription drugs to cover, as long as they meet certain requirements specified by Congress in the new law.
- A retiree will pay all of the first $250 of covered drug costs each year out of her own pocket.
- A retiree will pay 25 percent of covered drug costs between $250 and $2,250 during the year.
- A retiree will pay 100 percent of covered drug costs between $2,250 and $5,100 during the year.
- A retiree will pay no more than 5 percent of covered drugs costs that exceed $5,100. To be eligible for this "catastrophic" coverage, an individual retiree must pay $3,600 in covered prescription drug costs. Costs covered by a third-party, such as a group health plan, would not count toward this so-called "true out-of-pocket" amount.

Instead, CMS lays out several very different options and asks the public to comment on which standard is the right one and which ones are not appropriate. The standard CMS ultimately chooses will determine how good a benefit employers must offer retirees and how big a share of the benefit employers can require retirees to pay and still qualify for the federal subsidy.

In the preamble to the proposed rules CMS describes the different versions of the actuarial equivalence standard being considered by the government. Below is a brief description of each of these:

- Single Prong Test: Under this test, also known as the "gross value test," an employer's benefit is good enough to qualify for a federal subsidy if on average the total value of the benefit is at least equal to the total value of the standard Part D benefit. It does not matter what share of the benefit, if any, the employer pays. Under this test, the employer could contribute nothing and require the retiree to pay the full cost of the plan, yet the employer would still be paid the federal subsidy.
- Single Prong/No Windfall Test: As with the test above, an employer's benefit is good enough for a subsidy if on average the total value of the benefit is at least equal to the total value of the standard Part D benefit. However, the dollar amount of the subsidy paid to the employer cannot be greater than the dollar amount the employer pays toward the retiree coverage. The employer could design the plan so that it pays nothing towards retiree drug coverage after taking the federal subsidies into account.
- Two-Prong Test: This test begins with the single prong test but applies a second test in which the employer would also have to show it is paying for at least a specific minimum share of the total benefit. CMS offers several examples of the level at which it could set the minimum share or amount the employer must pay under the Two-Prong Test. These include:

    - The average per person amount Medicare would expect to pay as a subsidy to employers during the year, estimated by CMS to be $611 in 2006 when the program begins.
    - The expected amount of paid claims under the standard Part D prescription drug plan minus the monthly Part D premiums paid by the retiree, estimated by the CBO to be approximately $1,200 in 2006.
    - The after-tax value of the average per person amount Medicare would expect to pay as a subsidy to employers during the year. For employers subject to the federal corporate income tax, this would be higher than the $611 estimated subsidy payment and will vary depending on the employer's tax rate.

One of Congress's policy goals under MMA is to ensure that the subsidy is used to preserve retiree benefits and not used simply to improve the employer's bottom line or for other non-health care uses. The preamble to the proposed regulation endorses the principle that the subsidy should be passed through to the retirees to pay for retiree prescription drug benefits. In particular, the preamble states:

> "The intent of the MMA retiree prescription drug subsidy provisions is to slow the decline in employer-sponsored retiree insurance. By providing a special subsidy payment

to sponsors of qualifying plans, the MMA provides employers with extra incentives and flexibility to maintain prescription drug coverage for their retirees. Our intention is to make these subsidy payments as reasonably available to plan sponsors as possible. We wish to take into account as much as possible the needs and concerns of plan sponsors, consistent with necessary assurances that Federal payments are accurate and in accordance with statutory requirements, that the interests of retiree-beneficiaries are protected, and that employers do not receive ''windfalls'' consisting of subsidy payments that are not passed on to beneficiaries."[4]

The structure of the statute promotes cost shifting to retirees. Employers are allowed to shift to retirees the difference between what they are currently paying for retiree drug coverage and the amount necessary to meet actuarial equivalence. If the employer reduces benefits by shifting this extra cost to retirees, the employer is not disadvantaged, because the employer's subsidy under Part D is based upon the total spending for prescription drugs paid by both the employer and the employee. The ability to shift costs to retirees can only be blunted by adopting the highest rational standard for actuarial equivalence.

Our own bargaining experience and recent published data suggest that most employer-sponsored coverage currently exceeds the estimated value of the Medicare Part D benefit. For example, the Business Roundtable recently reported that typically, but not universally, medium and large employers sponsor health benefits that supplement Medicare, including drug benefits. According to testimony presented to the Senate Finance Committee on September 14, 2004, "A May 2003 survey found that of the 65 Business Roundtable companies that responded, all offer retiree benefits that supplement Medicare. The benefits average $2,333 per year per beneficiary, of which an average of $1,498 is spent on outpatient prescription drug coverage."

The CBO estimates the value of the Medicare Part D drug benefit is approximately $1,600 in 2006, of which approximately $1,200 will be paid by the Part D program and $400 will be paid by the beneficiary in a monthly premium. Consequently, the average spending found in the Business Roundtable study (approximately $1,500) is significantly higher than the expected government spending on each Part D beneficiary for 2006 (approximately $1,200). As a result, even if $1,200 were chosen as the figure employers are required to contribute to achieve actuarial equivalence, employers would have significant discretion to shift to their retirees all or part of the difference between what they now contribute and $1,200 and still qualify for the subsidy. Any figure lower than $1,200 would significantly exacerbate this inequity.

We have the following recommendations regarding the actuarial equivalence test that we believe are consistent with CMS's goals.

- CMS should adopt the Two-Prong Test for actuarial equivalence, which requires the portion of the prescription drug plan financed by the employer to be at least equal to the portion of the Part D benefit that is financed by Medicare. Only this test is consistent with the letter and intent of the MMA to provide for alternative drug coverage that is

[4] 69 Fed. Reg. 46737 (August 3, 2004).

actuarially equivalent to the standard Part D benefit. The comparison of the employer plan to the Part D benefit should be based on the benefits provided, not the cost.

- All of the other standards described by CMS in the preamble to the proposed rules could penalize retirees covered under a retiree drug plan and should be rejected. The Single Prong Test, the Single Prong/No Windfall Test, and the two versions of the Two-Prong Test that permit the employer to limit its contribution to the average subsidy amount it would expect to be paid from Medicare could all require a retiree to pay more for her drug coverage than she would if she were covered under a Medicare Part D prescription drug plan.

- In order to achieve the policy goals of Congress and CMS, the regulations should prohibit windfalls to employers. In no instance should the subsidy exceed the subsidy an employer provides for the retiree prescription drug benefit.

    - The maximum potential subsidy an employer may receive is $1,330 (28% of costs between $250 and $5,000). This may exceed the employer's contribution even if the standard is set at the net actuarial value of the Medicare Part D benefit (valued by CBO at $1,200 in 2006).

    - Other tests being considered by CMS would allow for even greater windfalls to an employer. The Single Prong (or Gross Value) Test would allow for enormous windfalls to employers since it would permit an employer to pay nothing toward the drug benefit and still collect federal subsidies. This option has been roundly criticized in the press, is inconsistent with the intent of Congress, and would undermine the integrity of the Medicare drug program.

    - CMS also should reject the Single Prong/No Windfall Test that would limit the amount of the subsidy the employer receives to the amount paid by an employer for retiree drug coverage. This test would allow an employer to effectively pay nothing toward retiree coverage (once the federal subsidy is taken into account) and massively shift costs to retirees at the same time.

    - Where the anti-windfall protections would prohibit an employer from claiming the largest possible retiree drug subsidy payable under the law, CMS should provide a mechanism permitting the plan sponsor to claim the larger subsidy, so long as it passes through to the affected retirees the value of the subsidy exceeding the employer contribution in the form of improved prescription drug benefits.

- Where a plan is fully insured, the regulations should require the insurance carrier to provide to the plan sponsor the information necessary to apply for the subsidy.

II. Definition of "Plan"

CMS indicated in its proposed regulation that it was aware of the fact that employers may have a tiered plan in which retirees receive different contributions based on different levels of service. In response to this issue, CMS proposed the following:

- As with the final COBRA rules, all health benefits provided by a group health plan sponsor will be presumed to be under a single plan unless it is clear from the plan instruments and instrumental operation that the plans are separate plan arrangements.

- Group health plan sponsors should apply the actuarial equivalence test to the group health plan as a whole. The preamble states that the standard will be met if, on average, the actuarial value of retiree drug coverage under the plan is at least equal to the value of standard prescription drug coverage under Part D.

The rules should give employers some flexibility when considering multiple plan offerings and sub-groups within a plan. However, the regulations must include strong protections against employers manipulating plan design and valuations in order to minimize the extent to which classes of retirees are offered, and employers receive a subsidy for, a plan that is inferior to the Medicare Part D standard. In the case of a collectively bargained plan, where benefits are negotiated with the union representing retirees who were part of the collective bargaining unit, CMS can say with certainty that the benefits constitute a separate plan.

Because the plan sponsor has the ability to define the nature of a "plan" it is critical to require that the plan definitions be clearly set forth in the plan documents and summary plan descriptions that are made available to the plan's retirees. Moreover, the regulations should prevent manipulation of the plan definition specifically for the purposes of obtaining a subsidy (e.g. prohibit manipulation that is not consistent with the definition used for COBRA purposes). This can be accomplished by adopting by reference the language of the entire COBRA regulation, which prohibits manipulation to avoid legal responsibilities. Significant changes in methods in any year should be disclosed in the plan sponsor's annual actuarial attestation. This would reduce the chance of errors and limit the risk that some employers will game the system. In addition, whatever approach an employer adopts should be documented and followed in future years.

III. Transparency

In order to protect the integrity of the program, CMS must adopt measures to ensure that the implementation and administration of the subsidy payments to employers are transparent to retirees, their bargaining representatives and the public. Such requirements are essential to achieving Congress's and the President's objectives that these substantial new subsidy payments be used to preserve and possibly improve retiree drug coverage, that no windfalls be created and that costs to the government be minimized.

Safeguards are particularly important for several reasons. First, because the actuarial equivalence test is applied to the average of all subgroups within a retiree health plan offered by an employer, there is the potential for significant variation in such subgroups and, by extension, the use of different plan designs to encourage higher cost beneficiaries to enroll in Part D plans. Second, if the plan is measured according to projected benefits as opposed to benefits received, projections can clearly be unrealistic. Third, due to differences in plan designs, an employer may offer some benefits to subgroups that are actuarially equivalent and others that are not. Retirees

should be able to confirm how the employer calculated actuarial equivalence for their particular subgroup.

Despite these potential abuses, the proposed regulations do not include a process for retirees to challenge an employer's attestation that its plan is actuarially equivalent, nor does it require transparency in regard to plan sponsors' attestations or the underlying assumptions and projections. Providing for such transparency and attestation challenges is critical to empowering retirees and other interested parties to act as guardians of this new federal subsidy.

We recognize that CMS has resource limitations on the extent to which it can review the accuracy of employer Attestations and claims for subsidy. CMS also has broader responsibilities to insure the integrity of the entire Medicare program, which may require vast resources to audit managed care plans and PDPs. By opening the employer subsidy process to scrutiny from retirees and their unions, CMS can allow them to serve as watchdogs with respect to employer retiree drug benefits.

We have the following recommendations to provide greater transparency and to ensure the integrity of the program:

- In general, all reporting and disclosure should be made public in a manner that is timely and permits easy access to the information.

- A Plan's Sponsor's "Attestation" of actuarial equivalence should include the assumptions and methods used to determine the plan's actuarial equivalence and should be available for public inspection shortly after it is filed with CMS. In considering the appropriate form for this disclosure, CMS should look to reporting and disclosure rules of the Employee Retirement Income Security Act (ERISA), with which most plan sponsors and their professional advisors are extremely familiar.[5] In particular, the annual Form 5500 Schedule B can be a useful model for disclosure formats, although we would oppose relying on the time frames required for ERISA disclosures, because the significant time lags in ERISA reporting typically mean that the information provided is out of date.

- If the public is to have any ability to measure the effect of the subsidy on preserving retiree health benefits, CMS must at a minimum require employers to report to retirees and unions the value of the subsidy received, as well as the aggregate claims data used to make the subsidy payments. To have the desired effect, such notices must be provided as soon as possible after the conclusion of the calendar year.

- Retirees and their unions should have the right to an appeals process regarding employers' actuarial equivalence attestations and subsidy amounts received.

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[5] Only private-sector and multiemployer plans are governed by ERISA. State and local government plans are not. However, the same principles of reporting and disclosure and open access to information are familiar to governmental plans due to the public environment in which they operate.

- The employer must be required to notify retirees who are being offered a drug benefit that is inferior to the standard Part D benefit. This situation could arise in at least two situations: first, if CMS adopts an actuarial equivalence standard that permits the actuarial value of the benefit not financed by a retiree to be less than the value of the standard Part D design not financed by a retiree; and second, if CMS adopts a "plan" definition allowing sponsors to average inferior contribution levels or benefit designs for some retirees with superior contribution levels or benefit designs for other retirees and still satisfy the regulatory standard for actuarial equivalence. Requiring such a notice not only will provide retirees with necessary information for deciding among their coverage options, but also influence the coverage sponsors offer to retirees. Because employers likely will not want to send out notices informing retirees that their coverage is inferior even though it satisfies the test of average actuarial equivalence, some employers may improve coverage for affected segments of retirees. We believe this will promote the core objectives of the statute.

- The regulations should require employers that offer a supplemental benefit that combines medical and drug coverage to offer a separate medical benefit that allows retirees to retain those benefits even though they may enroll in a Medicare Part D plan. This is particularly important for retirees who are offered drug benefits that are inferior to the standard Medicare Part D prescription drug benefit (i.e., the benefits do not constitute creditable coverage or the value of the benefit offered is less than the value of the standard Part D benefit). In the event CMS does not impose this requirement on employers, it should require employers to notify retirees that leaving the employer's plan to enroll in a Medicare Part D plan will automatically eliminate their employer-provided supplemental medical coverage, as well.

- Employers should provide a separate notice to individuals that they have creditable coverage, in order to ensure retirees are aware of their options and can make timely decisions necessary to avoid the late enrollment penalty for the Part D benefit. For example, providing notice as part of other disclosures, such as ERISA summary plan descriptions, is not sufficient.

IV. Annual Actuarial Equivalence Application Process

A plan sponsor must complete an annual application process before it can receive the subsidy. Proposed steps for the process include the following. The plan sponsor must submit the Actuarial Attestation no later than 90 days prior to the beginning of the calendar year for which it requests the subsidy. In order to receive the subsidy for 2006, the Actuarial Attestation and accompanying documents must be submitted by September 30, 2005. For plans that begin coverage in the middle of a year, the plan sponsor must submit an Actuarial Attestation no later than 90 days prior to the date coverage begins. For new plans that institute coverage after September 30, 2005, the plan sponsor must submit an Actuarial Attestation no later than 150 days prior to the start of the new plan.

CMS also proposes to require a plan sponsor to submit an Actuarial Attestation no later than 90 days prior to the implementation of a material change to the drug coverage of the plan that impacts the actuarial value of the coverage. (A material change means "any change that potentially causes the plan to no longer meet the actuarial equivalence test.") If the change would result in the benefit no longer being actuarially equivalent, beneficiaries would have to be

informed of the change 90 days prior to it taking effect. We support this recommendation with the following qualifications:

- The 90-day application requirement should be retained in final regulations.
- Extensions from the 90-day application requirement should be permitted only upon application showing justifiable need. However, any extension granted must allow sufficient time for retirees to make decisions about their options and avoid the late enrollment penalty for the Part D benefit.
- The requirements regarding notification of a material change in the plan's determination of actuarial equivalence should be clarified to assure that notice is provided 90 days prior to the effective date of the change.

V. Retiree Protections Against Improper Employer Disclosure

Retirees should not be penalized with respect to the Part D program if they make a choice based on their employer's incorrect representation regarding Part D coverage. Specifically, we support the proposed regulation's position that retirees who are misinformed or not informed about their employer's level of coverage should not incur a penalty for late enrollment in the Part D program. In addition, retirees should not incur a penalty if their employer's Actuarial Attestation was not filed in a timely manner.

VI. Plan Sponsor

Definition. CMS should confirm that the "plan sponsor" of a multiemployer plan is the same as provided for in ERISA Section 3(16)(B).

The proposed regulations (42 CFR § 423.882) repeat the statutory exception for certain jointly administered arrangements maintained by a single employer. In that case, contrary to Section 3(16)(B) of the Employee Retirement Income Security Act of 1974, as amended, the sponsor is deemed to be the employer if "the employer is the primary source of financing."

In many situations, a collective bargaining agreement defines the employer's retiree health obligation as a specified contribution to a trust, qualified as a voluntary employees beneficiary association (VEBA) under Section 501(c)(9) of the Internal Revenue Code, and as a result, the retiree health benefits to be provided are limited to those that may be funded by the employer and retiree contributions (as well as any investment return). There is no reason for these situations to be treated any differently than jointly administered multiemployer plans. It is the trust that finances the benefits and in order to avoid a windfall to the employer, it is the trust that should be entitled to payment of the subsidy. CMS should clarify that in these kinds of arrangements – in which the employer's only obligation is a defined contribution to a trust and the plan in fact is financed by the trust – the VEBA or similar plan setup, not the employer, is the primary source of financing.

Further, CMS should clarify which entity is the plan sponsor in certain public-sector arrangements that are not present in the private sector. For example, in the case of a plan covering the retirees of one or more public employers and maintained by a designated representative or group of designated representatives (typically, a retirement board, board of trustees or office designated as responsible by the public employer(s) for maintaining the benefits) of the parties establishing the plan, the plan sponsor should be that designated representative or group of representatives. Also in the public sector, in the case of a benefit financed by a welfare trust fund established or maintained by an employee organization through reimbursements to retirees, or that provides the prescription drug benefit itself, that trust fund providing reimbursements for the prescription drug benefit should be considered the plan sponsor, even if access to the benefit is offered through a group health plan established by another entity, such as a public employer.

Payments to Plan Sponsors. CMS's proposed regulations do not address how the Part D plan sponsor subsidy is paid if the retiree prescription drug benefits are insured (other than through a MA-PD or PDP arrangement). To ensure further that the subsidy is used to preserve retiree prescription drug benefits, the final regulations should assure that the Medicare Part D plan subsidy is paid to the plan sponsor. In no case should an insurer underwriting or administering the plan be paid the subsidy.

VII. The Treatment of HSAs

Comment was requested as to whether to treat payments from Health Savings Accounts (HSAs), Archer Medical Savings Accounts (MSAs), Flexible Spending Arrangements (FSAs), or Health Reimbursement Arrangements (HRAs) as group health plan payments for purposes of counting against True Out of Pocket ("TROOP") costs. CMS states that its strong preference is not to treat HSAs as group health plans, insurance or otherwise, or third party payment arrangements. Under this interpretation, a Medicare beneficiary could withdraw funds from his or her HSA, pay Part D drug expenses, and allow these expenses to count toward the beneficiary's out-of-pocket payments. Medicare catastrophic coverage would consequently begin sooner than if these payments were not counted as TROOP.

CMS states that it believes HSA funds should count toward the beneficiary's incurred costs since the funds are essentially analogous to a beneficiary's bank account. No position is taken regarding whether payments from an HRA or FSA would count against the beneficiary's TROOP costs.

We strongly oppose creating a special exception for these types of accounts by counting payments from them as TROOP costs. Giving preferential treatment to an account like an HSA would provide a financial advantage to employers that offer these types of accounts and would discriminate against employers that provide a comprehensive retiree medical and drug benefit.

VIII. Waivers for Plan Sponsors to contract with or become a Part D Plan or Medicare Advantage plan

Employers that do not choose to provide coverage that qualifies for the subsidy or provide coverage that supplements or wraps around the Part D benefit can instead contract with or become a PDP or Medicare Advantage (MA) plan. CMS indicates that an MA plan or a PDP plan may request, in writing from CMS, a waiver or modification of the Medicare Advantage or Part D requirements that hinder the design of, the offering of, or the enrollment in Medicare Advantage plans by employees or former employees receiving benefits from plans sponsored by employers, labor organizations, or multiemployer plans. MA and PDP plans that receive a waiver may restrict the enrollment to participants and beneficiaries in an employer-sponsored plan. Waivers might include restricting enrollment to the plan sponsor's retirees and offer a benefit that resembles existing active coverage. A waiver might also include authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group.

A waiver process should be established for employers and other plan sponsors to contract with or otherwise create Medicare Part D PDPs and MA plans that serve employment-based populations. Waivers should be published and made easily available online. Existing waivers that were made available to Medicare+Choice plans should be catalogued and placed online so that plan sponsors can determine what requirements have already been considered for waiver.

CMS recognizes that one option available to employers under the MMA is to provide retiree prescription coverage that supplements coverage offered under PDP or MA-PD plans. For this option to work smoothly for employers and other plan sponsors, particularly those with retirees living across the PDP and MA-PD regions to be established, CMS should take appropriate steps to encourage the development of supplemental plans by PDP and MA-PD providers. If both the Part D plan and the supplemental plan are offered a single provider, it may be easier to coordinate benefits.

CMS should consider extending waiver authority to purchasing coalitions involved with employer-sponsored plans. For example, many unions have developed purchasing coalitions that pool membership in order to arrange for contracts with Pharmacy Benefit Managers. These types of purchasing coalitions may be potential PDP plan sponsors. CMS should not preclude waivers for such entities.

Conclusion

CMS has stated in the proposed regulations that the federal subsidy has the potential to stem the erosion of retire health benefits. We believe this goal is laudable and that incorporating the comments included above into the final regulation is necessary in order to meet this goal. We urge CMS to issue final regulations that integrate our comments.

Thank you for your willingness to consider our views. We would be pleased to meet with you to discuss these comments and any other issues on which you are seeking input.

Sincerely,

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Assistant to the President
Government Affairs
AFL-CIO

Carolyn York

Carolyn York
Manager
Collective Bargaining and Compensation
NEA

Submitter : Dr. Steven Daviss **Date & Time:** 10/04/2004 08:10:01

Organization : Maryland Psychiatric Society

Category : Physician

Issue Areas/Comments

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Research indicates that, in general, the earlier one gets EFFECTIVE treatment, the better the outcome. Delays in getting these treatments may result in worse long-term outcome. Access to a variety of drugs with different mechanisms of action and side effect profiles is critical to these patients and their families.

The classification system used by CMS is based on a disease-linked therapeutic category or indications followed by pharmacologic classes primarily based on mechanism of action with some exceptions, i.e., based on chemical structure. However, the draft "Pharmacologic Classes" fail to adequately recognize mechanism of action. For example, lumped together in one class under the heading "Reuptake Inhibitors" are two different classes of tricyclic antidepressants, all the serotonin reuptake inhibitors, and all the dual serotonin and norepinephrine reuptake inhibitors. This lumping together ? also seen in the lumping together of all the atypical antipsychotics into a single drug class ? when carried through to the Pharmacy Benefit Managers who will craft formularies based on these pharmacologic classes, will:

-fail to pass the discouragement-from-enrollment test, and
-fail to pass the non-discrimination test.

Why?

1- Patients now on medications which are tailored to their SPECIFIC needs ? based on mechanism of action, drug side effects (which relate to receptor binding profile), and potential for drug interactions ? may be required to switch to less effective drugs with more unwanted side effects and greater risks of drug interactions.

2- Many psychotropic drugs are metabolized by the liver's P450 enzymes. Some people have genetic variations in these enzymes, which would cause increased drug levels and more side effects. As it turns out, people of African and Asian ancestry have a much greater risk of some of these genetic variations (3- or 4-fold in some cases). Failure to account for these pharmacogenetic differences in the classification scheme may require some individuals to suffer worse side effects due to their genetic profile, discriminating against these populations.

3- Other populations at risk of unintended discrimination will include seniors and those on multiple medications for other medical illnesses.

We anticipate that CMS will work with the APA and other organizations to correct these deficiencies and to improve the safety of drug use based on these categories.

Submitter : David Hanig **Date & Time:** 10/04/2004 08:10:01

Organization : WA State Medical Assistance Administration

Category : State Government

Issue Areas/Comments

Issues 1-10

BACKGROUND

Part 423.774
In completing re-determinations of eligibility, changes in the client?s circumstances must be addressed. However, they are not addressed in these rules. We suggest that the processes for re-determinations and appeals be the same for whether conducted by the State Medicaid agency or SSA. This would provide uniformity in the re-determinations and appeals process.
CMS envisions a verification process whereby States and SSA will build on the existing verification processes used for other programs, maximizing the use of automated data matches for verification of income and certain liquid resources. A major problem is access to data for the States (i.e. data matches with 1099 files from the IRS) and the timeframe needed for building access to data. We do not believe that the automation envisioned will be available when this program is implemented and recommend that this provision be removed.
The section notes that the Act provides that ?statements from financial institutions shall accompany applications in support of the information provided therein,? can not happen automatically. The financial institution statements must be provided by the individual; this will be problematic with this aged, blind and disabled population. Unless liberalized, this requirement will result in many elderly and disabled individuals losing prescription drug coverage. This is not acceptable.
If, as stated in this section, CMS will permit the use of a ?proxy signature process? to allow applications to be taken over the phone or by an Internet process, does this mean that CMS is relaxing their requirement for signatures on applications?
CMS states that the time and effort for an individual or personal representative to complete the low-income subsidy application, provide financial statements and certify that the information provided is accurate is 10 minutes. This estimate is grossly understated. It also does not include the time it will take the individual or personal representative to select a plan. Depending on the number of plans available, selecting a plan could take 30 minutes to two hours for this population.

Section H
CMS did not include the States costs for conducting eligibility determinations for low-income benefits in the estimate of net State savings. They roughly estimate the State share of costs for these determinations at approximately $100 million a year, beginning in FY 2005. Due to the complexity of the program and the incidence of cognitive impairment in this population, we believe this figure is underestimated and should be reconsidered.

Part 423.904
States will be required to begin accepting application forms for the low-income subsidy no later than July 1, 2005. This is not a reasonable expectation. Once rules are established, States will have to adopt new rules, program their technology systems and train staff. Interfaces between State and SSA systems also must be established. July 1, 2005 does not provide enough time to implement this new program. We recommend that states be allowed to provide applicants with the SSA application, provide assistance to complete the application, and forward the application to SSA for determination.

BENEFITS AND BENEFICIARY PROTECTIONS

Enrollment for the Prescription Drug Plans (PDPs) opens on November 15, 2005. If dual eligibles have not selected a plan, CMS states that they will be randomly assigned a plan by December 1 with an effective date of the benefit of January 1, 2006. These plans will have their own formulary and their own network of pharmacies. It is possible that clients will not be assigned to a plan that covers their specific ongoing medications or uses their preferred pharmacy.
? Impact on Clients. Individuals will have only 2 weeks to examine the choice of plans or face auto enrollment. Considering the incidence of dementia, mental disabilities, and confusion in the dual eligible population, a significant number will require assistance to choose a plan. Once they know their plan, they will have only a few weeks to compare the formulary to their own drug profile, obtain different prescriptions for the necessary changes, pick a new pharmacy, and transfer all their prescriptions to the new pharmacy. This all occurs over the holiday season. We recommend providing additional time for dual eligibles to select and convert to a plan. Dual eligibles should also be able to continue receiving existing medications without interruption until the plan can implement changes without destabilizing the condition of the beneficiary.
? Impact on Facilities. Facilities usually have working relationships with a single, main pharmacy. Their individual residents could be auto-

enrolled randomly in PDPs whose formularies are not a good match for the residents? medication profiles and whose network of pharmacies are not used to providing services to their facility and/or providing them the safeguards currently needed at the facilities. Facilities which currently work with a single, main pharmacy may find they need to develop new relationships with many different pharmacies. It is highly likely that facilities will attempt to get each resident enrolled with a ?house? plan. However, the ?house? plan?s formulary may not be the best choice for all of the clients? medication profiles, resulting in chaos as clients and the facility attempt to change medications to match the applicable formulary. Because the Medicare enrollment information is likely to be mailed directly to the resident or their designee, facilities will not know of the plans selected or auto assigned for all of their residents. Since most residents of nursing home, Assisted Living facilities, etc. have Medicare, this, at best, will be an extremely chaotic time for the facilities. We recommend provisions to assure that pharmacies providing services to long-term care facilities be able to participate with all local PDPs or MAs which serve individuals in those facilities.
? Impact on the State. The State will be unable to obtain federal match for any Part D medications for dual eligibles after January 1, 2006; therefore, any attempts to ease this transition would be very costly for the State. In addition, for the significant number of Medicare/Medicaid eligibles unable to choose their own plan (such as those with developmental disabilities, mental health issues, or dementia), the 2 weeks prior to auto enrollment will create an impossible workload for DSHS and AAA staff and providers who will be assisting clients with their choices. With such a tight timeframe and the holiday season, it will be impossible to hire sufficient staff, even if properly funded. Moreover, it is not yet clear whether the State will have responsibility to auto-enroll dual eligibles. If so, this would create a workload at a time when staff are dealing with end-of-calendar year requirements. We recommend providing additional time for dual eligibles to select and convert to a plan.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Transition Issues

There will be transition issues that adversely affect a very vulnerable population unless adequate provisions are made. Part D enrollment represents incredibly complicated system changes occurring over the holiday season. At best, dual eligibles will have 3 weeks to identify which of their current medications do not match their new plan?s formulary, contact their physician, obtain a new prescription, send that new prescription to their new pharmacy and pick up their medications. In addition, they may need to switch the remaining prescriptions to an in-network pharmacy. When you consider dual eligibles who reside in some sort of congregate care, either nursing facilities or a variety of community-based care settings, this becomes even more difficult. Facilities frequently use one major pharmacy and in this transition there will have to be extensive, timely work with residents to ensure that appropriate plans are chosen, or facilities will have to develop business relationships and communication with numerous, potentially unknown pharmacies. In order to protect the health and welfare of the most vulnerable beneficiaries, CMS should incorporate the following protections:
? Require Part D plans to reimburse current pharmacies for current medications for at least 6 months. This will allow a smooth transition for all parties and allow prescriptions to be switched to formulary medications and allow everyone to switch to in-network pharmacies in a manner that does not endanger health.
? Allow States to obtain federal financial participation for any wrap-around medication until July 1, 2006. It is not likely that auto- enrollment will be a completely smooth process without errors. In addition, many disabled and elderly individuals in the dual eligible population will be confused by change and paperwork. There will be beneficiaries who accidentally opt out of Part D and will lose all drug coverage, placing their health in jeopardy, increasing hospitalizations, and placing the facilities and homes in an untenable position. Licensing requirements (including federal regulations for nursing facilities) require them to meet the health needs of their clients; but there will be no resources to purchase these needed medications. States need the option to provide a matched program to assist dual eligible citizens whose health could be harmed in this transition without coverage.
? CMS must develop the system to notify the facilities of each resident?s plan choice.

GENERAL PROVISIONS

General

The responsibility is given to State Medicaid offices and Social Security for eligibility determinations for the low-income subsidies, increasing the workload substantially in providing information, making eligibility determinations for known and also for all the currently unknown clients, training staff and dealing with appeals. Despite the additional workload, states will receive at most 50% FFP. This represents an unfunded mandate and states require additional federal dollars to perform these new duties.

SPECIAL RULES FOR STATES

Part 423.34
This section states that a process will be established to automatically enroll full benefit dual-eligible individuals who fail to enroll in a PDP or MA-PD plan timely. We recommend that this function be fulfilled by a CMS hired outside contractor. Benefits include:
? Nationally consistent information dissemination
? Nationally consistent implementation
? Nationally consistent oversight of the function
? Reduction of information dissemination between States and CMS regarding this function.
Prior to the automatic enrollment this section mentions a widespread education and information campaign to equip full benefit dual-eligibles to make an informed decision on enrollment. This education and information campaign is not described: how the information will be distributed, especially for the transition of the full benefit dual-eligible people when this law is implemented 1/06. States need more information about how CMS will distribute the information and assist this population in selecting a plan that will work for them.
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There is no definition of ?institutionalized individuals? ? the assumption is that the definition is the same as in Part 423.772 and excludes full benefit dual eligible individuals receiving services under a waiver program or those in ICF/MRs.

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Under the proposed regulations, prescription drug plans are required to cover only two medications in each therapeutic category and class. PDPs are not at risk for down-stream health costs from an inadequate drug formulary and the better bid prices of a limited number of formulary medications create a fiscal incentive to limit formularies. This is acceptable for some categories and classes, but not all. For some clients there will be a significant risk to their health if they are required to switch medications, or the client and their physician will be required to appeal through a potentially cumbersome process. A multi-state consortium has examined several drug classes and concluded that anti-seizure medications and atypical antipsychotics should not be limited for current recipients of these medications. The regulations should be revised to reflect this and similar evidence-based pharmaceutical reviews in order to protect the health and safety of the beneficiaries. In the absence of this change, we anticipate that many individuals with mental disabilities will destabilize and require costly hospitalizations and endure increased symptoms. At a minimum, the regulations should require PDPs to provide current medications to current recipients of antipsychotics and anti-seizure medications indefinitely.

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The proposed regulations is not clear whether individuals in 1915c waivers and 1115 waivers should be treated as fully Medicaid eligible, making them eligible for full dual benefits. We recommend clarifying that individuals in 1915c and 1115 community-based care waivers be treated as full Medicaid dual eligibles.

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While all dual-eligible individuals and SSI beneficiaries will be eligible for the full low-income subsidy without regard to income and resources, co-payment subsidies for these individual will vary depending on their institutional status and income. Institutionalized full-benefit dual eligibles pay no co-payments. The definition of ?institutionalized? in Part 423.772 excludes waiver program individuals, resulting in waiver program clients paying co-payments. Waiver program clients also participate in the cost of their services. Their participation is reduced by the cost of their medical expenses and since the co-payments are considered a medical expense, the client?s participation will have to be adjusted regularly. This will create a significant workload for the Medicaid agencies. We recommend changing the definition of ?institutionalized individual? to include clients receiving waiver program services since they already have to participate in the cost of their care.

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Medicare Modernization Act (MMA)
Comments on Regulations
Washington State Summary

General

The responsibility is given to State Medicaid offices and Social Security for eligibility determinations for the low-income subsidies, increasing the workload substantially in providing information, making eligibility determinations for known and also for all the currently unknown clients, training staff and dealing with appeals. Despite the additional workload, states will receive at most 50% FFP. This represents an unfunded mandate and states require additional federal dollars to perform these new duties.

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- Reduction of information dissemination between States and CMS regarding this function.

Prior to the automatic enrollment this section mentions a widespread education and information campaign to equip full benefit dual-eligibles to make an informed decision on enrollment. This education and information campaign is not described: how the information will be distributed, especially for the transition of the full benefit dual-eligible people when this law is implemented 1/06. States need more information about how CMS will distribute the information and assist this population in selecting a plan that will work for them.

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program clients also participate in the cost of their services. Their participation is reduced by the cost of their medical expenses and since the co-payments are considered a medical expense, the client's participation will have to be adjusted regularly. This will create a significant workload for the Medicaid agencies. We recommend changing the definition of "institutionalized individual" to include clients receiving waiver program services since they already have to participate in the cost of their care and they are full-benefit dual eligible individuals.

According to this section states would:

- Use the rules of the SSI program in making income determinations for the low-income subsidy, rather than using more liberal methodologies under 1902(r) (2). This means the States will have to adopt new rules for this program.
- **Not** use the rules of the SSI program in making resource determinations. Countable resources and the resource standard would be different than SSI resource rules, again, requiring States to adopt new rules for this program.

CMS does not believe that this policy will have a significant impact on program costs because the administrative savings resulting from a more simplified program would offset the program costs associated with not counting non-liquid resource other than countable real estate.

We do not agree. The inconsistency between programs will result in new rules being adopted requiring staff training and additional programming for technology systems, and will be error prone in delivery of eligibility determinations.

Part 423.774

In completing re-determinations of eligibility, changes in the client's circumstances must be addressed. However, they are not addressed in these rules. We suggest that the processes for re-determinations and appeals be the same for whether conducted by the State Medicaid agency or SSA. This would provide uniformity in the re-determinations and appeals process.

CMS envisions a verification process whereby States and SSA will build on the existing verification processes used for other programs, maximizing the use of automated data matches for verification of income and certain liquid resources. A major problem is access to data for the States (i.e. data matches with 1099 files from the IRS) and the timeframe needed for building access to data. We do not believe that the automation envisioned will be available when this program is implemented and recommend that this provision be removed.

The section notes that the Act provides that "statements from financial institutions shall accompany applications in support of the information provided therein," can not happen automatically. The financial institution statements must be provided by the individual; this will be problematic with this aged, blind and disabled population. Unless liberalized, this requirement will result in many elderly and disabled individuals losing prescription drug coverage. This is not acceptable.

If, as stated in this section, CMS will permit the use of a "proxy signature process" to allow applications to be taken over the phone or by an Internet process, does this mean that CMS is relaxing their requirement for signatures on applications?

CMS states that the time and effort for an individual or personal representative to complete the low-income subsidy application, provide financial statements and certify that the information provided is accurate is 10 minutes. This estimate is grossly understated. It also does not include the time it will take the individual or personal representative to select a plan. Depending

on the number of plans available, selecting a plan could take 30 minutes to two hours for this population.

Section H

CMS did not include the States costs for conducting eligibility determinations for low-income benefits in the estimate of net State savings. They roughly estimate the State share of costs for these determinations at approximately $100 million a year, beginning in FY 2005. Due to the complexity of the program and the incidence of cognitive impairment in this population, we believe this figure is underestimated and should be reconsidered.

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States will be required to begin accepting application forms for the low-income subsidy no later than July 1, 2005. This is not a reasonable expectation. Once rules are established, States will have to adopt new rules, program their technology systems and train staff. Interfaces between State and SSA systems also must be established. July 1, 2005 does not provide enough time to implement this new program. We recommend that states be allowed to provide applicants with the SSA application, provide assistance to complete the application, and forward the application to SSA for determination.

CMS-4068-P-1271

Submitter : Mrs. Mary Ninos **Date & Time:** 10/04/2004 08:10:51

Organization : Coventry Health Care

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached Word document

CMS-4068-P-1271-Attach-1.doc

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4069–P
P.O. Box 814
Baltimore, Maryland 21244

Subject: Medicare Program: Establishment of the Medicare Advantage Program [File Code CMS-4069-P]

Coventry Health Care, Inc. (Coventry) is pleased to provide comments to the proposed rules published Tuesday, August 3, 2004, Part III Department of Health and Human Services, Centers for Medicare and Medicaid Services, 42CFR Parts 417 and 422 Medicare Program; Establishment of the Medicare Advantage Program; Proposed Rule.

Coventry Health Care is a managed health care company established in 1986 and based in Bethesda, Maryland operating health plans and insurance companies under the names Coventry Health Care, Coventry Health and Life, Altius Health Plans, Carelink Health Plans, Group Health Plan, HealthAmerica, HealthAssurance, HealthCare USA, OmniCare, PersonalCare, SouthCare, Southern Health and WellPath.

The Company provides a full range of managed care products and services, including HMO, PPO, POS, Medicare Advantage (MA), Medicaid, and Network Rental to 3.1 million members in a broad cross section of employer and government-funded groups in 14 markets throughout the Midwest, Mid-Atlantic and Southeast United States.

Coventry Health Care serves approximately 70,000 MA members through contracts with CMS in four of its subsidiary plans: Health America of Pennsylvania/ Health Assurance, Carelink Health Plans, Group Health Plan, Coventry Health Care of Kansas and PPO Demonstration contracts through Coventry Health and Life and Health Assurance.

Coventry supports the Medicare Modernization Act of 2003 (MMA) and applauds Congress for increasing benefits and coverage opportunities for Medicare Beneficiaries through this legislation. Coventry is committed to work with CMS to continue to provide high quality, affordable health care to our members. We appreciate CMS' providing this opportunity to comment and express our concerns on the proposed rule for Title I and II.

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General Comments on Competitive Bid

Although not specific to sections of the proposed rule, Coventry would like to convey some of our concerns regarding the competitive bid and its potential impact.

Pre-MMA, local plans received a pre-determined amount from CMS, subject to risk adjustment, to cover traditional Part A and Part B services and supplemental benefits, which in many cases included prescription drug benefits. Health Plans had the flexibility to designate supplemental benefits as optional or mandatory to best meet the needs of beneficiaries and respond to market demand. Efficient plans with strong provider networks and effective utilization, care and disease management programs had additional funds for supplemental benefits and could offer more competitive products than their less efficient counterparts.

Separating the bid into three distinct components and prohibiting subsidization of one component with another penalizes the more efficient plans and may ultimately result in increased medical costs. For example, for years the health care industry has struggled with increased prescription drug costs, inadequate information systems and data limitations on plans' abilities to identify, group and analyze episodes of care. With the advent of systems that identify episodes of care, it is now possible to determine the efficacy of specific prescription drugs. Research has shown that although a specific drug may cost more, the total episode of care may cost less than total episode costs associated with lower cost alternative drugs. Requiring plans to prepare separate Parts A & B and Part D bids, may ultimately result in higher total medical cost because the emphasis is placed on the individual components and not the cost of care in its entirety.

Additionally, the current structure of the bid process that requires multiple bid components based on estimated benchmarks that are actuarially normalized for average (not actual) populations will by design, require resubmission (possibly multiple times) once benchmarks are determined. This process is overly complex and burdensome to the private sector. CMS should consider a more straightforward bid process similar to the FEHBP.

Under the current ACR process, MA-plans file their basic employer group package. Employer groups then "buy-up" additional benefits to best meet the needs of their retirees. Coventry would like CMS to clarify the impact of competitive bid on the employer group waiver and whether employer groups can continue to offer limited drug benefits under part C if they forgo the Rx subsidy and Part D coverage is not purchased by or on behalf of the eligible retirees. Likewise please clarify whether MA plans offer a non- actuarially equivalent prescription drug benefit for Medicare beneficiaries who choose not to purchase Part D.

Availability of 2002 and 2003 5% sample data.
Because many of the plans who will apply to be a regional MA plan will not have experience in all areas, it is important that CMS work to make available the 2002 5% sample data (with a denominator file where the members can be tied to the claims) as well as the 2003 5% sample data as soon as possible.

Part 422 Medicare Advantage Program: File Code CMS 4069-P

Subpart A - General Provisions

Section 422.2 Definitions: Special Needs Individual (SNI): Coventry supports the establishment of special needs plans for dual eligibles, the institutionalized, and subgroups such as ESRD and AIDS. CMS should allow MA plans the flexibility to develop disease-focused innovations in health care delivery that use the appropriate mix of services to meet the individual's care needs, both acute and long-term. We encourage CMS to use demonstration authority to support the development of such plans. Special Needs Plans should be permitted to bid the Cost of Care against a Benchmark that recognizes the significantly more complex needs of these individuals and have the flexibility to disenroll members who no longer meet the criteria for membership

Subpart B - Eligibility, Election, and Enrollment.

The lock-in provision will decrease choices available to Medicare beneficiaries under the MMA. This provision will discourage Medicare beneficiaries from enrolling in private plans for fear of becoming trapped in a plan that may not meet their expectations or meet their future needs should their circumstances change. Currently beneficiaries understand that they can "opt out" of an individual MA Plan at any time, so there is no penalty for trying something new. This knowledge helps to overcome natural reluctance to change. Medicare Supplements are not bound by a "lock-in" and many potential members will prefer the fact that they can change to being legally unable to change insurers; in effect the proposed lock-in may discriminate against MA plans and will have a negative consumer effect. CMS' projections of tripling enrollment in private plans over the next 5 years will be seriously jeopardized if the lock-in provision is enacted. Operationally, the lock-in makes it difficult to maintain dedicated sales staff so critical to assisting Medicare Beneficiaries in making an informed choice. Rather CMS should allow Plans to develop incentives for members to stay with a Plan through quality improvement activities or more tangible benefit variations or value added services. Likewise Medicare Beneficiaries who are aging into Medicare should make positive selection of the insurer or health plan they prefer based on informed choice and should not default to either system.

CMS will need to clarify operational issues on the status of Part D members who fail to pay the Part D premium; will they be locked into the MA-PD Plan? Does the member default to a non-drug plan? Can members default to a zero premium plan if available in case of non-payment? Does that become an election under lock-in?

Subpart C - Benefits and Beneficiary Protections.

Coventry Health Care, Inc. supports the Centers for Medicare and Medicaid Services efforts to reduce overly burdensome administrative requirements. These include relaxing the 90-Day Notice Period for Non-payment of Premium to 30 days with notices, establishing a web site with functionality to include: document lookup, electronic enrollments on a secure site. CMS should consider the use of e-mail or web site as adequate distribution of certain required member notices, including EOC, SOB, ANOC. In this on-going process Coventry recommends that File and Use requirements should be clarified and reviewers should apply them consistently. Since CMS has indicated that many of the administrative and marketing requirements are under ongoing review, a degree of flexibility to allow for various 'gray area' situations should be built into the criteria. The File and Use program has not had much participation throughout its history in the M+C program and we would hope that CMS would review the limited participation as an indication that the program is not designed to encourage Plan participation. We would recommend an overhaul to the program to include a broader range of materials that can be approved under the File and Use umbrella, a more specific and precise list of what constitutes "materially accurate" or "materially inaccurate materials". We would also suggest that the File and Use be a designation that is perpetual and not granted on a calendar quarter basis.

Similarly the Internet is a relatively new and evolving Media, we would encourage less regulation to allow for creativity and innovation.

Coventry supports a re-definition of the ER Cost Sharing to indicate that it applies to use of Emergency Department. Ability to vary the ER Co Pay enables Plans to encourage members to contact their Primary Care Physician so that members health care needs are identified and coordinated without deterring patients who must have emergency care. CMS should consider raising the maximum copay of $50 on emergency services to $200, which is much more in line with copay requirements on commercial health plans.

Subpart D - Quality Improvement Program

We encourage CMS to consider the issue of parity between competing plans and Fee for Service (FFS) It is important that all Plans serving Medicare Beneficiaries focus on the needs of the members, from preventive care to palliative care. CMS should apply requirements for quality standards and health outcomes' improvements equally and avoid the imposition of strict criteria on certain MA Plans. The degree of flexibility CMS has

recently supported will allow plans to focus on member needs, encourage innovation and result in competition on quality outcomes.

Providing consumers with timely and appropriate information on measurable quality indicators is of vital importance. In a quality improvement environment this information must be timely to be relevant to the decision-maker. The current proposed Performance Assessments inputs are dated and don't accurately reflect the current status of the health plan. This outdated information should not be put forward to the public to use for decision making particularly given the market dynamics of the past several years. This is even more important if comparable data is not published for regional MA PPOs or traditional Fee for Service providers.

The use of HOS Survey data to stack-rank Health Plans when there is no benchmark should be discouraged. This survey should be paid for from savings.

Subpart F-Submission of Bids, Premiums, and Related Information and Plan Approval.

ESRD

Coventry encourages CMS to exclude the ESRD members from the 2006 competitive bid process because of the absence of data related to disease staging and lack of credibility of current plan data. The inclusion of ESRD with incomplete or unreliable data may jeopardize the competitiveness of the Plan bid for traditional Parts A and B services and compromise plans' abilities to assess savings available to fund supplemental benefits. This could lead to fewer benefits for Beneficiaries since MA Plans will be unable to assess true savings. In addition, the inclusion of ESRD increases the complexity of the initial first year bid.

Maximum Cost Sharing Calculation

In calculating the maximum cost sharing for the basic A/B bid the cost share should reflect the MA Plan-specific proportional amounts based on the MA organization's pricing and utilization estimates. MA Plan members have traditionally used a different mix of services than Fee for Service beneficiaries. Plans seek to use the most appropriate level of care. Negotiated provider and physician arrangements are also a factor. This results in higher rates of home care and sub-acute services and lower inpatient stays. This efficiency should be reflected in the actuarially equivalent cost share. This meets the goal to increase benefits to the Medicare beneficiary through improved efficiency and effectiveness within the health care delivery system.

Application of Risk Adjuster in Calculation of the Saving

Further analyses are needed to determine whether CMS should adopt a Plan specific or state-wide/region specific methodology for the calculation of savings. Given variations in cost and utilization, a state-wide/regional approach may inadvertently penalize some

Plans and create windfalls for others if cost, utilization, and population risk scores underlying the bid differ widely from benchmarks.

Plan specific risk adjusters increase the administrative burden of calculating savings. Depending upon the statistical/actuarial validity of a plan's population, plan specific risk scores may prove unreliable and result in under/over calculation of savings. Plan specific scores are also more likely to be subject to fluctuation caused by enrollments/disenrollments, changes in member demographics as well as the progression of disease states. If plan specific risk scores differ markedly from their peers, they may be placed at a competitive disadvantage because, "on paper", they cannot support the same level of supplemental benefits as other plans within the region.

County specific risk scores may mitigate problems associated with both approaches and would be consistent with CMS reimbursement prior to Competitive Bid.

Induced Utilization

Under competitive bid, plans must bid for FFS Part A & Part B services and supplemental benefits separately. CMS has indicated that the induced utilization related to reductions in copays should be recorded in the supplemental benefit bid. Coventry believes that the current FFS utilization already includes utilization increases related to copay reductions because a large proportion of the Medicare FFS beneficiaries purchase Medicare supplement policies. The inclusion of induced utilization under supplemental benefits penalizes health plans and decreases funds available to fund supplemental benefits because CMS retains 25% of the calculated savings. From a financial perspective, Coventry believes that the induced utilization component relative to MA plan copay reductions as they relate to actual FFS utilization is negligible and should not be included in the calculation of the supplemental bid. The impact of induced utilization is a legitimate concern for Part D.

Actuarial Certification

In the preamble on Federal register page 46891, the proposed rule states that CMS would verify the reasonableness of the actuarial utilization and pricing projections for optional and mandatory supplemental benefits in the same way they would verify the enrollment numbers and enrollment mix for an optional supplemental product. Coventry requests that CMS clarify and further explain this process.

Coventry would like clarification from CMS on how to develop the 1.0 bid for 2006.

Will CMS require an actuarial certification for each bid component or for each bid or at the H number level? Providing the certification at the H number gives the health plan the maximum flexibility in designing plans to meet market needs.

Subpart G-Payments to Medicare Advantage Organizations

HOSPICE

MA Beneficiaries who choose to enroll in a Medicare Hospice program should also assign their Medicare Rx benefits to the Hospice. Prescription drugs are usually an integral component of hospice care and should be managed by the Provider. Once the member enrolls in a hospice the Health Plan no longer is involved in care management and should not be responsible for prescription drug management.

Additionally, CMS should consider a demonstration allowing beneficiaries to elect hospice while still receiving life saving treatment as a means to overcoming the fear and perceived finality of electing hospice. The well publicized extremely low rate of hospice elections and the short duration of services should trigger some innovative approaches to identifying how to better transition beneficiaries with terminal or advanced illness into a care environment that provides needed and appropriate care, while improving quality of life.

Information in section 422.320. CMS should clarify the requirements to "inform each Medicare enrollee eligible to select Hospice care under 418.24 of this chapter about the availability of Hospice care…". Should this information be provided routinely to certain members based on criteria to be developed or at the request of Physician, Beneficiary, or family?

MSAs

Coventry supports most of the measures CMS is implementing to increase the attractiveness of Medical Savings Accounts (MSA) plans. We are however concerned about CMS' ability to risk adjust premiums and contributions for these members. Given the complexities of risk adjustment, unavailability of mechanisms for member claim/encounter submissions and absence of member incentives to submit claims/encounter data, Coventry is concerned that risk scores for many of these members will be artificially low. In the absence of systems and incentives that encourage members to submit medical expenses that are applied against the deductible, MSA contributions may not be commensurate with the health status and thus risk associated with these members. As a result, members will exceed the deductibles "prematurely" and the plan will be responsible for all medical payments without the benefit of the risk-adjusted revenue. Coventry encourages CMS to explore mechanisms that will increase the likelihood that the risk scores associated with MSA participants will be captured or allow MSAs to elect payment based on demographic tables only. Additionally, CMS should consider allowing MSA Plans to structure non-uniform contributions to MSAs. Since CMS' payment rates to Plans are not uniform, CMS should consider allowing Plans to propose a prospective schedule that determines the amount of the CMS contribution based on the age/sex band of the individual, determined annually as of the first of the year.

Please clarify whether the Proposed Provider rules will now require a Provider accepting Medicare assignment to limit their fee to 100% of Medicare Allowable for members of a Medicare MSA.

Subpart J - Special Rules for MA Regional Plans

Coventry strongly supports the availability of affordable Medicare options to all Medicare beneficiaries that the MMA provides. To this end it is important that regulations meant to encourage these options not disadvantage local Plans or compromise the ability of local plans to compete with regional plans or traditional fee for service options.

CMS should provide similar financial and administrative incentives that will encourage local health Plans to continue to grow and to provide services to Medicare Beneficiaries in uncovered counties. Flexibility in network adequacy standards is as critical to local plans as to regional plans in areas with limited provider competition. The same alternatives for meeting access requirements should be available to both regional and local Plans. This would include funding to contract with essential hospitals. Additionally, CMS should revisit the moratorium on local MA plans for 2006, permitting local as well as regional plans to file expansion or new markets by 6/05 for entry in 1/06.

Inter-Area Adjustment

Coventry would like to understand what potential inter area adjustments CMS is considering in order to comment on the viability of a methodology for adjustment to the revenue. For example is CMS considering a FFS payment relativity adjustment and if so how would this work?

Medicare Program: Medicare Prescription Drug Program [file code:CMS-4068-P]

Although Coventry supports the MMA legislation, we wish to express concerns related to the implementation of the Title I regulation. The administrative burden and costs associated with implementing the grievance and appeals process and ensuring compliance with quality and POS notification requirements may deter sponsors from entering the market. Health Plans may need to re-contract networks to ensure compliance at the point of sale. This will result in additional administrative costs and burden and hinder market entry. CMS should work with the plan sponsors to determine which standards must be implemented immediately and which components can be phased into the program over time.

The aggressive time frames for a June 2005 bid, the unavailability of risk adjusters until April 2005 and the absence of reliable Medicare pharmacy utilization data impedes sponsor's abilities to generate actuarially sound Part D bids and may further limit sponsor participation. Given the ambiguities and the uncertainties surrounding the process would a delayed implementation be possible?

Subpart D-Quality Assurance

423.153(b) Quality Assurance: The current health care delivery system, especially pharmacy is heavily fragmented. Patients may utilize multiple pharmacies including suppliers in Canada and Mexico, receive scripts from multiple providers, receive free-samples form physicians and use different sources of payment depending upon drug coverage - MA plan, discount drug card as well as purchase over-the-counter (OTC) medications. The ability to capture all medications taken by an individual patient including OTC medications is a formidable task and virtually impossible in the absence of a universal electronic prescribing system. The ability to accurately report on medication errors is severely compromised by this fragmentation and is not a reliable quality measure. Coventry supports all efforts to help minimize medication errors but does not believe that health plans should be evaluated based on this statistic given that they have limited abilities to impact the physician or pharmacists prior to filling the prescription. Coventry recommends that CMS work with potential plans to determine which standards can be readily implemented and which should be phased in over time or perhaps eliminated in their entirety.

423.153(c) Medication Therapy Management Programs (MTMP)
The goals of this program is to, (1) enhance the enrollee's understanding through education and counseling on the use of medications, (2) Increase adherence to prescription medications, (3) Detection of adverse drug events and patterns of prescription under-use, (4) performing health assessments, formulation of treatment plans and managing high cost medications, (5) offering a component of coordinated disease management. Currently there is not consensus within the industry on how this program is defined or administered. To date we do not have national accepted payment standards nor do we have the monitoring standard in place for pharmacists.

Many health plans do various forms of MTMP. Coventry recommends that CMS collaborate with health plans and National Pharmacy Organization to evaluate options for MTMP.

Subpart F – Submission of Bids and Monthly Beneficiary Premiums

Coventry strongly encourages CMS to collect the Part D premium as a reduction to the Social Security payment for all Medicare Beneficiaries enrolled in Part D. This clarifies to the beneficiary the nature of the benefit and ensures against members dropping in and out of Part D. There should not be an additional fee charged by the SSA if premium rebates are required.

Can CMS establish safe have rules of qualifying plan designs? Can MA plans offer a non-qualifying plan for members who choose not to enroll in Part D or for employer groups?
Can supplemental benefits be offered to low income members if a portion of the supplemental benefit covers cost share or premium on Part D (which is part of the low-income subsidy)?

Impact Analysis

There is concern that CMS has not developed its pricing estimates using a robust enough experience base; instead relying heavily on self-reported data obtained through the Medicare Current Beneficiary Survey (MCBS) and through high level estimates of projected growth in pharmacy costs derived from the National Health Expenditure projections. It is recommended that CMS seek to obtain program level pharmacy experience from the FEHBP retiree program and other public programs that reflect a large number of geographically diverse Medicare beneficiaries so as to not rely fully on self-reported data, which tends to be biased and incomplete.

There is concern that CMS has not adequately reflected the potential for selection bias in its initial cost estimates. Instead, CMS has relied on the extraordinarily high participation in Part B as indicative of the participation it will see in Part D. There are striking differences in the structure of the benefit, and of the availability of other options that will lead healthier beneficiaries to forego participation.

Because of the proposed structure of the benefit and the doughnut hole, it is easier for Medicare beneficiaries to determine the point at which they would break-even financially if they were to participate. Given a $35 monthly premium and relying on CMS cost estimates, that break-even point occurs at between $800 and $900 of annual pharmacy expense for a beneficiary that does not qualify for low income subsidies. There is a large percentage of beneficiaries (estimated in the 50% range according to the Society of Actuaries: Projected Cost Analysis of Potential Medicare Pharmacy Plan Designs, July 9, 2003) that fit into the segment of beneficiaries with <$1000 of annual pharmacy cost. There will be a large number of other programs including Manufacturer discount programs, limited pharmacy benefits available under MA plans (for those not electing Part D) and other discount programs that will provide attractive alternatives to the healthier segment of beneficiaries.

CMS has proposed a late enrollment penalty as a deterrent for beneficiaries not to forego participation. However, as currently structured, where the penalty is 1% of member premium per month not enrolled, the monthly penalty at a $35 monthly premium amounts to $.35 per month and is inadequate to meet assumed participation levels. At a minimum, we would recommend that CMS consider a more substantial penalty, i.e. 1% of the full program premium per month. Based on the above, CMS' estimate that 99% of "non low income": and non-actively working beneficiaries participate in Part D in 2006 is unrealistic.

In its pricing estimates, CMS assumes a sliding scale of savings estimated to result from the Part D Program. These savings are assumed to result from discounts and cost containment programs. In 2006, the estimate is 15%, growing to 23% in 2010. These savings are estimated to apply to all segments of the program. Because there are severe limitations to cost sharing provisions for the low income population, it is not realistic to expect the same level of savings for this population, where there is little ability to incentivize use of cost effective drugs.

Because of the significant risk of anti-selection under the Program as currently structured for individual Medicare beneficiaries, CMS should consider permitting PDPs to elect to serve employer group sponsored programs only (as a risk segment), where the anti-selection risk is much smaller. There will be a need for employer-sponsored options; allowing PDPs to elect to serve only a group segment will result in more choices and higher potential for employer groups to maintain retiree pharmacy coverage.

Because risk-adjustment for Part D is new, organizations preparing bids will not have the benefit of being able to estimate the impact of risk-adjustment until very late in the bid process, which may not allow sufficient time for full evaluation.

Coventry appreciates the opportunity to submit these comments on the Medicare Advantage program and the Prescription Drug Benefit proposed rules. If you have any questions regarding our comments or require any additional information, please do not hesitate to contact me at (301) 581-5519 or mninos@cvty.com.

Sincerely,

Mary Ninos
Vice President Government Programs
Coventry Health Care, Inc.
6705 Rockledge Drive
Suite 9000
Bethesda, MD 20817

CMS-4068-P-1272

Submitter : Ms. Julie Ward **Date & Time:** 10/04/2004 08:10:22

Organization : United Cerebral Palsy

Category : Consumer Group

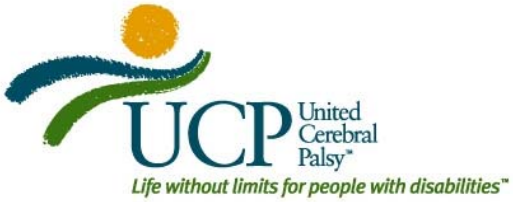
Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter from United Cerebral Palsy regarding the Medicare Prescription Drug Benefit regulations.

CMS-4068-P-1272-Attach-1.doc



October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS – 4068 – P
P.O. Box 8014
Baltimore, MD 21244-8014

To Whom It May Concern:

United Cerebral Palsy (UCP) appreciates the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632, CMS File Code CMS-4068-P. UCP is gravely concerned that the proposed regulations fall short of protecting the health and safety of individuals with disabilities. In order to ensure that Medicare beneficiaries with disabilities have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must be protected from tiered cost-sharing. Furthermore, the inadequate outreach provisions and the cumbersome exceptions and appeals process create nearly insurmountable access barriers for these individuals, their families and providers that serve them. UCP urges the Center for Medicare and Medicaid Services (CMS) to significantly revise the proposed rules to meet the needs of the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

United Cerebral Palsy has been committed to progress for people with disabilities for the last 50 years. The national office and its nationwide network of approximately 100 affiliates strive to ensure the inclusion of people with disabilities in every facet of society. UCP affiliates serve more than 30,000 children and adults with disabilities and their families every day through a variety of programs including therapy, assistive technology training, individual and family support, community living, employment assistance and advocacy. Over 65% of the people served by UCP have disabilities other than cerebral palsy. Individuals served by UCP may have developmental disabilities, mobility impairments, learning disabilities and speech impairments and frequently rely on Medicaid and Medicare for access to health care services.

Every person with a disability is a unique individual, with different medical problems, which mirror the range of health problems that occur in the general population. However, research is showing that older persons with disabilities are more likely to develop secondary conditions or have them worsen over time. Secondary conditions occur because of the presence of the primary disability and may include continuous pain, excessive fatigue, changes in skills or physical conditions fractures from fall or pressure sores from continuous use of a wheelchair.

As they age, adults with cerebral palsy experience multiple physical stresses such as joint and muscle pain, bone and muscle mass losses, changes in gait, arthritic changes, increased respiratory problems causing heart and lung complications and spine and joint changes affecting join and weight bearing. It is estimated that 10% of adults with cerebral palsy have cardiovascular problems and there appears to be excess mortality as compared to the general population. Cerebral palsy is also often associated with neurological conditions that require medication treatment, for example about 33% of adults with cerebral palsy have seizures. Many individuals with cerebral palsy also use medications to treat dystonia and muscle spasticity

The medical management of these primary and secondary conditions is complex. Finding the right medications may take time and careful attention must be made to drug interactions and side effects. For these reasons we strongly support open access to medically necessary medications and strong consumer protections in the regulations.

While we fully endorse the comments of the Consortium for Citizens with Disabilities and the Medicare Consumers Working Group, we are using this opportunity to emphasize the concerns of people with cerebral palsy and their families. UCP believes that significant revisions in the proposed rule are needed in order to ensure that people with disabilities have access to a quality prescription drug benefit and to ensure that full benefit dual-eligible beneficiaries (“dual eligibles”) are not disadvantaged further by inadequate access to needed care. We recommend that CMS take the following steps to protect the health of people with disabilities and chronic conditions:

- Delay the implementation of the Part D program for dual-eligibles
- Expand outreach to Medicare beneficiaries with disabilities
- Designate special populations who will receive affordable access to an alternative formulary
- Impose reasonable limits on cost containment tools
- Strengthen and improve the inadequate and unworkable exceptions and appeals processes
- Require plans to dispense a temporary supply of drugs in emergencies

SUBPART B—ELIGIBILITY AND ENROLLMENT

A successful implementation of the MMA will require strong regulatory protections to ensure that people with disabilities are adequately informed that they must enroll in the Part D program and select a private prescription drug plan. In addition, for many people with disabilities, Medicaid prescription drug coverage will end—dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) must be clearly informed of the need to take action to prevent interruptions in access to prescription drugs.

The final rule must ensure that the enrollment process takes into account the unique needs of people with disabilities and recognizes the exceptional challenges of appropriately educating, screening, and enrolling people with disabilities.

423.34(d)(1), Temporarily Extend Medicaid FFP for Full Benefit Dual Eligibles

UCP is deeply troubled by the very real possibility that CMS will not be able to implement the MMA under the current timeframe in a way that adequately responds to the needs of people with disabilities and that ensures that access to prescription drugs will not be interrupted for dual eligibles for whom drug coverage will transfer from Medicaid to a private Medicare Part D plan. Therefore, in the strongest possible terms, we request that CMS immediately indicate its support for legislation that would delay the implementation of the MMA for dual eligibles.

Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006.

CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit starting on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the likelihood that not all 6.4 million dual-eligibles will be identified, educated, and enrolled in six weeks (from November 15, 2005, the beginning of the enrollment period to January 1, 2006), we recommend that the transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months.

The statute requires auto-enrollment on a random basis for all dual eligibles not enrolled on January 1, 2006. UCP has grave concerns regarding how this process might occur for the following reasons:

- It is very likely that many, if not a majority, of dual eligibles will not be able to enroll by January 1, 2006. Existing caseworkers in non-profits, government offices, or SPAPs will not have sufficient time with all 6.4 million dual eligible beneficiaries to educate them on the myriad choices, finding new providers, counseling them on formularies, or shepherding them through a complex enrollment process.

- Assigning dual eligibles on a random basis will—by statute—steer dual eligible beneficiaries into the lowest-cost plan. As a result of being the lowest cost plan, beneficiaries will have significantly restricted access to medications currently being administered to dual eligible beneficiaries.

- Because many dual eligibles will be enrolled in plans not tailored specifically to their unique needs, many beneficiaries will be forced—within a short span of time—to switch critical medications, find a new network pharmacy, and, at worst, go without medications simply because they did not receive enrollment materials in time.

A delay in implementation is critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation.

423.36(c)(4), Special Enrollment Periods and Dual Eligibles

The selection of an appropriate prescription drug plan for people with disabilities will be especially challenging given their extensive and complex needs. Moreover, individuals may find that despite their best efforts to evaluate their private plan options, they have selected a plan that does not meet their needs or, their needs may change. For these reasons, we support granting dual eligibles special enrollment periods.

It is critical that dual eligibles receive notice explaining their right to a special enrollment period when they enroll in a plan, and every time their PDP changes its plan in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

423.44(d)(2), Disenrollment for Disruptive or Threatening Behavior

We are very concerned that the proposed rules would allow prescription drug plans to disenroll beneficiaries if their behavior is “disruptive, unruly, abusive, uncooperative or

threatening." These provisions create great potential for discrimination against individuals with mental illness and cognitive disabilities.

The proposed provisions will be used purposefully to discriminate against persons with mental illness or other disabilities or will result in discrimination as an indirect consequence of plans not making adequate accommodations for individuals with disabilities, e.g., by training plan personnel on the special needs of these individuals and providing simplified processes for them to use to access the medications they need. Therefore, plans must be required to develop mechanisms for accommodating the needs of beneficiaries with these disabilities, and CMS must provide safeguards to ensure that these individuals do not lose access to drug coverage. The provisions to allow involuntary disenrollment for disruptive behavior must not be included in the final rule.

Additionally, we urge CMS to exclude the proposed expedited disenrollment process in the final rule. This process is offensive and unnecessary - and could lead to abuse by private plans that do not have the cultural competence needed to serve some people with disabilities or who wish to avoid potentially high cost individuals who have significant mental health needs or other types of disabilities.

Alternatively, CMS must provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and must waive the late enrollment penalty for these individuals. Individuals most likely to be disenrolled for disruptive behavior do not have the resources to pay for needed medications out of pocket and would suffer great hardship from losing drug coverage for an extended period.

Section 423.46, Late Enrollment Penalty

UCP urges CMS to delay implementation of a late enrollee penalty for all enrollees for two years. The drug benefit is a new and particularly complex program, especially for many people with disabilities. In our view, many beneficiaries with disabilities will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. During the initial implementation process, people should not be penalized because of the complexity of the program.

After the first two years, CMS should require plans to allow individuals with disabilities a waiver or grace period if they miss an enrollment deadline. These individuals face additional challenges and may need additional time to select a plan and enroll. Furthermore, the rationale for imposing late penalties – i.e., to discourage healthier beneficiaries from waiting to enroll until later – is less likely to apply to people with disabilities who are likely to require on-going treatment for one or more conditions or illnesses.

In addition, after the first two years, implementation of the late enrollment penalty should be delayed for individuals eligible for the low-income subsidy. Again, individuals may not understand that they have to apply separately for the subsidy and a drug plan, and may think application for the subsidy is sufficient. UCP also recommends that the final rule allow enrollees to appeal late enrollment penalties.

Section 423.48, Information about Part D

UCP believes that people with disabilities must have access to information in order to make informed judgments about private plan options. The final rule (rather than guidance) should include binding and enforceable standards defining the information plans must provide to beneficiaries and how they must make this information available. CMS has important obligations to ensure that information is accessible to people with various types of disabilities and the proposed rule is inadequate in this regard.

CMS must require plans to make information available in accessible formats for people who are blind or have low-vision. Materials must also be available in "plain English" for individuals with cognitive disabilities or low-literacy. On request, plans must be required to provide information in Braille, large print, audio-tape or computer disc. In addition, CMS should require that PDPs' Internet web sites are accessible for individuals with vision impairments.

Information should also be provided in languages other than English to reflect the languages spoken in a plan's service area. This should include adequate information about drug plan options and should be provided annually, in writing, and include details about the plan benefit structure, cost-sharing and tiers, formulary, pharmacy network, and the appeals and exception processes.

Need for Targeted Outreach to Beneficiaries with Disabilities

Targeted and hands-on outreach to Medicare beneficiaries with disabilities, especially those with low-incomes, is vitally important in the enrollment process. We strongly urge CMS to develop a specific plan for facilitating enrollment of beneficiaries with disabilities in each region that incorporates collaborative partnerships with state and local agencies and disability advocacy organizations.

SUBPART C- BENEFITS AND BENEFICIARY PROTECTIONS

No section of the proposed rule is more important to ensuring that the Part D program provides a prescription drug benefit that will meet the diverse needs of people with disabilities than subpart C. UCP is deeply concerned that the proposed rule fails to

meet even minimal standards for ensuring that people with disabilities will be able to access Part D drug coverage that meets their needs.

Definition of "Long-Term Care Facility" to Explicitly Include ICF/MRs and Assisted Living Facilities

For people with disabilities residing in residential facilities, including intermediate care facilities for persons with mental retardation and related conditions (ICF/MRs) and assisted living facilities, it is necessary that Part D prescription drug coverage is compatible with the manner in which residential facilities deliver prescription drugs. The final rule must ensure that persons with disabilities residing in residential living facilities are not subject to additional cost-sharing, or out-of-network cost-sharing if they access prescription drugs through a long-term care (LTC) pharmacy.

For this reason, we recommend that the final rule include a definition of "long-term care facility" that explicitly includes ICF/MRs and assisted living facilities. We believe that many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

423.104(e)(2)(ii), Establishing Limits on Tiered Copayments

UCP strongly opposes the provision in the proposed rule that permits Part D plans to "apply tiered co-payments without limit."

The final rule must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs. Permitting unlimited cost-sharing tiers could allow a Part D plan to effectively bar access to clinically necessary covered Part D drugs because cost-sharing is unaffordable and the exceptions process does not include adequate safeguards or standards to ensure a fair review of an individual's request for an exception to a Part D plan's non-preferred cost-sharing.

Moreover, allowing plans unlimited flexibility in establishing cost-sharing tiers increases their opportunity to discriminate against people who need costly medications or who need multiple medications. We also believe that permitting multiple cost-sharing tiers will greatly complicate the ability of CMS to determine actuarial equivalence and to determine that the design of a plan does not substantially discourage enrollment by certain eligible Part D individuals under the plan.

Section 423.120, Access to Covered Part D Drugs

Balancing Convenient Access with Appropriate Payment for Long-Term Care Pharmacies

UCP believes that CMS must propose a way to ensure that plan enrollees residing in long-term care facilities must have access to the LTC pharmacy in the facility where they reside. We could support one of two approaches for achieving an appropriate balance of convenient access with appropriate payment.

The first option is for the final rule to require PDPs to contract with all LTC pharmacies. Alternatively, the final rule could require PDPs to make available a standard contract to all LTC pharmacies. However, plan enrollees residing in facilities where the LTC pharmacy has elected not to contract with a prescription drug plan must be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy.

Further, we believe that there are overlapping responsibilities for the delivery of services between LTC facilities and prescription drug plans. To the extent that prescription drug plans are responsible for coordination and medication management, the final rule should encourage plans to contract with LTC pharmacies to provide these services to the plan's enrollees in long-term care facilities.

1860D-11(e)(2)(D) Authority to Review Plan Designs to Ensure that They Do Not Substantially Discourage Enrollment by Certain Part D Eligible Individuals

UCP is very concerned that plans will discourage enrollment of people with complex medical needs who will need access to a wide variety of medications. CMS must take advantage of every opportunity to ensure this does not happen.

We urge CMS to use the authority provided under section 1860D-11(e)(2)(D) to review plan designs, as part of the bid negotiation process, to ensure that they are not likely to substantially discourage enrollment by certain Part D eligible individuals.

CMS needs to analyze formularies, cost-sharing tiers and cost-sharing levels, and how cost-sharing (including both tiers and levels) is applied to assure that people with the most costly prescriptions are not required to pay a greater percentage of the cost of those drugs.

CMS also needs to assure that a variety of drugs are included in a formulary at the preferred cost-sharing tier to treat chronic conditions and conditions that require more costly treatments. Furthermore, as recommended previously, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-

based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through high cost-sharing for out-of-network access.

423.120(b), Formulary Requirements

UCP has many concerns related to formulary requirements and urges CMS to release a final rule that strengthens the consumer protection requirements and requires special treatment for specific populations.

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must be protected from tiered cost-sharing or burdensome prior authorization procedures that could create insurmountable access barriers.

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing bed rest, unnecessary hospitalizations and even death, on the other. Often, people with disabilities need access to the newest medications, because they have fewer side effects and may represent a better treatment option than older less expensive drugs.

Medicare beneficiaries with disabilities also require access to a broad range of medications. For example, people with spinal cord injuries or diseases of the spinal cord must have access to a broad range of antibiotics. Bacterial infection is a leading cause of hospitalization and death for these individuals. Because bacterial resistance to antibiotics is currently a very serious and growing issue CMS must ensure broad and timely access to a wide variety of antibiotic medications. Bacterial resistance coupled with the common problem associated with individual beneficiary allergies make broad antibiotic access a matter of life and death for this population and the elderly.

Many individuals have multiple disabilities and health conditions making drug interactions a common problem. Frequently, extended release versions of medications are needed to effectively manage these serious and complex medical conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects, making it more important for the doctor to be able to prescribe the best medication for the individual. Often that process takes time since many people with significant disabilities must try multiple medications and only after much experimentation find the medication that is most effective for their circumstance.

The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury or debilitating side effects, as well as hospitalization or other types of costly medical interventions. It can also impact a person's decisions about work. The Ticket to Work and Work Incentives Improvement Act (TTWWIIA) expanded options for states to cover working people with disabilities under their Medicaid programs. Many of these individuals would already be Title II/Medicare eligible. Because of the state buy-in they have been able to access prescription drugs through Medicaid. If the Medicare formularies are limited for people with disabilities, an important purpose of TTWWIIA would be thwarted.

UCP recommends that the final rule provide for alternative, flexible formularies for special populations that would include coverage for all FDA-approved covered Part D drugs. Further, because of the clinical importance of providing access to the specific drugs prescribed, drugs prescribed to these defined populations must be made available at the preferred level of cost-sharing for each drug. We recommend that this treatment apply to the following overlapping special populations:

- **Dual Eligibles:** In enacting the MMA, Congress and the Administration both promised that dual eligibles (persons eligible both for Medicare and Medicaid) would be better off when coverage for prescription drugs is transitioned from Medicaid to Medicare Part D coverage. Historically, the Medicaid prescription drug benefit has been closely tailored to the poor and generally sicker population it serves, providing beneficiaries with a range of drugs that they need with little or no co-payment. Under federal law, states that elect to provide prescription drugs in their Medicaid programs must cover all FDA-approved drugs from every manufacturer that has entered into an agreement with the Secretary of Health and Human Services to pay rebates to states for the products they purchase.

  Dual eligibles include people with disabilities and other serious conditions who need a wide variety of prescription drugs. Medicare prescription drug plans, as programs serving dual eligibles, must be able to respond to a range of disabilities and conditions, including physical impairments and limitations like blindness and spinal cord injury, debilitating psychiatric conditions, and other serious and disabling conditions such as cancer, cerebral palsy, cystic fibrosis, Down syndrome, mental retardation, Parkinson's disease, multiple sclerosis, autism, and HIV/AIDS. If dual eligibles are not to be worse off when Part D prescription drug coverage begins, then they must have continued access to an alternative and flexible formulary that permits treating physicians to prescribe the full range of FDA-approved medications.

- **Institutionalized Populations:** Many, but not all, Medicare beneficiaries residing in nursing facilities and other residential facilities are dual eligibles. The same rationale provided for dual eligibles applies to providing institutionalized individuals access to flexible formularies on the basis of their complex and multiple prescription drug needs. Moreover, although we recommend that any alternative formulary include

access to all FDA-approved medications, should the final rule permit a more restrictive alternative formulary, it must ensure that all drugs included on the formulary of participating LTC pharmacies are included on the plan's formulary, and drugs that are preferred by the LTC pharmacies' formularies must be treated by the plan as a preferred drug.

Institutionalized individuals have limited capacity to pay cost-sharing for non-preferred drugs or to purchase drugs for which coverage has been denied. It is imperative that any alternative formulary provides strong protections that prevent individuals from being charged cost-sharing. For dual eligibles residing in institutions, a condition of eligibility requires them to pledge all, but a nominal personal needs allowance, to the cost of their care. For non-dual eligibles, the high cost of nursing home coverage leaves few remaining resources to pay non-preferred cost-sharing or to purchase drugs for which coverage has been denied.

- **Persons with Life-Threatening Conditions**: These are individuals with a diverse range, but limited number of conditions in which the absence of effective treatment would be life-threatening.

  These individuals must have unrestricted and affordable access to the full range of available treatments. We believe that the MMA intended to ensure that beneficiaries will have access to all needed medications, including newly approved medications. Provisions in the proposed rule are inadequate for persons with life-threatening conditions for whom access to life-saving medications cannot be weighed against the financial interests of for-profit Part D plans. The MMA requires Pharmacy and Therapeutics (P&T) Committees to consider scientific evidence when developing formulary policies. This is an inadequate protection for persons with life-threatening conditions because scientific or clinical evidence often does not exist to support or undermine a new indication for an approved drug or when breakthrough drugs receive FDA approval. This is especially problematic for rare conditions. Further, a major criticism of the MMA is that plans appear to be permitted to wait up to one year before even considering whether to include new drugs on their formulary. Therefore, these individuals must have immediate access to all FDA-approved medications.

- **Persons with Pharmacologically Complex Conditions:** Medications to treat many complex conditions are not generally interchangeable, including those with the same mechanism of action, and have fundamental differences that render them pharmacologically unique.

  In these circumstances, it is inappropriate to permit private plan formulary and cost-sharing policies to drive utilization to specific preferred drugs within a class. UCP recommends that the final rule require the Secretary to seek input from affected

groups and the general public and publish annually a list of conditions for which pharmaceutical management is complex and which have access to an affordable and flexible alternative formulary. This category should encompass.

- Persons with conditions that are recognized for their pharmacological complexity must include, at a minimum, conditions such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS;

- People who require multiple medications to treat many conditions—where drug-to-drug interactions are a critical challenge and where certain formulations might be needed to support adherence to treatment; and,

- Persons taking drugs with a narrow therapeutic index. These drugs are clinically effective and safe only at a narrow dosage range, and generally require blood level monitoring and highly individualized dosing requirements. To allow automatic substitution without physician approval can be deadly.

423.120(b)(1), Development and Revision by Pharmacy and Therapeutics (P&T) Committee

UCP strongly recommends that the final rule ensures that P&T committee decisions are binding on plans.

P&T committees can provide important checks on the profit-seeking motives of private drug plans by bringing research findings and clinical experiences to bear on decisions that will restrict access to certain medications. P&T committees must be empowered to make policy decisions regarding formulary tiers and any clinical programs to encourage the use of preferred medications, including formulary tiers and any clinical programs to encourage the use of preferred medications including prior authorization, fail first and step therapy.

In order to fulfill these critical functions the P&T committees must be charged with a strong mission to promote and protect the health of the beneficiaries. In all cases, the P&T committee should be responsible for ensuring that adequate access is provided for the most clinically efficacious drugs in the preferred tier for all classes of covered drugs. The final regulations should require a majority of the members to be independent and free of conflicts.

The final rule must require P&T committees to have formalized contractual relationships to advise the P&T committee in decision making with respect to areas where the P&T committee does not have adequate clinical expertise. At a minimum, this must include current clinical expertise and current experience in the following areas of medicine:

geriatric medicine, oncology, cardiology, neurology, infectious disease, mental illness, and rare disorders.

The final rule should also require P&T committees to do the following:

- Hold public hearings and receive input from the public prior to the adoption of or revision to plan formularies.
- Specify that meetings of the P&T committee should be open to the public and occur at least quarterly.

In addition, plans should be required to seek input in the P&T committee process from affected enrollee populations, including elderly populations, and a diverse range of organizations representing people with disabilities.

Ensuring the Adequacy of the USP Model Guidelines

We do not support the CMS position that the USP model guidelines should not be required to include classes of drugs if there is no FDA approved drug with an on-label indication for each class, even though there are FDA-approved drugs with commonly accepted off-label uses that would fall within a class. Further, we do not believe it is appropriate for physicians to be given the new burden to "document and justify off-label use in their Part D enrollees' clinical records."

We have urged the USP to make significant changes to the model guidelines to ensure that individuals have access to the medication they require. We are very concerned that in many cases two drugs per class will not provide a sufficient level of access to ensure a quality prescription drug benefit for individuals with disabilities. CMS must ensure that the model guidelines do not create access barriers to clinically appropriate off-label drugs or to newer, more effective medications within the classes.

We were also significantly concerned that the model guidelines did not have classes for the medications used to treat serious long term conditions like multiple sclerosis and that the classes for psychiatric medications and the anti-convulsants require significant revisions.

Standards for determining PDP/MA Formulary Discrimination

We strongly believe that any review standards developed by CMS must be published as legally enforceable regulations and not as guidelines. We urge CMS to develop criteria and standards that do not allow plans to discourage enrollment by requiring higher levels of cost sharing on drugs that disproportionately affect specific groups of beneficiaries. CMS needs to develop standards that can assess whether the formulary

is directing utilization away from efficacious treatments and commonly recognized treatment protocols.

Providing a quality drug benefit to individuals with disabilities will require access to a broad range of medications including many of the newer drugs with fewer side effects. For example, a formulary that only included two anti-convulsants would clearly be discriminatory to people with seizures since epilepsy medications are not interchangeable. Different drugs control different types of seizures and the response to the medication is very individualized. No one or two products of currently available anticonvulsants will be successful for all people with seizures. Access to the medication an individual requires to control their seizures can be a matter of life and death for people with epilepsy.

CMS must also ensure that the formularies do not exclude whole classes of drugs such as immunomodulating drug therapies use to treat multiple sclerosis. This is a significant concern with the USP model guidelines and must be addressed in order to avoid discrimination toward the people who rely on these medications.

Notification Requirements for Formulary Change

UCP believes that the proposed rule provides inadequate notification provisions regarding formulary changes. They are inadequate both for effectively notifying and protecting beneficiaries.

We recommend that if the final rule limits the notice requirements to persons directly affected by the change, then plans must be required to provide notice in writing, mailed directly to beneficiary, 90 days prior to the change, and the notice must inform the beneficiary of their right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary.

423.128 (d), Access to Call Centers

We believe that it is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center. The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program. This is a critical requirement that must be included in the final rule.

423.128(e), Required Information in the Explanation of Benefits

We support the inclusion in the final rule of provisions in the proposed rule regarding elements of the explanation of benefits. These elements, however, must be supplemented by the following:

- **Appeals Rights and Processes:** Information about relevant requirements for accessing the exceptions process, the grievance process, and the appeals process.

- **Access for all Beneficiaries to Formulary Information:** Plans should be required to provide information to all Part D eligible individuals, and not just plan enrollees, about the plan formulary. (See our comments in Subpart B, Section 423.48, Information about Part D.)

- **Including Formulary in Explanation of Benefits**: While we are supportive of the provision in the proposed rule that requires plans to make available access to the plan's formulary, in isolation, this is insufficient. Beneficiaries need precise and detailed information about the formulary both to make an informed choice about enrollment and then to minimize their out-of-pocket costs once enrolled in a plan. Simply giving beneficiaries a description of how they can obtain information about the formulary is insufficient to further the goals of the statute. Plan descriptions should include a detailed formulary, listing not only all the drugs but the tier and amount of co-payment upon which each drug is placed, especially if plans will be allowed to require beneficiaries to pay 100% of the cost of certain formulary drugs.

- **Plan terminations:** 423.128(c)(iii) requires plans to tell all Part D eligible individuals that the part D plan has the right to terminate or not renew its contract, but only if the individuals request this information. Information about the potential for contract termination needs to be included in all plan descriptions and in all marketing materials, and not just if requested by an enrollee or Part D eligible individual.

  Based upon experience with the Medicare+Choice market, the drug plan market will experience volatility that results in adverse consequences to many beneficiaries. The Medicare+Choice model summary of benefits requires this information to be in the summary of benefits and in the evidence of coverage; the same rule should apply for Part D.

SUBPART D – COST CONTROL AND QUALITY IMPROVEMENTS REQUIREMENTS FOR PRESCRIPTION DRUG BENEFIT PLANS

Section 423.150, Scope

The need to limit and prohibit unacceptable cost containment strategies—UCP has serious concerns that the proposed rule contains no restrictions on the ability of plans to use cost-containment tools such as dispensing limits, or prior authorization.

Indeed, the preamble to the proposed rule appears to specifically encourage plans to use such cost management tools, without constraint, to limit the scope of the prescription drug benefit. We believe that this is completely inappropriate, and inconsistent with commitments made by CMS to the Congress and the public.

We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration, and scope of coverage for covered Part D drugs. Specifically, the final rule must prohibit plans from limiting access to covered Part D drugs through limits on the number of drugs that can be dispensed within a month, limiting the number of refills an individual can obtain for a specific drug, or by placing dollar limits on the amount of the prescription drug benefit. For example, research in the mental health field has demonstrated that fewer than six mental health medications per month seriously risks patient health.

UCP also strongly recommends that the final rule explicitly prohibit plans from requiring therapeutic substitution. While the MMA authorizes the use of formularies which could lead prescribers' practices to alter their practice in order to comply with standard Part D plan preferences for covered drugs within a class, we believe that the ultimate authority to decide which specific drug a Medicare beneficiary will receive must reside with the treating physician. Therefore, to protect patient safety and health, the final rule must prohibit plans from requiring or encouraging pharmacists to engage in therapeutic substitution without the advance knowledge and written concurrence of the treating physician. We are encouraged that the preamble to the proposed rule indicates that therapeutic substitution will be prohibited without the prescriber's approval, this prohibition must appear in the text of the final rule.

Further, the use of prior authorization has become a common practice in the private sector and Medicaid. For many Medicare beneficiary populations, the manner in which prior authorization and fail first (or step therapy) systems have been implemented in these other contexts has been clearly unworkable both from the perspective of beneficiaries and treating physicians. Prior authorization can delay necessary and appropriate treatment putting at risk the health and safety of individuals who depend on medications for the management of their conditions.

Prior authorization is particularly burdensome to people in group home settings and institutions where often there may not be a well-informed and aggressive advocate or health care professional to ensure that residents with disabilities get the medication they need.

The final rule must establish clear standards and requirements for Part D plans that elect to adopt prior authorization and fail first policies. In particular, the final rule must require plans to ensure that any system of prior authorization is easily accessible to beneficiaries and physicians, and must impose negligible burdens with respect to time needed to complete the prior authorization process, expense, and information documentation.

Most state Medicaid programs exempt certain types of prescription drugs from prior authorization/fail first policies because of the complexity of the underlying condition, the recognized need for physicians to have broad prescribing flexibility, and the grave clinical consequences that could result if necessary access to prescription drugs is denied. Medicaid experience also shows that when certain populations are not exempted from prior authorization, significant problems arise. We propose that the final rule require the Secretary to consult with the public and publish annually a list of conditions which will be exempted from prior authorization/fail first policies, and should include conditions such as mental illness, epilepsy, HIV/AIDS, multiple sclerosis and cancer, that are widely acknowledged for the difficulty and complexity of pharmaceutical management.

Further, UCP strongly recommends that when prior authorization is imposed, whenever the prior authorization process has not been completed within 24 hours of the time that a prescription was first presented at a pharmacy, plans must be required to dispense a temporary supply of the prescribed drug pending the completion of the prior authorization process, including any time needed to receive an exception process and appeal decision. The final rule must also provide for exigent circumstances when an emergency temporary supply of a prescription drug must be dispensed immediately, without allowing for a 24 hour prior authorization period.

Requiring beneficiaries who have been stabilized on a particular psychiatric or anti-convulsant medication to switch to another medication can be very dangerous for the beneficiary and is not fiscally prudent. It is very difficult to determine which medication will work best for an individual and most have to try many different kinds of medications. Moreover some of these medications stay in the system for a long time (e.g., up to six weeks) and modifications of drug therapy must be done very carefully to avoid dangerous drug interactions. Each failed trial results in suffering and possible worsening of a person's condition.

We recommend that the final rule require plans when enrolling new enrollees to continue for at least six month any prescription drug regimen for all individuals who

have been stabilized on a course of treatment. Moreover, the plan must provide an organization determination within the first month of enrollment for all covered Part D drugs that are part of the treatment regimen and notify, in writing, the beneficiary whether each drug in the regimen is covered and the beneficiary's cost-sharing requirement. Should the plan determine that any drugs in the regimen are not covered, all individuals stabilized on a treatment regimen should be automatically eligible for an exception request, and plans should be prohibited from discontinuing access to all drugs in the regimen pending final resolution of the appeals process.

Cost management tools subject to P&T Committees—In response to a question in the preamble of the proposed rule, we strongly recommend that P&T committees should approve and oversee implementation of utilization management activities of health plans offering the Medicare drug benefit. These committees should be empowered to make policy decisions and be charged with a mission to promote and protect the health of beneficiaries. In overseeing utilization management activities, P&T committees must be empowered to ensure that beneficiaries have access to a variety of drugs that reflect current utilization patterns, research and clinical experience and that take into account the efficacy and side effects of medications in each therapeutic class and the complex needs of an ethnically diverse, co-morbid, and medically complex population.

SUBPART M—GRIEVANCES, COVERAGE DETERMINATIONS, AND APPEALS

Many people with disabilities who are dually-eligible for Medicaid and Medicare have cognitive or mental disabilities which make it more difficult for them to navigate a cumbersome and multi-step appeals process. The final rule must ensure that these individuals who currently receive their prescription drugs through Medicaid are not harmed by the enactment of the MMA. Additionally, for many individuals with a variety of physical and mental disabilities, access to appropriate medication is one of the major factors which allow them to live full and more independent lives in their communities. CMS must ensure that the final rule is consistent with the principles and goals of the President's New Freedom Initiative to ensure that all people with disabilities have the opportunity to live in the community where they belong.

The proposed rule fails to meet the requirements of the Due Process Clause of the Fifth Amendment to the Constitution.

UCP believes that the proposed rule fails to meet Constitutional due process requirements and fails to satisfy the requirements of the statute. As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid beneficiaries, whose prescription requests are not being honored, receive a 72-hour supply of medications pending the

initial coverage request. They are entitled to notice and face-to-face hearings, pending an appeal if their request is denied and they file their appeal within a specified time frame. Currently, all state Medicaid appeals processes are completed more expeditiously than Medicare appeals. Based on this fact and on the fact that the majority of people with disabilities who are dually-eligible for Medicaid and Medicare, have major health care needs, UCP believes it is completely inappropriate for the proposed rule to expose these individuals to a weakened due process system.

The appeals process as described in Subpart M does not accord dually-eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights; with an adequate opportunity to a face-to-face hearing; with an adequate opportunity to have access to care/prescription drugs pending resolution of the appeal; or with a timely process for resolving disputes. While UCP recognizes that the most efficient means of protecting enrollees – which would be to amend the MMA to provide for an appeals process similar to Medicaid -- is beyond the authority of CMS, UCP does believe that CMS can take steps in the final regulations to improve notice and the opportunity for speedy review.

Sections 1860D-4(f), (g), and (h) require that sponsors of Part D plans establish grievance, coverage determination and reconsideration, and appeals processes in accordance with Section 1852 (f) & (g) of the Social Security Act. In addition, CMS – in the settlement of *Grijalva v. Shalala* and in the Medicare Plus Choice program – already has established the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review. UCP strongly recommends that CMS incorporate a similar fast-track process for Part D, which would be more in keeping with due process requirements.

Require plans to have an expedited appeals and exceptions process and to dispense a temporary supply of drugs pending the resolution of an exception request or an appeal.

The proposed system does not ensure that beneficiaries' rights are protected and does not guarantee that beneficiaries have access to needed medications. This is a major cause for concern for UCP. For millions of individuals with disabilities such as epilepsy, mental illness, HIV, Multiple Sclerosis, and spinal cord injuries -- treatment interruptions can lead to serious short-term and long-term problems. For this reason, UCP strongly recommends that the final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

Many people with epilepsy depend on specific medication to control their seizures. A disruption in their medication regimen can cause breakthrough seizures, the consequences of which can be very severe and can include loss of driving privileges, absence from work and hospitalization. Access to a temporary supply of drugs is also

critical for people with physical disabilities such as spinal cord injury (SCI). Urinary tract infections, a common secondary condition of SCI, can worsen quickly and result in kidney infections which can lead to autonomic dysreflexia, a life threatening condition.

For many people with mental illness, access to the one specific medication or the critical combination of specific drugs, is what helps them maintain their mental and physical health as well as their independence and the ability to live a full life in the community. Treatment interruptions for these individuals are just as dangerous to them as is a treatment interruption to a person with a physical disability such as epilepsy.

Our concerns related to treatment interruptions are heightened due to the absence of any adequate protections to ensure that individuals can receive a timely resolution of an appeal. We are also extremely concerned about the lengthy period of time that is allowed to pass before an individual has access to a fair and independent review of their appeal by an independent decision maker at the Administrative Law Judge (ALJ) level. We recognize that the expedited time-frames and the general 72-hour standard are a significant improvement over the standard time-frame of 14 days to make a determination and 30 days for a reconsideration. Nonetheless, from the perspective of individuals with serious and complex health conditions and disabilities, 72 hours is an unacceptable delay.

UCP strongly recommends that the final rule clearly specify that all disputes relating to coverage of Part D drugs for people with disabilities automatically qualify for an expedited decision (for all types of requests including a request for an exception, a grievance, and all level of the appeals). Moreover, we strongly recommend that the final rule clearly require plans to dispense a temporary supply of the drug in dispute pending the final outcome of an appeal.

Strengthen and improve the inadequate and unworkable exceptions and appeals processes by establishing clear standards; expediting decisions; minimizing evidence burdens on physicians; and ensuring that drugs provided through the exceptions process are made available at the "preferred drug" level of cost-sharing.

We are also concerned that the appeals processes outlined in the proposed rule are overly complex, drawn-out, and inaccessible to beneficiaries with disabilities. We are specifically concerned about the impact of such a burdensome process on individuals with cognitive and mental disabilities. We strongly recommend that CMS establish a simpler process that places a priority on ensuring ease of access and rapid results for beneficiaries and their doctors. We also strongly recommend that the final rule include a truly expedited exceptions process for individuals with immediate needs. Under the proposed rule, there are too many levels of internal drug plan appeals that a beneficiary must navigate before receiving a truly independent review by an administrative law judge (ALJ) and the timeframes for plan decisions are unreasonably long.

UCP believes that the provisions in the MMA that call for the creation of an exceptions process are a critical consumer protection that -- if properly crafted through enforceable regulations -- could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. However, as structured in the proposed rule, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and appeals process.

UCP is particularly concerned that the proposed rule would require treating physicians to assert that an exceptions request is based on both clinical experience and scientific evidence. This is an inappropriate standard that most doctors could not meet because scientific experience is not always available to support the knowledge which they acquire through clinical experience treating people with a range of disabilities – from HIV to mental illness – to epilepsy – to cerebral palsy – to spinal cord injury – to MS. UCP recommends that this requirement be eliminated from the final rule.

UCP recommends that CMS revamp the exceptions process to:

1. Establish clear standards by which prescription drug plans must evaluate all exceptions requests;
2. Minimize the time and evidence burdens on treating physicians; and
3. Ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

SUBPART P –PREMIUMS AND COST SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

432.772, Definitions

Institutionalized individual: The definition should include those individuals eligible for home and community based services under a Medicaid waiver (see, e.g., definition of "institutionalized spouse" at 42 U.S.C. § 1396r-5(h)(1)(A)), since those individuals must meet the acuity standards for Medicaid coverage in a nursing facility, and should include individuals in ICF/MRs and individuals in any institution in which they are entitled to a personal needs allowance.

423.782(a)(2)(iii), Dual eligible beneficiaries must not be denied medications for failure to pay co-payments.

Dual eligible beneficiaries will be required to pay $1 for generic drugs and $3 for brand-name drugs under Medicare Part D. Currently under Medicaid statute, an individual cannot be denied a medication for failure to pay a co-payment. Many people with disabilities depend on multiple medications including brand name medications. Even minimal co-payments will create a financial burden for individuals who will be left to choose between paying for medications and meeting other needs, like food and housing.

UCP strongly recommends that in the final rule dual eligibles must maintain the protection that they currently have under Medicaid and not be denied a drug for failure to pay cost sharing.

423.782(a)(iv) and §423.782(b)(2), Low-income individuals should not be denied medications for failure to pay co-payments.

Low-income Medicare beneficiaries between 100% and 150% of the FPL face considerable cost-sharing requirements in the proposed regulations that could prevent them from filling necessary prescriptions. Studies have demonstrated that even minimal levels of cost sharing restrict access to necessary medical care for individuals with low incomes. Individuals between 100% and 135% of FPL must pay $2 for generics and $5 for brand-name drugs. Those between 135% and 150% are required to pay a 15% co-insurance for their drugs. For individuals who require expensive treatments or multiple medications, this requirement will impose an enormous financial burden on thousands of individuals who will be unable to pay out-of-pocket for these medications. Beneficiaries eligible for the full or partial low-income subsidy should not be denied a prescription for failure to pay a co-payment or other co-insurance.

UCP appreciates the opportunity to comment on the proposed rules. If you have questions about our comments please contact Julie Ward, jward@ucp.org or (202) 973-7146.

Sincerely,

Leon Triest
UCP Co-Chair
The Arc and UCP Public Policy Collaboration Steering Committee

CMS-4068-P-1273

Submitter : **Date & Time:** 10/04/2004 08:10:11

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Pharmacy Access Standards: Patient autonomy in choosing healthcare services is a defining characteristic that pharmacists ethically respect when it comes to interacting with our patients. Thus, allowing patients to have fair access to the pharmacy and pharmacy services of their choice is crucial to upholding the patient-pharmacist relationship.

Level Playing Field: While mail order pharmacies do provide some advantages at this time for patients in obtaining their prescription medications, it is important to again consider that it is the patient?s choice in determining which services they would prefer, whether this is thru mail order or thru the traditional retail setting. Face-to-face interactions with patients are essential in developing and furthering the patient-pharmacist relationship. This relationship is the key to the patient care focus of the pharmacy profession.

Medication Therapy Management (MTM) Program: While it is feasible that plans inform providers which patients are eligible for MTM, it can be foreseen that eligibility requirements for MTM may not always allow likely targeted beneficiaries to be selected for eligibility. For example, requirements for eligibility should not deny access to any patient desiring participation in a medication therapy management program due to income or access requirements. While it may not be as feasible to allow access to all individuals who have a need for these services, it should be considered that baseline MTM services are likely to be necessary for many patients, and then follow-up MTM services may be required with discretion to meet the providers? goals for patient outcomes. For example, all patients could have access to baseline MTM services, and further services could be made available based on the plan?s coverage criteria and limitations.

E-Prescribing Incentives: As a student pharmacist, I feel that there are several incentives as to why e-prescribing could be considered a positive widespread initiative within the pharmacy profession. First and foremost, the initiative decreases medication errors in the prescribing and dispensing processes. This initiative also allows for greater accuracy in physician verification and increased awareness about generic prescribing opportunities. Also, access to formulary tier information would prove to be very valuable to all healthcare professionals who depend on access to information about formularies. This includes retail pharmacists, who on a day-to-day basis field many questions from patients related to their prescription drug coverage.

CMS-4068-P-1274

Submitter : Mr. David Viele **Date & Time:** 10/04/2004 08:10:58

Organization : First Health Services Corporation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4068-P-1275

Submitter : Mr. Charles Fallis **Date & Time:** 10/04/2004 09:10:27

Organization : National Association of Retired Federal Employees

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

BACKGROUND

The nearly 400,000 members of the National Association of Retired Federal Employees (NARFE) have significant concerns regarding a broad range of policies and issues presented in the proposed regulations to implement Medicare Part D, the Medicare prescription drug benefit in 69 Federal Register 46632 (August 3, 2004) (File Code CMS-4068-P). We are writing to highlight several critically important areas, which we feel deserve particular attention.

BENEFITS AND BENEFICIARY PROTECTIONS

Qualified prescription drug coverage: We recommend that the final rule define ?person? so that family members can pay for covered Part D cost sharing.

Treatment of Health Savings Accounts (HSAs) as group health plans: We recommend that the final rule clearly state that health saving accounts (HSAs) meet the definition of employment-based retiree health coverage in Sec. 1860D-22 and the ?insurance or otherwise? provision in Sec. 1860D-24 of the MMA. The law precludes contributions from employer sponsored health plans from being counted as incurred costs and counting toward the deductible or out of pocket limit. We do not believe that contributions from one employer-sponsored benefit should receive differential treatment over contributions from another type of employer-sponsored benefit. Therefore, the final rule must not preferentially treat contributions from HSAs and Health Reimbursement Accounts (HRAs) by counting them as incurred costs when contributions from employer-sponsored group health coverage are not counted as an incurred cost.
Establishing limits on tiered copayments: We strongly oppose the provision in the proposed rule that permits Part D plans to ?apply tiered co-payments without limit?. The final rule must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs.

The MMA permits tiered cost sharing so that Part D plans are permitted to incentivize the use of preferred drugs within a class, when it is clinically appropriate. By placing no limits on the use of tiered cost-sharing, the proposed rule undermines the balance achieved by the Congress between permitting plans to use formularies with numerous provisions (including the Pharmacy and Therapeutics (P&T) committee requirements and the exceptions process) that seek to ensure that individuals receive all of the covered Part D drugs they need when medically necessary.

The absence of reasonable limits on cost-sharing tiers combined with an inadequate and unworkable exceptions process would provide Medicare Part D enrollees with a catch-22. Permitting unlimited cost-sharing tiers could permit a Part D plan to effectively bar access to clinically necessary covered Part D drugs because cost-sharing is unaffordable and the exceptions process does not include adequate safeguards or standards to ensure a fair review of an individual?s request for an exception to a Part D plan?s non-preferred cost-sharing. Moreover, allowing plans unlimited flexibility in establishing cost-sharing tiers increases their opportunity to discriminate against people who need costly medications or who need multiple medications. We also believe that permitting multiple cost-sharing tiers will greatly complicate the ability of CMS to determine actuarial equivalence and to determine that the design of a plan does not substantially discourage enrollment by certain eligible Part D eligible individuals under the plan. We also note that, in 2004, 85 percent of private sector plans that use tiered cost sharing had only two or three tiers, (Employer Health Benefits, 2004, Annual Survey, Kaiser Family Foundation and Health Research and Educational Trust, 2004).

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Employer Retiree Subsidy

Allowable retiree costs: In considering allowable costs for a qualified retiree prescription drug plan, CMS must apply a test that considers only an employer?s financial contribution to retiree prescription drug coverage, net of any payments by the retiree.

In addition, to be consistent with the requirements of the law under Section 1860 D?22 and CMS?s own stated goal (69 Federal Register 46741,

August 3, 2004), CMS must require the employer?s contribution to be at least as generous as the net value of the standard Medicare Part D benefit (i.e., the expected amount of paid claims under Medicare Part D minus beneficiary premiums).

Furthermore, as the Preamble discussion makes clear (p. 46736ff), accounting for retiree costs eligible for the subsidy will be a difficult accounting problem that may be subject to confusion or abuse. We believe one of the best ways to ensure a fair and equitable use of the subsidy amounts is to make the information on employer costs and reimbursements from Medicare public data which employee organizations and advocates can monitor.

Actuarial Attestation: CMS has proposed the use of random audits to ensure qualifying employment-based retiree prescription drug plans meet the actuarial equivalence test. However, we suggest that CMS take additional protections against improper payment of the federal subsidy. In order to help accomplish that, the attestation submitted by employers must include information on the assumptions that are the basis for the valuation of the plan for purposes of determining actuarial equivalence. This information must be available for public inspection.

Late enrollment penalties: The appropriate regulation should make it clear that employees should be held harmless from late enrollment penalties in the event that a retiree plan is discovered to have been in violation of creditable coverage due to an error or misrepresentation of the value of a retiree plan.

Payment methods, including provision of necessary information: The information required to be submitted to ensure accurate subsidy payments should include information on how actual spending compares to projected spending (submitted as basis for actuarial equivalence attestation). Such information should be available for public inspection.

Appeals: To provide further protection against improper payment of the employer subsidy, third parties (such as employee and retiree organizations or other advocates) should be granted the right to appeal a CMS determination regarding the actuarial equivalence of an employer?s retiree prescription drug plan.

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

Basic alternative benefit designs that go beyond actuarially equivalent standard coverage: We are strongly opposed to the provisions of Section 423.104(g). We recommend that the final rule exclude provisions for ?enhanced alternative coverage?. The MMA provides for standard prescription drug coverage and alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices.

We believe that the proposed provisions at Section 423.104(g) exceed the authority of the statute and defeat the purpose of the Act, which is to provide meaningful choice of prescription drug plans by eligible Part D beneficiaries. The different options make it virtually impossible to compare plans, and thus make it nearly impossible for older people and people with disabilities to make an informed choice of private plan options. See, for example, Geraldine Dallek, Consumer Protection Issues Raised by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Kaiser Family Foundation, July 2004.

Further, a 2001 study found that ?elderly consumers have much more difficulty accurately using comparative information to inform health plan choice than nonelderly consumers have,? (Judith H. Hibbard and others, ?Is the Informed-Choice Policy Approach Appropriate for Medicare Beneficiaries??, Health Affairs, May/June 2001, Vol. 20, number 3; 199-203). The authors state that, ?given the population-related differences we observed, moving Medicare in the direction of mirroring the market approach used for the under sixty-five population may not be feasible or desirable.? Given that the MMA adopts a consumer choice model, it is imperative that the final rule ensure that elderly beneficiaries and people with disabilities have access to plans with benefit designs that are sufficiently standardized to permit an objective comparison among plan options.

Access to negotiated prices when the beneficiary is responsible for 100 percent cost sharing: We strongly oppose allowing any plan to impose 100 percent cost sharing for any drug. Such cost sharing should be considered as per se discrimination against the group or groups of individuals who require that prescription.

Further, the purpose of the drug benefit is to provide assistance with the high cost of prescription drugs. Therefore, the final rule should require plans to pass along all of their negotiated savings to beneficiaries.

Counting purchases of on-formulary covered Part D drugs as incurred costs: We strongly recommend that the final rule ensure that all beneficiary costs used for the purchase of covered Part D drugs count as incurred costs, including any costs incurred by individuals to purchase a covered Part D drug that is on the plan?s formulary, which has been prescribed by a physician, but which has been denied coverage by the Part D plan.

Requiring PDP sponsors and MA organizations to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call centers: We believe that it is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center. The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program. This is a critical requirement that must be included in the final rule.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Late Enrollment Penalty: We urge CMS to delay implementation of Section 423.46 for all enrollees for two years. The drug benefit is a new program and particularly complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. We see from the Medicare-endorsed prescription drug discount card that, even with significant outreach, the majority of individuals eligible for the low-income subsidy have not yet taken advantage of the $600 subsidy available to them.

We disagree with CMS' observation that healthy beneficiaries will not apply; we believe that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness and cognitive disabilities. The Medicare Part D program is new and confusing. Indeed, people delayed enrollment in the Medicare drug card because they did not understand the program and found the choices overwhelming. Many Medicare beneficiaries will need more than 6 months to understand the program, understand how Part D coordinates with other drug coverage they may have, and then to choose the drug plan that is right for them. During the initial implementation process, people should not be penalized because of the complexity of the program.

Until such time as beneficiaries become familiar with the program, they should not be penalized because of its complications.

Outreach and funding the State Health Insurance Assistance Programs (SHIPs). The preamble references concerns with outreach and enrollment. An extensive network of local, face-to-face counseling services will be needed. The toll free phone number and literature alone will not be adequate.

SHIPs, Area Agencies on Aging (AAA), and other local groups can provide the kind of detailed help needed, but they need additional resources. We believe that the SHIPs and AAAs, and related local counseling services are woefully under-funded. Current funding for SHIPs, even after the much-needed and welcome increases announced this spring, are about 50 to 75 cents per year per beneficiary. This is barely enough for 2 mailings per year, let alone the highly labor intensive one-on-counseling that is needed. The Senate-passed version of the MMA had originally proposed $1 per beneficiary for the SHIPs, but unfortunately that was deleted in the final law. We urge that SHIP/AAA funding be increased further.

Approval of marketing material and enrollment: The marketing rules for the Prescription Drug Plans (PDPs) and Medicare-Advantage (MA)-PDPs should be developed in the historical context of other Medicare programs. From selective marketing to outright fraud, Medicare programs historically have been afflicted with marketing abuses and scams. We urge that CMS be vigilant to identify and prohibit these problematic areas and practices as it develops final regulations.

Procedures to determine and document creditable status of prescription drug coverage: It is absolutely essential that beneficiaries understand whether or not they have creditable coverage. Failure to understand the issue of creditable coverage can lead to a lifetime of higher Part D premiums.

CMS must set forth specific requirements that plans provide information to Medicare beneficiaries enrolled in those plans clearly stating whether or not the coverage they have is creditable.

GENERAL PROVISIONS

We believe that the legislation and regulations should make no Medicare beneficiary worse off than they would have been without this law. The Medicare Moderization Act (MMA) should be a means to improve the quality and quantity of care provided to its constituencies. To ensure that our primary goals are met, we ask the Secretary to institute a second round of comments before promulgating final regulations. The proposed regulations contain many substantive areas about which the Centers for Medicare and Medicaid Services (CMS) seeks broad guidance and for which the agency?s proposal expresses several optional approaches. We find it difficult to imagine that the regulations as proposed will be ready for implementation without a second comment period to follow any CMS revisions that are made.

SUBMISSION OF BIDS, PREMIUMS AND RELATED INFORMATION, AND PLAN APPROVAL

Explanation Of Benefits: We support the inclusion in the final rule of provisions in the proposed rule regarding elements of the explanation of benefits. These elements, however, must be supplemented by:

? Appeals rights and processes: Information about relevant requirements for accessing the exceptions process, the grievance process, and the appeals process.

? Access to formulary information: Plans should be required to provide information to all Part D eligible individuals, and not just plan enrollees, about the plan formulary. Moreover, while we are supportive of the provision in the proposed rule that requires plans to make available access to the plan?s formulary, in isolation, that is insufficient. Beneficiaries need precise and detailed information about the formulary both to make an informed choice about enrollment and then to minimize their out-of-pocket costs once enrolled in a plan. Simply giving beneficiaries a description of how they can obtain information about the formulary is insufficient to further the goals of the statute. Plan descriptions should include a detailed formulary, listing not only all the drugs but the tier and amount of co-payment upon which each drug is placed, especially if plans will be allowed to require beneficiaries to pay 100 percent of the cost of certain formulary drugs.

? Plan terminations: 423.128(c)(iii) requires plans to tell all Part D eligible individuals that the part D plan has the right to terminate or not renew its contract, but only if the individuals request this information. Information about the potential for contract termination needs to be included in all plan descriptions and in all marketing materials, and not just if requested by an enrollee or Part D eligible individual. Based upon experience with the Medicare+Choice (M+C) market, the drug plan market will experience volatility that results in adverse consequences to many beneficiaries. The Medicare+Choice model summary of benefits requires this information to be in the summary of benefits and in the evidence of coverage; the same rule should apply for Part D.

Requiring that an explanation of benefits be provided at least monthly for individuals utilizing their prescription drug benefits in a given month: We recommend that the final rule retain the provision that requires an explanation of benefits be provided at least monthly for individuals utilizing their prescription drug benefits in a given month. The explanation of benefits should include the drugs the plan paid for, the beneficiary cost sharing, whether the deductible has been met, and how much remains to be met in out-of-pocket costs before stop-loss coverage begins. The notice should also tell people how to appeal or to request an exception.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

The grievance and appeals sections need to be simplified and improved. They weaken constitutionally protected rights for all Medicare beneficiaries. As drafted, the time frames for every step of the process is too long. The proposed regulations do not provide adequate and timely, constitutionally required notice, and they do not adequately provide for emergency supplies of medicines while an individual is appealing. Many events (such as a change in formulary) that can harm beneficiaries do not appear to be appealable. CMS should set the criteria plans must use for evaluating requests for exceptions, and not leave the standards to each individual plan. As drafted, the proposed rule sets an impossibly high requirement for receiving an exception to cover non-formulary drug or to provide a formulary drug at a lower tiered cost sharing.

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National Association of Retired Federal Employees
606 North Washington Street
Alexandria, VA 22314

October 4, 2004

Mark McClellan, MD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-814

Dear Administrator McClellan:

The nearly 400,000 members of the National Association of Retired Federal Employees (NARFE) have significant concerns regarding a broad range of policies and issues presented in the proposed regulations to implement Medicare Part D, the Medicare prescription drug benefit in 69 Federal Register 46632 (August 3, 2004) (File Code CMS-4068-P). We are writing to highlight several critically important areas, which we feel deserve particular attention.

We believe that the legislation and regulations should make no Medicare beneficiary worse off than they would have been without this law. The Medicare Moderization Act (MMA) should be a means to improve the quality and quantity of care provided to its constituencies. To ensure that our primary goals are met, we ask the Secretary to institute a second round of comments before promulgating final regulations. The proposed regulations contain many substantive areas about which the Centers for Medicare and Medicaid Services (CMS) seeks broad guidance and for which the agency's proposal expresses several optional approaches. We find it difficult to imagine that the regulations as proposed will be ready for implementation without a second comment period to follow any CMS revisions that are made.

Employer Retiree Subsidy

Allowable retiree costs: In considering allowable costs for a qualified retiree prescription drug plan, CMS must apply a test that considers only an employer's financial contribution to retiree prescription drug coverage, net of any payments by the retiree.

In addition, to be consistent with the requirements of the law under Section 1860 D—22 and CMS's own stated goal (69 *Federal Register* 46741, August 3, 2004), CMS must require the employer's contribution to be at least as generous as the net value of the standard Medicare Part D benefit (i.e., the expected amount of paid claims under Medicare Part D minus beneficiary premiums).

Furthermore, as the Preamble discussion makes clear (p. 46736ff), accounting for retiree costs eligible for the subsidy will be a difficult accounting problem that may be subject to confusion or

abuse. We believe one of the best ways to ensure a fair and equitable use of the subsidy amounts is to make the information on employer costs and reimbursements from Medicare public data which employee organizations and advocates can monitor.

Actuarial Attestation: CMS has proposed the use of random audits to ensure qualifying employment-based retiree prescription drug plans meet the actuarial equivalence test. However, we suggest that CMS take additional protections against improper payment of the federal subsidy. In order to help accomplish that, the attestation submitted by employers must include information on the assumptions that are the basis for the valuation of the plan for purposes of determining actuarial equivalence. This information must be available for public inspection.

Late enrollment penalties: The appropriate regulation should make it clear that employees should be held harmless from late enrollment penalties in the event that a retiree plan is discovered to have been in violation of creditable coverage due to an error or misrepresentation of the value of a retiree plan.

Payment methods, including provision of necessary information: The information required to be submitted to ensure accurate subsidy payments should include information on how actual spending compares to projected spending (submitted as basis for actuarial equivalence attestation). Such information should be available for public inspection.

Appeals: To provide further protection against improper payment of the employer subsidy, third parties (such as employee and retiree organizations or other advocates) should be granted the right to appeal a CMS determination regarding the actuarial equivalence of an employer's retiree prescription drug plan.

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We disagree with CMS' observation that healthy beneficiaries will not apply; we believe that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness and cognitive disabilities. The Medicare Part D program is new and confusing. Indeed, people delayed enrollment in the Medicare drug card because they did not understand the program and found the choices overwhelming. Many Medicare beneficiaries will need more than 6 months to understand the program, understand how Part D coordinates with other drug coverage they may have, and then to choose the drug plan that is right for them. During the initial implementation process, people should not be penalized because of the complexity of the program.

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SHIPs, Area Agencies on Aging (AAA), and other local groups can provide the kind of detailed help needed, but they need additional resources. We believe that the SHIPs and AAAs, and related local counseling services are woefully under-funded. Current funding for SHIPs, even after the much-needed and welcome increases announced this spring, are about 50 to 75 cents per year per beneficiary. This is barely enough for 2 mailings per year, let alone the highly labor intensive one-on-counseling that is needed. The Senate-passed version of the MMA had originally proposed $1 per beneficiary for the SHIPs, but unfortunately that was deleted in the final law. We urge that SHIP/AAA funding be increased further.

Approval of marketing material and enrollment: The marketing rules for the Prescription Drug Plans (PDPs) and Medicare-Advantage (MA)-PDPs should be developed in the historical context of other Medicare programs. From selective marketing to outright fraud, Medicare programs historically have been afflicted with marketing abuses and scams. We urge that CMS be vigilant to identify and prohibit these problematic areas and practices as it develops final regulations.

Procedures to determine and document creditable status of prescription drug coverage: It is absolutely essential that beneficiaries understand whether or not they have creditable coverage. Failure to understand the issue of creditable coverage can lead to a lifetime of higher Part D premiums.

CMS must set forth specific requirements that plans provide information to Medicare beneficiaries enrolled in those plans clearly stating whether or not the coverage they have is creditable.

Qualified prescription drug coverage: We recommend that the final rule define “person” so that family members can pay for covered Part D cost sharing.

Treatment of Health Savings Accounts (HSAs) as group health plans: We recommend that the final rule clearly state that health saving accounts (HSAs) meet the definition of employment-based retiree health coverage in Sec. 1860D-22 and the “insurance or otherwise” provision in Sec. 1860D-24 of the MMA. The law precludes contributions from employer sponsored health plans from being counted as incurred costs and counting toward the deductible or out of pocket limit. We do not believe that contributions from one employer-sponsored benefit should receive differential treatment over contributions from another type of employer-sponsored benefit. Therefore, the final rule must not preferentially treat contributions from HSAs and Health Reimbursement Accounts (HRAs) by counting them as incurred costs when contributions from employer-sponsored group health coverage are not counted as an incurred cost.

Establishing limits on tiered copayments: We strongly oppose the provision in the proposed rule that permits Part D plans to "apply tiered co-payments without limit". The final rule must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs.

The MMA permits tiered cost sharing so that Part D plans are permitted to incentivize the use of preferred drugs within a class, when it is clinically appropriate. By placing no limits on the use of tiered cost-sharing, the proposed rule undermines the balance achieved by the Congress between permitting plans to use formularies with numerous provisions (including the Pharmacy and Therapeutics (P&T) committee requirements and the exceptions process) that seek to ensure that individuals receive all of the covered Part D drugs they need when medically necessary.

The absence of reasonable limits on cost-sharing tiers combined with an inadequate and unworkable exceptions process would provide Medicare Part D enrollees with a catch-22. Permitting unlimited cost-sharing tiers could permit a Part D plan to effectively bar access to clinically necessary covered Part D drugs because cost-sharing is unaffordable and the exceptions process does not include adequate safeguards or standards to ensure a fair review of an individual's request for an exception to a Part D plan's non-preferred cost-sharing. Moreover, allowing plans unlimited flexibility in establishing cost-sharing tiers increases their opportunity to discriminate against people who need costly medications or who need multiple medications. We also believe that permitting multiple cost-sharing tiers will greatly complicate the ability of CMS to determine actuarial equivalence and to determine that the design of a plan does not substantially discourage enrollment by certain eligible Part D eligible individuals under the plan. We also note that, in 2004, 85 percent of private sector plans that use tiered cost sharing had only two or three tiers, (*Employer Health Benefits, 2004, Annual Survey*, Kaiser Family Foundation and Health Research and Educational Trust, 2004).

Basic alternative benefit designs that go beyond actuarially equivalent standard coverage: We are strongly opposed to the provisions of Section 423.104(g). We recommend that the final rule exclude provisions for "enhanced alternative coverage". The MMA provides for standard prescription drug coverage and alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices.

We believe that the proposed provisions at Section 423.104(g) exceed the authority of the statute and defeat the purpose of the Act, which is to provide meaningful choice of prescription drug plans by eligible Part D beneficiaries. The different options make it virtually impossible to compare plans, and thus make it nearly impossible for older people and people with disabilities to make an informed choice of private plan options. See, for example, Geraldine Dallek, *Consumer Protection Issues Raised by the Medicare Prescription Drug, Improvement and Modernization Act of 2003*, Kaiser Family Foundation, July 2004.

Further, a 2001 study found that "elderly consumers have much more difficulty accurately using comparative information to inform health plan choice than nonelderly consumers have," (Judith H. Hibbard and others, "Is the Informed-Choice Policy Approach Appropriate for Medicare Beneficiaries?", *Health Affairs*, May/June 2001, Vol. 20, number 3; 199-203). The authors state that, "given the population-related differences we observed, moving Medicare in the direction of

mirroring the market approach used for the under sixty-five population may not be feasible or desirable." Given that the MMA adopts a consumer choice model, it is imperative that the final rule ensure that elderly beneficiaries and people with disabilities have access to plans with benefit designs that are sufficiently standardized to permit an objective comparison among plan options.

Access to negotiated prices when the beneficiary is responsible for 100 percent cost sharing: We strongly oppose allowing any plan to impose 100 percent cost sharing for any drug. Such cost sharing should be considered as per se discrimination against the group or groups of individuals who require that prescription.

Further, the purpose of the drug benefit is to provide assistance with the high cost of prescription drugs. Therefore, the final rule should require plans to pass along all of their negotiated savings to beneficiaries.

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Requiring PDP sponsors and MA organizations to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call centers: We believe that it is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center. The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program. This is a critical requirement that must be included in the final rule.

Explanation Of Benefits: We support the inclusion in the final rule of provisions in the proposed rule regarding elements of the explanation of benefits. These elements, however, must be supplemented by:

- **Appeals rights and processes:** Information about relevant requirements for accessing the exceptions process, the grievance process, and the appeals process.

- **Access to formulary information:** Plans should be required to provide information to all Part D eligible individuals, and not just plan enrollees, about the plan formulary. Moreover, while we are supportive of the provision in the proposed rule that requires plans to make available access to the plan's formulary, in isolation, that is insufficient. Beneficiaries need precise and detailed information about the formulary both to make an informed choice about enrollment and then to minimize their out-of-pocket costs once enrolled in a plan. Simply giving beneficiaries a description of how they can obtain information about the formulary is insufficient to further the goals of the statute. Plan descriptions should include a detailed

formulary, listing not only all the drugs but the tier and amount of co-payment upon which each drug is placed, especially if plans will be allowed to require beneficiaries to pay 100 percent of the cost of certain formulary drugs.

- **Plan terminations:** 423.128(c)(iii) requires plans to tell all Part D eligible individuals that the part D plan has the right to terminate or not renew its contract, but only if the individuals request this information. Information about the potential for contract termination needs to be included in all plan descriptions and in all marketing materials, and not just if requested by an enrollee or Part D eligible individual. Based upon experience with the Medicare+Choice (M+C) market, the drug plan market will experience volatility that results in adverse consequences to many beneficiaries. The Medicare+Choice model summary of benefits requires this information to be in the summary of benefits and in the evidence of coverage; the same rule should apply for Part D.

Requiring that an explanation of benefits be provided at least monthly for individuals utilizing their prescription drug benefits in a given month: We recommend that the final rule retain the provision that requires an explanation of benefits be provided at least monthly for individuals utilizing their prescription drug benefits in a given month. The explanation of benefits should include the drugs the plan paid for, the beneficiary cost sharing, whether the deductible has been met, and how much remains to be met in out-of-pocket costs before stop-loss coverage begins. The notice should also tell people how to appeal or to request an exception.

Grievances, Coverage Determinations And Appeals

The grievance and appeals sections need to be simplified and improved. They weaken constitutionally protected rights for all Medicare beneficiaries. As drafted, the time frames for every step of the process is too long. The proposed regulations do not provide adequate and timely, constitutionally required notice, and they do not adequately provide for emergency supplies of medicines while an individual is appealing. Many events (such as a change in formulary) that can harm beneficiaries do not appear to be appealable. CMS should set the criteria plans must use for evaluating requests for exceptions, and not leave the standards to each individual plan. As drafted, the proposed rule sets an impossibly high requirement for receiving an exception to cover non-formulary drug or to provide a formulary drug at a lower tiered cost sharing.

Thank you for considering these comments on the proposed regulations to implement Medicare Part D, the Medicare prescription drug benefit in 69 Federal Register 46632 (August 3, 2004).

Sincerely,

Charles L. Fallis
President
National Association of Retired Federal Employees

CMS-4068-P-1276

Submitter : Tim Palmer **Date & Time:** 10/04/2004 08:10:14

Organization : Kings Daughters Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As a pharmacist of Kings Daughters Hospital Home Infusion in Madison Indiana, I am pleased to submit my comments on the proposed rule to implement the new medicare part D prescription drug benefit. Being a small town infusion provider I find myself being both the pharmacist and the billing clerk for our company and therefor have a great appreciation for the daunting task that CMS confronts in implementing this benefit. I applaud CMS for recoginizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system. The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients homes but the essential services, supplies and equipment that are intergral to the provision of home infusion therapy (dispnesing fee option 3 as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans. At that point, Medicare will finally be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

My experience leads me to believe that dispensing fee option 3 is the only proposed option that will enabel Medicare beneficiaries to receive home infuison therapy under the Part D benefit. CMS should follow the well established home infusion per diem model encoded using the national hcpcs S codes. If implemented properly this model will ensure access and avoid duplication of services just as it does in the private payer sector.

Thank you in advance for your consideration
Sincerely,

Tim Palmer R.Ph.
Kings Daughters Hospital Home Infusion
1 KDH Drive
Madison, IN 47250
(812)265-0670 ext 224
PalmerT@kdhhs.org

CMS-4068-P-1277

Submitter : Mr. Paul Tibbits Jr **Date & Time:** 10/04/2004 08:10:52

Organization : American Diabetes Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4068-P-1277-Attach-1.doc

COMMENTS ON THE PROPOSED RULE FOR THE MEDICARE PROGRAM: MEDICARE PRESCRIPTION DRUG BENEFIT

Submitted by the American Diabetes Association
October 04, 2004

Nathaniel Clark, MD
National Vice President, Clinical Affairs

It is the understanding of the American Diabetes Association (ADA) that the proposed rules governing the Medicare Modernization Act (MMA) should promote widespread participation from both drug plans and Medicare beneficiaries. They are also intended to protect consumers from insurer practices that will discourage enrollment. However, ADA is concerned that the proposed rules, as written, will not accomplish these goals. ADA submits the following comments and recommendations regarding the proposed rules for Medicare Part D.

Subpart C - Benefits and Beneficiary Protection.

423.104(e)(2)(ii), Establishing limits on tiered copayments.
ADA opposes the provision that permits Part D plans to "apply tiered co-payments without limit." ADA recommends that the final rule limit the use of tiered cost-sharing by permitting no more than three cost-sharing tiers and by requiring Part D plans to use the same tiers for all classes of drugs.

In allowing tiered cost-sharing, Congress has attempted to balance the need to ensure that beneficiaries have access to all of the covered Part D drugs they need when necessary with the need for cost containment. The MMA permits Part D plans to incentivize the use of preferred drugs within a class when it is clinically appropriate to do so. But by placing no limits on the use of tiered cost-sharing, the proposed rule undermines the balance Congress intended to achieve.

Permitting unlimited co-payment tiers could effectively bar Medicare Part D enrollees from accessing clinically necessary drugs because the cost-sharing might become unaffordable. Moreover, allowing plans unlimited flexibility in establishing cost-sharing tiers increases the potential for discrimination against people who need costly medications or who need multiple medications. ADA also believes that permitting multiple cost-sharing tiers will greatly complicate the ability of CMS to determine actuarial equivalence and to determine whether or not the design of a plan substantially discourages enrollment by certain eligible Part D individuals. ADA also notes that in 2004, 85% of private sector plans that use tiered cost-sharing had only two or three tiers, (*Employer Health Benefits, 2004, Annual Survey*, Kaiser Family Foundation and Health Research and Educational Trust, 2004).

423.120(b) - Formulary requirements.
ADA recommends that the final rule ensures that Pharmaceutical & Therapeutic (P&T) committee decisions are binding on plans. Many Medicare beneficiaries and consumer advocates are gravely concerned by the financial incentives in the MMA for for-profit plans to design formularies and utilize cost management strategies in a way that maximizes profits at the expense of enrollees' interests and in contravention of current standards of clinical practice. The existence of P&T committees, whose purpose is to consider existing scientific knowledge and clinical experience in designing formularies, would be dramatically undermined and would run counter to the statute, unless P&T committee decisions are binding on plans.

ADA also believes that Congress intended for P&T committee decisions to be binding on plans. If P&T committee decisions were intended to be merely advisory, then the provisions requiring independent physician and pharmacist participation would be unnecessary. In other comments, ADA will make clear that it has serious concerns about the independence and integrity of P&T committee decision making. The final rule must take greater steps to shield P&T committee decisions from financial considerations and it must reinforce the independence and broad-based clinical expertise of P&T committees.

423.120 (b)(1) - Development and revision by a pharmacy and therapeutic committee.

The preamble to the proposed rule suggests that P&T members should be "independent and free of conflict with respect to the sponsor and plan" as well as pharmaceutical manufacturers. ADA strongly supports this interpretation and recommends that it be incorporated into the final rule. The essential function of P&T committees is to ensure that formulary- and benefit-design decisions are based on existing scientific knowledge and clinical experience. This function cannot be adequately performed when P&T committees consist of a majority of members who are not independent. As with plan employees, employees of pharmaceutical manufacturers have a conflict and cannot be relied upon to give an impartial and fair view of existing scientific knowledge and clinical evidence.

- **Recommendations for ensuring the independence of P&T committees.** ADA recommends that the final rule include stronger provisions for ensuring the independence and integrity of P&T committees. Critical improvements needed for P&T committees to function effectively are:

    - **P&T Committee Charge:** The final rule should include a charge for P&T committees to "ensure that the interests of enrollees, taking into account the unique needs and co-morbidities commonly associated with aging populations and people with disabilities served by Medicare, are protected by all formulary and benefit design decisions made by the Part D plan." The final rule should also make clear that P&T committees have responsibility for the implementation of the formulary, including the application of a plan's cost-sharing structure (including assigning drugs to specific cost-sharing tiers). In all cases, the P&T committee should be responsible for ensuring that adequate access is provided for the most clinically efficacious drugs in the preferred tier for all classes of covered drugs.

      The final rule should also include provisions for sanctions against P&T committee members when P&T committee decisions are in gross violation of this charge.

    - **P&T Committee Required:** The final rule must clearly state that all prescription drug plans are required to operate a P&T committee, without regard to whether or not they operate a formulary. In cases where plans do not operate formularies, the P&T committee would have responsibility for

implementing the cost-sharing structure and assigning specific drugs to each cost-sharing tier.

- **Expertise:** The final rule should require a numerical majority of P&T committee members to be independent and free of conflict with respect to the sponsor, the plan, and pharmaceutical manufacturers.

  The preamble to the proposed rules encourages plans to "select P&T committee members representing various clinical specialties in order to ensure that all disease states are adequately considered in the development of plan formularies." While ADA recognizes that it will not be possible for any committee to have adequate expertise in all areas, it believes that due to the increasing rates and prevalence of diabetes in the Medicare-eligible population, the final rule should require P&T committees to include at least one member with expertise in endocrinology. At a minimum, the final rule must require P&T committees to have formalized relationships to advise the P&T committee in decision-making in this field if P&T committee members do not have adequate clinical expertise in the area of endocrinology.

- **Transparency and Consumer Involvement:** The final rule must require P&T committees to develop formularies and make benefit-design decisions in a way that is transparent to plan enrollees and the general public. The final rule should require P&T committees to hold public hearings and receive input from the public prior to the adoption or revision of plan formularies. Further, during the P&T committee process, plans should be required to seek input from affected enrollee populations, including a diverse range of disabled populations.

- **Timely Review:** The final rule should require P&T committees to meet at least quarterly, and have processes for making formulary revisions between regularly scheduled meetings based upon new clinical information or FDA approval of medications that could be used for the treatment of life-threatening conditions.

423.120(b)(2) - Inclusion of drugs in all therapeutic categories and classes

The MMA charged the United States Pharmacopeia (USP) with developing "a model set of guidelines that consists of a list of drug categories and classes that may be used by prescription drug plan sponsors and Medicare Advantage organizations to develop formularies for their qualified prescription drug coverage, including their therapeutic categories and classes."[1] The ADA is concerned that the model guidelines set forth by USP will create problems for beneficiaries with diabetes attempting to access their necessary medications in a timely way.

ADA's concerns with the initial draft of USP's guidelines and CMS's proposed rules focus on four (4) areas. These include the following items:

[1] SSA § 1860D-4(b)(3).

1. Drug Classification System for Medications
2. Inclusion of Syringes and Related Insulin Delivery Devices
3. Procedures for Adopting New Therapeutic Categories and Pharmacological Classes
4. Implementation

1. Drug Classification System for Medications

ADA is extremely concerned with the current draft of USP's drug classification system. The Association believes that the pharmacological classes listed under USP's "Blood Glucose Regulating Agents" are not adequate to ensure that Medicare beneficiaries will have proper access to the medications necessary to control and treat their diabetes. The Association is equally concerned that the draft will not provide adequate coverage for insulin needs of people living with diabetes.

The current USP guidelines list "insulins" as one class and "hypoglycemic agents, oral" as another class. In addition, there are then four (4) "recommended subdivisions" of insulin and five (5) "recommended subdivisions" of oral agents.

It is critically important to note that each of the nine (9) aforementioned "recommended subdivisions" is a medically distinct product that functions in a uniquely different way. In order for a person with type 2 diabetes to have access to the best and most medically effective treatment regimen, s/he requires that all nine (9) of the "subdivisions" be available to them. Furthermore, it is equally important for a person with type 1 diabetes to have access to all four (4) recommended subdivisions for insulin. Because each individual responds differently to a particular type of insulin or oral agent, it is imperative that all options be available in order to appropriately respond to each person's specific need.

Because the MMA and Medicare regulations require drug plans to include only two (2) drugs from each pharmacological class, USP's current draft risks severely limiting the options available to Medicare beneficiaries with diabetes. Indeed, under the current draft, an approved formulary could include only two (2) insulin types and two (2) oral agents and remain in full compliance with Medicare regulations. This would be disastrous for older Americans living with diabetes.

Insulin

The goal of insulin therapy for patients with diabetes is to control blood glucose levels. Insulin therapy is always extremely individualized, and the appropriate treatment plan depends strongly on what type of diabetes the patient has, how long the patient has had diabetes, and his/her daily routine, activity level, and food intake. Insulin treatment regimens are designed to mimic the actions of a normal pancreas, which continually releases a small amount of insulin into the bloodstream 24 hours a day, while also releasing a bolus of additional insulin in response to each meal consumed.

Insulin is available in rapid, short, intermediate, and long acting forms that may be injected separately or mixed in the same syringe. Because different patients will respond differently to each of the insulin types, all patients must have access to all types in order to create a treatment plan that most effectively mirrors what their bodies would do if they produced insulin naturally. With the proper insulin treatment, blood glucose levels will be successfully lowered, thus significantly reducing the risk of costly hospitalizations and complications in the future. As such, it is absolutely necessary that Medicare beneficiaries are guaranteed access to the four (4) types of insulin.

Oral Hypoglycemic Agents

ADA is also concerned that the draft guidelines provide insufficient access to oral medications for type 2 diabetes. Type 2 diabetes is a complex disease with several causes, all of which lead to increased blood glucose levels. For example, some people with type 2 diabetes produce insulin, but their blood glucose level remains high because their cells are resistant to the action of the insulin. Others also produce insulin, but too much glucose from the liver is released into the blood, causing their blood glucose levels to increase. Over time, most patients with type 2 diabetes produce level of insulin which is simply insufficient to control their blood glucose level.

The various types of oral medications for diabetes are designed to address each of these issues:

- Alpha-glucosidase inhibitors act by slowing the digestion of starches. This prevents post-prandial (after-meal) blood glucose levels from rising too high and improves long-term blood glucose control.
- Meglitinides stimulate the pancreas to release more insulin. This class of drugs is shorter acting than the traditional sulfonylurea and is designed to be taken immediately before each meal.
- Biguanides keep the liver from releasing too much glucose.
- Sulfonylureas stimulate the pancreas to release more insulin. This class of drugs acts more gradually than the meglitinides and is designed to be taken once or twice a day.
- Thiazolidinediones make the body (particularly muscle cells) more sensitive to insulin, and thus are ideal for patients with insulin resistance.

All Medicare drug plan formularies must include drugs from each of the 'recommended subdivisions' so that beneficiaries with type 2 diabetes are assured of having access to the appropriate type of oral agent. For example, if a person is producing a normal amount of insulin but their cells are insulin resistant, it will only be of limited assistance if the only two (2) approved drugs are sulfonylureas and meglitinides. Yet a drug plan could choose to cover two only these two types of oral agents and still be compliant with Medicare's proposed rules and the USP draft model formulary guidelines. Such scenarios are unacceptable and must be addressed.

Cardiovascular Medications

Additionally, because the treatment of type 2 diabetes now focuses on the treatment of blood pressure and lipids in addition to blood glucose, ADA also feels it is necessary to

address the above classification concerns in the areas of "Cardiovascular Medications" as identified by the proposed USP guidelines. The proposed "Cardiovascular" category currently contains medications to treat several distinct disorders. The classes are then subdivided into separate medications; however, because each of these medications has a distinct mechanism of action, it is critically important that each of them be available to enrollees with diabetes in order to secure the best treatment possible.

For example, "Diuretics" contains 4 subdivisions and "Antilipemic" contains 5 subdivisions. For enrollees with diabetes, any limitation of medications in these classes – such as requiring only 2 drugs per class be allowed –based on the current proposed classification system, would not be in keeping with good clinical practice. Indeed, patients with diabetes often also have hypertension and/or dyslipidemia and are commonly treated with multiple medications which fall within the same class (as identified by USP).

Recommendations

With an aim of protecting the needs of people living with diabetes, ADA recommends the following changes to USP's drug classification system:

A. Reclassify the recommended subdivisions for oral agents as distinct pharmacologic classes to ensure that people with type 2 diabetes have coverage for at least two (2) drugs in each class of drug per the direction provided by Congress in the MMA; and
B. Reclassify the recommended subdivisions for insulin as distinct pharmacologic classes to ensure that people with type 1 and type 2 diabetes have coverage for the four (4) classes of insulin required to manage diabetes.
C. Reclassify the recommended subdivisions for all cardiovascular medications as distinct pharmacologic classes allow for the proper treatment of hypertension and dyslipidemia.

ADA could also support the following approach as an alternative to the above proposal:

A. Require all formularies to cover at least one insulin from each subdivision category identified as rapid, short, intermediate, and long-acting by the USP guidelines; and
B. Require all formularies to cover at least one oral hypoglycemic agent from each subdivision category identified as alpha glucosidase inhibitors, meglitinides, biguanides, sulfonylureas, and thiazolidinediones by the USP guidelines.
C. Require all formularies to cover at least one cardiovascular medication from each subdivision category identified by the USP guidelines.

2. Inclusion of Syringes and Related Insulin Delivery Devices

According to the legislative language in the MMA, as well as the CMS proposed rules for the MMA, medical supplies associated with the injection of insulin –including syringes,

needles, alcohol swabs, and gauze– are considered to be drugs covered under Part D benefits. However, these items are not specifically identified in USP's draft model guidelines as a covered benefit under formularies. ADA is concerned that these items have been overlooked and if not included in the model guidelines will similarly be overlooked by approved Part D plans in the future. ADA recommends that USP clearly indicate in their model guidelines that drug plans must cover these supplies as drugs under the new Medicare drug benefit.

3. Procedure For Adopting New Therapeutic Categories and Pharmacological Classes

ADA supports research in the areas of new treatments for diabetes as well as a cure for diabetes. However, the draft model formulary is unclear on how Medicare drug plans should incorporate new drugs and treatments as they are discovered. Phrases contained in the USP guideline, including those requiring formularies to update covered drug lists "from time to time" and "periodically," are extremely vague. Furthermore, there is no guidance for drug plans –and therefore no guarantees to beneficiaries– to ensure that the most medically effective treatments and/or drugs will receive coverage. ADA urges USP to amend the draft model guidelines to include criteria and a specified process for accommodating new categories, classes, and products (including new indications of existing products).

4. Implementation

Many Medicare beneficiaries currently receive their diabetes supplies under Medicare Part B. Under the current system, all patients with diabetes can receive a blood glucose testing monitor, blood glucose test strips, lancets, and glucose control solutions. The number of test strips and lancets covered by Medicare depends on whether or not the patient uses insulin or not. Patients who use insulin receive up to 100 test strips and lancets per month, while those who do not use insulin receive up to 100 test strips and lancets every three months. Furthermore, under Part B, those individuals who require an insulin pump can receive the pump, related supplies, and the insulin used with the pump.

The new Part D drug benefit is intended to "fill the gaps" and offer coverage for those supplies and medications not available under Part B. According to Proposed Rule 42 CFR 423.100, drug plans under Part D are required to cover insulin, syringes, needles, alcohol swabs, and gauze.

ADA applauds CMS for ensuring that all Medicare beneficiaries with diabetes will have access to these necessary supplies and medications. However, there exists potential for significant confusion in implementing and administering this benefit. For example, a new beneficiary who requires an insulin pump should receive the necessary supplies and medication through Medicare Part B, not Part D.

ADA also believes that coverage for insulin pens should be required under Medicare Part D. Individuals who are elderly and disabled often have visual or motor impairments that make handling syringes and vials of insulin extremely difficult. Insulin pens come equipped with pre-measured cartridges of insulin and/or with a "click" system of dosing,

thus significantly improving and simplifying the process for individuals with impaired vision. Insulin pens will be a cost-effective addition to the formulary, as they will minimize the risk of hypo- or hyperglycemic reactions due to incorrect dosing, and thus limit the potential for expensive hospitalizations.

423.120(b)(4) - Periodic evaluation of protocols.
ADA recommends that the final rule require PDPs to conduct, at minimum, quarterly evaluations and analysis of their protocols and procedures related to their formularies. Advances in the clinical management of diabetes are unpredictable, making it essential that the final rule require regular ongoing and timely review of formulary protocols and procedures.

423.120(b)(5) - Provision of notice regarding formulary changes.
The notification provisions regarding formulary changes are inadequate for effectively notifying and protecting beneficiaries. ADA recommends that if the final rule limits the notice requirements to persons directly affected by the change, then plans must be required to provide notice in writing, mailed directly to beneficiary, 90 days prior to the change. The notice must also inform the beneficiary of their right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary.

423.120(b)(6) - Limitation on formulary changes prior to the beginning of a contract year.
ADA recommends that the final rule place strict limits on mid-year formulary changes, requiring plans to justify a decision to remove drugs from a formulary. Permitted reasons for discontinuing coverage would include the availability of new clinical evidence indicating that a particular covered Part D drug is unsafe or contraindicated for a specific use.

Furthermore, in the event that all manufacturers discontinue supplying a particular covered Part D drug in the United States, ADA strongly recommends that plans be required to continue dispensing such a drug until the end of the plan year for all persons currently taking said drug as part of an ongoing treatment regimen.

Subpart D – Cost Control and Quality Improvements Requirements for Prescription Drug Benefit Plans.

423.150 - Scope.
ADA has significant concerns that there are currently no proposed restrictions on the ability of plans to use cost-containment tools such as dispensing limits or prior authorization. Instead, the preamble to the proposed rule appears to specifically encourage plans to use such cost management tools, without constraint, to limit the scope of the prescription drug benefit. ADA believes that this is completely inappropriate, and inconsistent with commitments made by CMS to the Congress and the public.

In response to a question for the record at the confirmation hearing in the Senate Finance Committee for CMS Administrator Mark McClellan, Dr. McClellan stated in response to

Senator Baucus' question number 27, that, "beneficiaries who elect to enroll in this new open-ended drug benefit will have no limits on the number of prescriptions filled, no limits on the maximum daily dosage, and no limits on the frequency of dispensing of a drug." ADA strongly recommends that the final rule prohibit plans from placing limits on the amount, duration, and scope of coverage for covered Part D drugs. Specifically, the final rule must prohibit plans from limiting access to covered Part D drugs through limits on the number of drugs that can be dispensed within a month, limiting the number of refills an individual can obtain for a specific drug, or by placing dollar limits on the amount of the prescription drug benefit.

ADA also strongly recommends that the final rule prohibit PDPs from requiring therapeutic substitution. While the MMA authorizes the use of formularies which could lead prescribers to alter their drug recommendation in order to comply with standard Part D plan preferences for covered drugs within a class, we believe that the ultimate authority to decide which specific drug a Medicare beneficiary will receive must reside with the treating physician. Therefore, to protect patient safety and health, the final rule must prohibit plans from requiring or encouraging pharmacists to engage in therapeutic substitution without the advance knowledge and written concurrence of the treating physician. While ADA is encouraged that the preamble to the proposed rule indicates that therapeutic substitution will be prohibited without the prescriber's approval, this prohibition must appear in the text of the final rule.

Further, the use of prior authorization has become a common practice in the private sector and Medicaid. For many Medicare beneficiary populations, the manner in which prior authorization and fail-first (or step therapy) systems have been implemented in these other contexts has been clearly unworkable both from the perspective of beneficiaries and treating physicians. While prior authorization/fail-first policies may be used appropriately in some contexts to manage the pharmaceutical benefit, the final rule must establish clear standards and requirements for Part D plans that elect to adopt prior authorization and fail-first policies. In particular, the final rule must require plans to ensure that any system of prior authorization is easily accessible to beneficiaries and physicians, and must impose negligible burdens with respect to time needed to complete the prior authorization process, expense, and information documentation.

ADA recommends that CMS encourage Part D PDPs to implement innovative approaches to controlling costs without restricting access. A number of states have developed pharmacy case management programs that focus more on the volume of prescriptions than the disease (as in disease management programs). Such programs use claims data to identify consumers with a large number of prescribers and/or prescriptions, or physicians who provide a large number of prescriptions to many consumers. Other alternative cost containment approaches include:

- Case management of chronic illness to improve coordination of all medical and mental health care, including medications;

- Disease-specific case management programs;

- Closer data review to identify fraud, deviation from clinical best practice, outlier prescribers, and clinicians that are "under"dosing; and,

- Requiring plans to analyze plan-level claims data to identify prescribing patterns, potential areas for fraud and abuse and consumers who are taking multiple medications for the same condition.

Subpart M - Grievances, Coverage Reconsiderations, and Appeals.

As mentioned earlier in these comments, diabetes therapy is very individualized and requires that patients have access to a wide range of medications in order to properly control their blood glucose levels. ADA is pleased to note that CMS has required PDPs to implement coverage determination and exceptions processes for patients in the event that their plan does not offer coverage for the medication they require. However, ADA believes that the proposed rules are overly burdensome to Medicare beneficiaries.

Having two tracks separate tracks –determined by whether the enrollee (1) pays out of pocket for a drug and files an appeal, or (2) is unable to pay out of pocket for their drug and files an appeal– is far too complicated. The timeframes, paperwork, and processes should be simplified into one expedited course of action that beneficiaries can easily understand.

423.566(b) - Actions that are coverage determinations.

ADA recommends that the presentation of a prescription to the pharmacy constitute a coverage determination. If the pharmacy does not dispense the prescription, then the request for coverage should be deemed denied, and the enrollee should be entitled to notice and to request a re-determination. Without such clarification, enrollees will not be informed of their rights, and the appeals process will become meaningless.

423.568 (b) - Timeframe for requests for payment.

ADA recommends that this subsection be eliminated. There should be no distinction in time frames when an enrollee requests payment.

423.568(c) - Written notice for PDP sponsor denials.

The current proposed rules place the responsibility for providing notice of a coverage determination on the plan sponsor. This presumes that a beneficiary will present a prescription, the pharmacy will contact the PDP sponsor, and the sponsor will then have up to 14 days to make a final coverage determination.

In reality, however, pharmacies will most often simply tell beneficiaries that their PDP will not cover the drug. Without notice provided by the pharmacy, most enrollees will not know to tell the pharmacy to submit the prescription anyway so they can get a notice from which to appeal. Enrollees may also not know or understand their right to seek expedited consideration of the initial coverage determination, or an exception if the drug is not on the formulary or on too high a tier. If enrollees pay out of pocket and then seek

reimbursement from the plan, current rules make them ineligible for expedited consideration.

The regulations should require PDP sponsors to develop a notice clearly explaining the right to seek a re-determination, and to ask for expedited review in any situation. Additionally, the pharmacy should be required to give such a notice to the enrollee. Any potential burden of such a requirement is reduced by the need to maintain electronic communications between the pharmacies and the plans in order to keep up-to-date with formularies, coinsurance, and calculations of an enrollee's out-of-pocket expenses.

423.568(d) - Form and content of the denial notice.
The proposed rules require that approved notice language be "in a readable and understandable form." While the intent is commendable, the regulations need to be more specific regarding the required content of said notices.

CMS should take its guidance in this arena from a recently-settled Florida class action lawsuit filed on behalf of Medicaid recipients. It was determined that the state had not provided proper written notification regarding the right of appeal to people whose prescription coverage was denied. The settlement's provisions require the state to provide:

- Written notification that explains why the coverage request was denied;
- Detailed information on how to resolve the issues that triggered the rejection;
- Specific instructions that explain how consumers can request an appeal; and
- Steps that consumers can take to receive medication coverage pending the outcome of an appeal.

Hernandez et al. v. Medows, U.S. District Court for the Southern District of Florida (May 2003).

ADA urges that the final rules require Medicare Part D denial notices to include the same information.

In addition, all notices need to be available in alternate formats to accommodate people with disabilities, and available in languages other than English where non-native English speakers represent a significant portion of the population. ADA supports the August, 2000 HHS OCR guidance detailing how programs can meet their Title VI obligations to provide written materials in languages other than English. The requirements of plans and the rights of beneficiaries in this area must be spelled out in much more detail. There is also an overarching need to consider literacy problems and encourage simplicity.

423.570(c) - How the PDP sponsor must process requests.
All coverage determinations and appeals concerning drugs, including those where the enrollee has paid for the drug, should be treated as requests for expedited review. A patient would suffer adverse consequences if required to wait for the longer time periods; many people will simply go without prescribed medications pending the outcome of the

review. Doubling the time frames and disallowing expedited review in cases where beneficiaries pay for drugs out-of-pocket could adversely affect the health of those who forego other necessities like food and heat in order to pay for their medicine.

At a minimum, all appeals should be automatically given expedited consideration. When a beneficiary seeks expedited review of a request to continue a drug that is no longer on the formulary, the PDP sponsor should be required to process the request as fast as the beneficiary's condition requires. At a minimum, the enrollee should be given a 72-hour supply of the medicine, which is renewable if the plan decides to take longer than 72 hours to review. In such cases, the medication should be treated as an on-formulary drug.

In the event that the final rules do not automatically assign appeals and coverage determinations as requests for expedited review, the rules then state that any such request made by a doctor on behalf of the enrollee should be given an expedited review.

423.572 (b) - Extensions of timeframe.
The timeframe (of 72 hours) can be extended by the plan up to 14 days on showing that extension is in the interests of enrollee. The regulations should define "interests of the enrollee" to include those situations in which the drug plan seeks additional information to substantiate the enrollee's request, or when the enrollee requests additional time to gather supporting information. The rules should also require PDPs to inform enrollees of such extensions immediately, both orally and in writing, rather than "by the expiration of extension."

There should be no allowable extension of time period for requests in cases where payment of drugs has already been received. This imposes extreme hardship on low-income beneficiaries and those with multiple prescriptions who may choose to unnecessarily spend money on their medications (rather than on other urgent necessities of life) because of the uncertainty and length of the appeals process.

423.578 (a)(2) - Requests for exceptions to a PDP's tiered cost-sharing structure.
This subsection fails to meet the statutory requirement that guidelines for an exception process be established by the Secretary. The MMA statutory language is not permissive; it does not say that PDPs may establish additional criteria if they wish. It states that the Secretary is to establish criteria and the plans are to abide by them. PDPs should have no discretion in this area whatsoever. The fact that PDPs may establish differing tiered structures is not relevant to beneficiaries' statutory right to request an exception to whatever structure PDPs devise.

Furthermore, in the instance where the proposed rules do include guidance for such criteria, the criteria listed are not within the original intent and scope of the statute. Indeed, the statute provides that an exception applies if a physician determines that a preferred drug would not be as effective or would have adverse effects, or both. However, the proposed rules provide for a "limited number of elements that must be included in any sponsor's exception criteria" - elements that are irrelevant and do not

apply in light of the statutory provision. For example:

- The cost of the requested drug compared to the cost of the preferred drug should have no bearing on such a decision given that this comparison is not related to differing drugs' efficacies and/or adverse effects.

- Using similar reasoning, the number of drugs in a PDP's formulary within the same class as the requested drug cannot be considered in judging differing drugs efficacies and/or adverse effects.

423.578(b) - Request for exceptions involving a nonformulary drug.
In the preamble, CMS states that "[r]equiring sponsors to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied" and will help ensure these formularies "are based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs." However, the proposed rules give drug plans complete discretion in determining the criteria they will use to determine exceptions requests. In addition, independent review entities "would not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." By failing to adequately define the criteria plans may use to consider exceptions requests or provide any meaningful oversight over these criteria, these proposed regulations would not ensure that formularies are based on scientific evidence and would not establish a transparent process. The rules, as written, thus subvert CMS's stated goals.

The criteria and process described in 423.578(b)(2) will make it virtually impossible to succeed in obtaining an exception. The process is not transparent, as the preamble suggests, because it is left wholly to the discretion of each PDP. ADA urges CMS –and not each individual PDP sponsor– to establish the criteria for evaluating such requests. Without uniform criteria, enrollees in different plans will be treated differently. The need to tailor supporting certificates to the different requirements of each plan will place a substantial burden upon prescribers/providers who file certificates as part of the process.

§423.578(b)(5) of the proposed rules authorizes PDPs to obtain several different types of information in the prescribing physician's statement certifying that an off-formulary drug is needed. This list is excessively long and repetitive, and encourages PDPs to establish burdensome paperwork requirements as a hurdle to prevent physicians and consumers from following through on an exceptions request. Moreover, this proposed rule also leaves the required information entirely up to the plan's discretion by including a vague descriptive phrase: "any other information reasonably necessary." The requirements for this written certification should be standardized to facilitate use of the exceptions process by providers and consumers. These standards would also help achieve CMS's stated goal of establishing a transparent process.

ADA recommends that the final rules establish fixed criteria for evaluating a prescribing doctor's determination that using all formulary drugs would not be effective or would cause adverse consequences to the enrollee. Requiring the amount of evidence suggested

in the proposed rules makes it virtually impossible to receive an exception. Instead, CMS should allow the weight of clinical evidence or the physician's experience to meet the standard.

- To meet the statutory standard, the burden should be placed on the PDP to show why the doctor's decision is not definitive.

- The amount and type of evidence proposed in the certificate would make it impossible to meet the standard. "Gold standard" clinical trials generally do not include the elderly, people with disabilities, and people with co-morbidities. While some minimal evidence exists of this nature, there may not be such evidence for all drugs and conditions. Again, the regulations should require the certificate meet the statutory standard –that "preferred drugs" are not as effective or have adverse effects– and the criteria should recognize a physician's experience in evaluating whether such a statutory standard is met.

- For dosing exceptions, the rules state that evidence must exist that the number/amount of doses available under a dose restriction has been ineffective, is likely to be ineffective (based on sound clinical evidence and/or medical/scientific evidence), or will adversely affect the drug's effectiveness or patient compliance. The standard should additionally include "or cause an adverse reaction or other harm to the enrollee."

423.578(c)(2) - When a sponsor does not make a timely decision.
The rules provide for a one month's supply of a drug, but only if the plan does not act in a timely manner in an exceptions determination. If the request for an exception is not given expedited treatment, the sponsor can take two weeks to issue a decision, meaning the enrollee would wait two weeks before getting the supply of medicine. Even if the exception is treated as a request for expedited review, the enrollee would still have to wait 72 hours (less if they could show the decision needed to be made more quickly because of their condition.) However, most people wait to the last minute to refill a prescription, often because of drug plan and pharmacy restrictions.

As such, any enrollee requesting a refill (for a drug that has been removed from the formulary between refills) or presenting a new prescription for a non-formulary drug should receive a one month's supply while the exception determination is being made. Furthermore, plans should be required to make exception determinations and notify the enrollee in 24 hours as required under Medicaid for prior authorization determinations. 42 U.S.C. 1386r-8(d)(5)(A).

423.578(c)(3) - When an exceptions request is approved.
The lowest coinsurance amount should apply anytime an enrollee wins an exception through this process because the drug at issue has been determined medically necessary with no on-formulary drug as a suitable alternative. The exception for the non-formulary drug should thus meet the criteria for an exception to the tiered cost-sharing structure as well.

The rules need to clearly set forth the requirement that notice be provided when a decision is made on an exception request. The notice should explain that the decision is a coverage determination and explain appeal rights that are available.

ADA commends CMS for specifying that, once an exception request is granted, a plan sponsor may not require the enrollee to keep requesting exceptions in order to continue receiving the drug. However, ADA remains concerned that the "exception" to this protection –which allows the plan to discontinue a drug if safety considerations arise– is too broad. The final rules should be revised to permit reversal of a previously granted exception only if the FDA determines that the drug is no longer safe for treating the enrollee's disease or medical condition.

ADA is deeply concerned that the timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed provisions raise similar concerns. It is inequitable to require longer time frames if a beneficiary has paid out of pocket for a needed medication when the only alternative would be to wait two to four weeks for a determination or an emergency one-month supply of the needed drug. Beneficiaries' health and safety may well be at risk if they are forced to forego other necessities because of the added, and most likely very significant, expense of paying out of pocket for their medicines. Although the proposed regulations include some provisions for an emergency supply of medications while a plan is considering an exceptions request, it is unreasonable and bad health policy to make beneficiaries wait two to four weeks before the drug plan must provide an emergency supply. In addition, plans should be required to demonstrate that an extension of the standard time frame for exceptions determinations is in the best interest of the enrollee and the final rule must charge independent review entities with exercising oversight over these extensions. Plans should be required to make determinations regarding exceptions requests and notify the enrollee of these determinations in 24 hours as required under Medicaid for determinations regarding prior authorization requests (42 U.S.C. 1396r-8(d)(5)(A)).

423.580 - Right to a redetermination, and 423.584(a) - Expediting certain re-determinations.

These proposed rules only authorize an enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) to request a re-determination (or an expedited re-determination). However, the enrollee's authorized representative must also be allowed to request such re-determinations.

Additionally, because the proposed rules allow an enrollee's authorized representative to file a request for Determinations and Exceptions, it is not appropriate to then disallow such a representative from further pursuing a claim through re-determination, reconsideration, and higher levels of appeal. In fact, the proposed rules define an authorized representative as an individual authorized to act on behalf of an enrollee "in dealing with any of the levels of the appeals process."

423.584 - Expediting certain re-determinations.

The rules need to describe in greater detail the notice responsibilities for both standard and expedited re-determinations, including what must be provided in the notice. Given that the next level of review –to the independent review entity (IRE) – is not automatic (as it is with Medicare Advantage plans), this becomes a critically important step. The notice must be required to explain the reason for the denial (including specific medical and scientific evidence), the right to request review or expedited review to the IRE (including timeframes), and the right to submit evidence in writing and in person.

423.590 - Timeframes.
The rules should be amended so that a PDP can only extend the timeframe for a re-determination if requested to do so by the enrollee, or if the plan can demonstrate that the extension is in the **best interest** of the enrollee, for example, the plan needs to obtain additional information to support the enrollee's request.

ADA renews its earlier comments that all re-determination requests, and particularly those involving exceptions, should be treated as expedited, and that plans should not be given more time to resolve re-determination requests involving payment requests.

423.600 - Reconsideration by the IRE.
CMS needs to clarify in the final rules that the role of the IRE is to provide independent, de novo review, especially in regard to the exceptions process. The preamble states that "…The IRE's review would focus on whether the PDP had properly applied its formulary exceptions criteria for the individual in question…..the IRE will not have any discretion with respect to the validity of the plan's exceptions criteria or formulary." However, if the IRE does not review all of the evidence and issue a reconsideration decision based on its own analysis, then enrollees will be denied a truly independent review.

Further, because CMS is required by the statute to set standards for the exceptions process, as noted above, the IRE must have authority to determine whether PDPs' exceptions criteria comply with the statute. Otherwise, enrollees will have no mechanism for review of arbitrary and improper standards.

Since the Part D process is intended to follow the Medicare Advantage process, the regulations should follow the Medicare Advantage regulations and require that ***denials automatically be sent to the IRE for reconsideration***. The regulations as written create a barrier to the first level of independent review for enrollees who have difficulty following the complicated process. Further, ADA disputes CMS's statement in the preamble (pg. 46722) that many of the drug appeals will involve small monetary amounts. Rather, most will involve medications for chronic conditions that enrollees take on an on-going basis; the yearly sum of which will be quite substantial, especially when compared with the income level of most Medicare beneficiaries.

If the final regulations continue to place the burden of requesting a reconsideration on the enrollee, the must at the very least clarify that an authorized representative can act on the enrollee's behalf. Again, without such clarification, enrollees who lack the capacity to file a reconsideration request will be denied their rights of due process. In addition, the

prescribing doctor should also be permitted to request a reconsideration, especially since the enrollee needs the doctor's statement in order to request IRE review of an unfavorable exception request.

423.600(d) - Timeframe.
In order for the process to be truly transparent, the regulations must additionally establish a specific timeframe in which the IRE must issue its decision. Enrollees will have no knowledge of the contract between CMS and the IRE and thus will not know how long they will have to wait for a reconsideration decision. If contractual, the time frame can change with each new contract, putting enrollees at greater risk of adverse health consequences from being denied needed medicines. The regulation must also state that an enrollee may appeal to an Administrative Law Judge (ALJ) if the IRE fails to act within the regulatory time frame.

423.602 - Notice of reconsideration.
The language concerning the contents of a notice of reconsideration is too ambiguous. As written, the notice must "inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under 423.610." This could be interpreted to mean that the notice informs the enrollee the s/he has the right to an ALJ hearing *only* if her claim is large enough. Or it could be interpreted to mean that the IRE only has to notify the enrollees of their rights to an ALJ hearing if their claims meet the threshold amount. The latter interpretation is problematic for several reasons, including the fact that one can aggregate claims (see our comments on §423.610). The final regulation should instead state that notices must unequivocally inform enrollees of their right to an ALJ hearing, and the procedure for requesting such a hearing, including the dollar amount required to request a hearing.

423.610 - Right to an ALJ Hearing.
Through the legislative language contained in the MMA, Congress recognized the special needs of low income populations and that even small co-pays can force lower-income individuals to forgo filling prescriptions. ADA urges CMS to provide exceptions to the ALJ threshold requirements for those receiving the Medicare subsidy. Because individuals who receive the low-income subsidy have lower out of pocket costs, it is more difficult for them to reach the threshold amount than it is for higher-income individuals not receiving the subsidy. In order to compensate for this inequity, we recommend that the threshold amount for a lower-income individual be calculated as if the individual were not receiving the subsidy.

The intent of 423.610(c) remains unclear: "Two or more appeals may be aggregated by the enrollee… if (i) the appeals have previously been reconsidered by an IRE…" This provision could be interpreted to require an enrollee to file a new appeal each month for a prescription to treat an on-going chronic condition. Such a requirement would be unduly burdensome for enrollees, drug plans, the IRE, and the ALJs. The final regulation needs to clarify that an enrollee should be able to consider the total yearly cost of the medication if the medicine treats an on-going chronic condition –or for the number of

refills authorized if the underlying condition is not chronic– in order to satisfy the jurisdictional amount when the plan denies coverage.

Subsection (ii) states that the request for the hearing must list all of the appeals to be aggregated and must be filed within 60 days after all of the IRE reconsideration determinations appealed have been received. This requirement, too, remains vague: in consolidating appeals, it is unclear if the 60 days apply from the issuance of the first denial or the issuance of the last denial being appealed.

423.634 - Reopening and revisions determinations and decisions & 423.638 - How a PDP sponsor must effectuate expedited re-determinations or reconsidered re-determinations.

Subsection (c) in both of these sections allows the PDP to take up to 60 days to implement a reversal by the IRE, an ALJ, or higher. ADA strongly reiterates the opinion that such an extended timeframe is entirely unacceptable, given that additional delays will likely cause increased health consequences to people who have foregone medication pending the outcome of the appeal process. Favorable decisions should be implemented in the same 72 hour time period as reversals at earlier levels of review.

CMS-4068-P-1278

Submitter : **Ms. Elizabeth Blackston** **Date & Time:** **10/04/2004 08:10:46**

Organization : **Office of the Illinois Attorney General**

Category : **State Government**

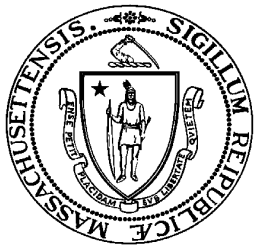
Issue Areas/Comments

GENERAL

GENERAL

Marketing

CMS-4068-P-1278-Attach-1.doc



October 4, 2004

Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Re: Docket No. CMS-4068-P

Dear Dr. McClellan:

We write to comment on the Rule 4068-P proposed by CMS. The Offices of the Attorneys General of Illinois and Massachusetts protect our states= consumers from deceptive and unfair acts and practices by enforcing our consumer protection and fraud laws, and a host of other state statutes and federal statutes. Our Offices have conducted many investigations and brought a number of law enforcement actions concerning telemarketing and other types of fraud. We write to share our experience in that area as it pertains to marketing of the Medicare Prescription Drug Benefit provided for by the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

We believe that, in addition to door-to-door solicitations, telemarketing solicitations should be banned. Also, we believe that Prescription Drug Programs should be prohibited from offering additional products or services to Medicare beneficiaries. These positions and the basis for these positions are described in detail below.

I. Telemarketing Should Be Prohibited

Section 423.50 (e) of the proposed rules provide standards for marketing which include a prohibition on door-to-door solicitations. Telemarketing solicitations to Medicare beneficiaries also should be prohibited. The potential for confusion and fraud is high for the population at large, and may be even higher for elder and disabled Medicare beneficiaries. The National Fraud Information Center estimates that telemarketing fraud amounts to $40 billion annually.

Our offices are concerned with abusive telemarketing practices associated with marketing of discount prescription drug plans. We have received complaints about these practices in connection with the current Medicare prescription drug discount card program, and are acting upon them. For example, the Office of the Illinois Attorney General has received consumer complaints regarding unauthorized debits from consumers= checking accounts as a result of telephone solicitations from sellers falsely claiming or implying to be offering discount prescription drug plans authorized by the federal government. On September 17, 2004, Illinois filed a lawsuit in federal court against a company that Illinois alleged had made such fraudulent telemarketing solicitations[1].

In addition to preventing almost unlimited potential for fraud, a prohibition on telemarketing solicitations would allow for a simple message to consumers: ALegitimate Medicare Drug Discount Programs and Part D benefit providers will not solicit you by telephone. If you receive a call from someone claiming to be an authorized Medicare provider, hang up.@

II. Prescription Drug Plans Should Be Prohibited from Offering Additional Products to Medicare Beneficiaries

In the preamble to its Notice of Proposed Rulemaking, CMS seeks comments on the advisability of allowing additional products, such as financial services, to be provided in conjunction with PDP services. Because of the potential for fraud and confusion, as well as for public policy reasons, this should be prohibited.

A. Additional Offerings After Consumer Provides Billing Information

Permitting additional products to be offered could allow Prescription Drug Plans to work a disservice on Medicare beneficiaries. We are concerned that beneficiaries who, having read a direct mail solicitation, seen a television ad, or been solicited by phone (if telemarketing is permitted B we believe it should *not* be), have contacted PDP sponsors to enroll in a PDP and have provided credit card, checking account and/or other billing information will then be subjected to additional sales pitches. In addition, PDPs may later use this billing information for unauthorized sales of additional products and services without the necessity of the consumer providing the information again.

Our Offices have seen this deceptive practice B i.e. the use of preacquired account information B in connection with other merchants. We are troubled that this practice could be permitted by CMS in connection with marketing by Prescription Drug Plans. There are a number of reasons why we are concerned about this. First, often in these situations the consumer does not understand that any positive response to the additional sales pitches is interpreted by the merchant to be a purchasing decision, and that billing information provided

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[1] **People v. Global Benefits Group Corp., Inc., Eileen deOliveira, Leonardo deOliveira, John Doe 1, d/b/a Medications 4 Less, and John Doe 2, d/b/a Euro Banca (U.S. District Court, Central District of Illinois, Springfield Division, 04-CV-3205).**

in conjunction with the initial purchase will be used for these additional purchases. Second, in addition to consumer confusion, there is the potential for fraud on the part of the seller. The billing information the consumer already has provided can be used by an unscrupulous merchant to make a sale even if the consumer declined the additional offer or did not understand he or she was making a purchasing decision.

This area for potential abuse has raised strong concerns in our states. For example, the Office of the Illinois Attorney General has brought three law enforcement actions against companies which we alleged were engaged in such confusing and fraudulent sales pitches[2]. Two of those actions involved both additional sales pitches after consumers had called to order a product advertised on television (inbound calls) as well as direct telemarketing (outbound) calls. The other action involved inbound telemarketing calls only. In all three cases, the consumers did not understand they were making a purchasing decision with respect to the second offer, and in some cases, they were charged for products which they affirmatively declined, which charges the sellers were able to effectuate because of the previously provided billing information.

B. Potential to Create False Impression of Government Endorsement

If additional products are offered in conjunction with government-sponsored benefits, such a combination has the potential to create the impression that such offerings somehow have been endorsed by the government when in fact no such endorsement exists.

The potential for consumer confusion already has been made clear to states during this interim period when prescription drug discount cards are available. States are currently looking into claims that an insurance company that marketed B through direct mail and television advertising B an ordinary prescription drug discount card may have deceptively dressed the card as a Medicare-endorsed, government-issued product, complete with official-looking seals and government-agency-seeming titles. We are concerned that CMS is considering allowing additional products to be offered when such a great potential for confusion and fraud exists.

C. Public Policy

In addition to the potential for fraud and confusion among Medicare recipients, public policy dictates that when a consumer avails himself or herself of a government-sponsored benefit, he or she should not be subjected to sales pitches for products that are not government-sponsored or regulated.

For the reasons stated above, the Offices of the Attorneys General of Illinois and

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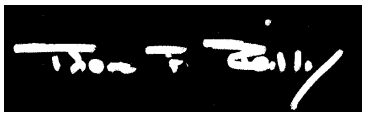
[2] *In Re* MemberWorks, Inc., AVC No. 04-AVC-0008 (Sept. 2004).
People v. Blitz Media, Inc. d/b/a Paradise Value Discount Directory and American Values Discount Directory and Brian MacGregor, No. 01CH592 (7th Judicial Cir. 2001).
People v. Triad Discount Buying, 01CH136 (7th Judicial Cir. 2001).

Massachusetts respectfully request that CMS consider their comments and prohibit telemarketing solicitations and the offering of additional products to Medicare beneficiaries.

Respectfully submitted,



Attorney General Lisa Madigan **Attorney General Tom Reilly**
Attorney General of Illinois **Attorney General of Massachusetts**

CMS-4068-P-1279

Submitter : Ms. Lynne Gross **Date & Time:** 10/04/2004 08:10:05

Organization : Anthem Blue Cross and Blue Shield

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached comment letter

CMS-4068-P-1279-Attach-1.pdf

Lynne Gross
Vice President & General Manager
Government Programs

Anthem Blue Cross and Blue Shield
220 Virginia Avenue
Indianapolis, IN 46206
Tel 317-287-5478
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October 4, 2004

The Honorable Mark McClellan, MD, Ph.D.
Administrator
The Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 445-G
Washington, D.C. 20201

Attention: CMS-4068-P

Re: Comments on Proposed Rule: Medicare Prescription Drug Benefit (CMS-4068-P), as issued on August 3, 2004.

Dear Dr. McClellan:

Anthem Blue Cross and Blue Shield (Anthem) appreciates the opportunity to comment on the Proposed Rules implementing Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

Developing a new program of this size - arguably the biggest single change to Medicare since the program's inception - is an enormous task. We applaud you and your staff for the outreach you have done to educate stakeholders and to solicit input as you develop these regulations.

Anthem, Inc., through its subsidiary companies, provides health care benefits to more than 12.5 million people. Anthem is the nation's fourth largest publicly traded health benefits company, and an independent licensee of the Blue Cross and Blue Shield Association serving Indiana, Kentucky, Ohio, Connecticut, New Hampshire, Colorado, Nevada, Maine and most of Virginia. Anthem is fairly unique compared to most other health plans in that we have our own pharmacy benefits management (PBM) company, Anthem Prescriptions Management, LLC, which administers the prescription drug benefits for most of our customers.

Anthem also has extensive experience in various roles related to the Medicare program.

- Anthem has been a Medicare contractor since the program's inception.
- Anthem is the leading Medicare supplement insurer in the majority of states where we operate.
- Anthem has participated in the Medicare Advantage program since 1994.

- Anthem is a leading provider of employer sponsored retiree insurance to Medicare beneficiaries in the states where we operate.
- Anthem offers a Medicare Approved Drug Discount card in the states where we operate.

The new prescription drug benefit is an important addition to the Medicare program that will provide financial assistance for Medicare beneficiaries and that has the potential to improve the overall quality of health care. The details of this new program will be critical to ensuring that beneficiaries and the federal government have long-term access to cost effective prescription benefits. In that spirit, Anthem offers comments on five important, overarching issues that we believe are critical to the program's success. In the attachment we provide detailed comments on specific sections of the regulation.

- **Designate 50 state-based Part D regions:** Most health plans, including Blue Cross and Blue Shield Plans, are separately licensed in each state they serve. Anthem is no different. Anthem operates as a Blue Cross and Blue Shield licensee in nine different states under various legal entities. If CMS were to establish multi-state regions this will make it difficult for the majority of health plans, both Blues and non-Blues, to participate as a Prescription Drug Plan (PDP). In addition, establishing multi-state regions could impact the number of plans that are able to participate in 2006 due to the short time period between when regions are named and when applications are due.

  We believe it is in the best interest of the program and beneficiaries to start with 50 state-based regions, with a separate region for Puerto Rico.

- **Provide for effective formulary design:** Balancing access and cost is critical to quality formulary design. Access does not necessarily mean having more choices of prescription drugs. More important is having the right drug classes represented. The formulary requirements need to be carefully developed to ensure that health plans are not faced with situations where a therapeutic class consists of only a few 'copy cat' drugs in a class, with none being clinically superior. If CMS develops requirements for formularies that are too broad health plan will have little ability to negotiate lower prices, particularly if there are only two or three drugs in the class. This inability to effectively negotiate price has the potential to dramatically increase costs for beneficiaries and the federal government.

- **Assure appropriate justification of cost-sharing exceptions:** The proposed regulations reduce the MMA standards applicable to the exceptions process for tiered and closed formularies. While we believe exceptions are appropriate when medically necessary, the need for these exceptions must be adequately justified.

In addition, CMS should clarify the regulation to say that exceptions do not entitle beneficiaries to the lowest copay level that usually is associated with generic drugs. The reason most generic drugs have the lowest co-pay is because they are usually a lower-cost alternative to brand name prescription drugs and have the same efficacy. Allowing brand name drugs to be obtained at the lowest copay through an exceptions process will greatly increase cost.

- **Allow flexibility for use of private sector management tools:** As you are aware, our industry uses a number of management tools such as drug utilization review, prior authorization, therapeutic interchange and lower copayments to help encourage the use of prescription drugs in a safe and cost effective manner. For example, drug utilization review programs look not only for over use of medications, but under use that can cause medical complications. These management tools continue to evolve and overly detailed requirements may inhibit a plan's ability to provide quality, and safe, drug coverage to beneficiaries in the most cost effective manner.

- **Develop accurate risk adjusters:** The payment received by Part D plans under the program is highly dependent upon the accuracy of the risk adjusters which are intended to reflect the beneficiary's prescription drug costs. It is important for CMS to use the best information available to develop both a medical risk adjuster which reflects differences in utilization due to health conditions and a low-income risk adjuster which reflects differences in utilization among this subset of beneficiaries. The low-income risk adjuster is necessary as this population will have an enhanced benefit with lower cost sharing. It is very likely that combination, as well as other factors will result in higher utilization that may not be fully accounted for by the medical risk adjuster.

Anthem appreciates the opportunity to offer these comments for your consideration along with the detailed comments provided in the attachment. We welcome any questions you have regarding our comments or as you develop the final regulation that modernizes Medicare.

Sincerely,

Lynne Gross
Vice President and General Manager
Anthem Blue Cross & Blue Shield
Government Programs

Attachments:
Anthem Blue Cross and Blue Shield Part D Regulations - Detailed Comments
Part §423 – Voluntary Medicare Prescription Drug Benefit

Attachment

Anthem Blue Cross and Blue Shield
Part D Regulations - Detailed Comments

PART §423 – VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

Subpart B – Eligibility and Enrollment

Enrollment periods (§423.36)

Proposed Rule: The Proposed Rule at §423.36 outlines the enrollment periods during which a person can enroll in Part D. In addition to the normal enrollment periods, the proposed regulation also includes circumstances under which a person could qualify for a special enrollment period.

Issue: The special enrollment period (SEP) for an individual who is full-benefit dual eligible is not clearly limited to individuals who have been automatically enrolled in a PDP in §423.36 (c)(4) as it is in §423.36 (d)(3)(ii). The language in §423.36 (d)(3)(ii) appears to indicate that the SEP for full-benefit dual eligibles would be limited to those automatically enrolled in a PDP; however, the proposed regulation as written at §423.36 (c)(4) does not limit the SEP to those individuals who were automatically enrolled in a PDP. As written, full-benefit dual eligibles could switch PDPs at any time. This could lead to adverse selection and increased administrative cost.

Anthem Recommendation: Modify the language in §423.36 (c)(4) to be consistent with the language in §423.36 (d)(3)(ii) that limits the special enrollment period for dual eligibles to persons who have been automatically enrolled in Part D.

Issue: As written, the SEP regulation at §423.36 (c)(1),(3), (5),(6) and (8) does not denote a time within which a beneficiary must exercise their SEP. It appears to be appropriate to apply a timeframe within which a beneficiary must exercise their SEP.

Anthem Recommendation: Provide for a 63 day period in which a person must exercise their SEP to apply to a PDP or MA-PD following the events outlined in §423.36 (c)(1),(3), (5),(6) and (8) in order to be eligible for a special enrollment period.

Disenrollment by the PDP (§423.44)

Proposed Rule: The Proposed Rule at §423.44 provides for the circumstances under which a PDP may disenroll a beneficiary from Part D and the processes to be followed when taking this action.

CMS Request for Comments: CMS has requested comments on limiting the ability of stand-alone PDPs to disenroll individuals for nonpayment of premium and disruptive behavior.

Issue: The regulation contains requirements that a PDP must follow before disenrolling a beneficiary for non-payment of premium or disruptive behavior. These provisions provide the beneficiary with protection to ensure their coverage is not cancelled without proper notice and due process. The potential to lose coverage is the only leverage a PDP has to ensure timely payment of premium or to address disruptive behavior. While a person who is disenrolled for

these reasons could be subject to a late penalty when they re-enroll in Part D, the actual amount of the penalty would be minimal since they could re-enroll at the next annual enrollment period.

Anthem Recommendation: CMS should not require PDPs to re-enroll individuals who were disenrolled for nonpayment of their premiums or who were found to have had disruptive behavior when the PDP followed the proper procedures. In addition, retain the provision in §423.44(d)(3) allowing the PDP to collect any past due premiums.

Procedures to Determine and Document Creditable Status of Prescription Drug Coverage: Disclosure of Non-creditable Coverage (§423.56(c) and (§423.56(e))

Proposed Rule: The Proposed Rule at §423.56(c) and §423.56(e) requires sponsors who provide prescription drug coverage to Medicare beneficiaries (including coverage under Medicaid, Medigap, TRICARE and veterans programs, individual and group insurance, SPAPs and IHS/ITU coverage) to provide disclosure to CMS and to enrollees if their drug coverage is not "creditable," (i.e., that the gross value of the drug coverage provided is *not* actuarially equivalent to the value of the standard Medicare Part D benefit).

CMS Request for Comments: CMS has requested comments on the format, placement, and timing of the creditable coverage notice recognizing that it is important that beneficiaries have this information as they evaluate Part D and that providing this notice could be an administrative burden if the requirements are too cumbersome. CMS has also asked whether it would be a significant burden to include information in the notice regarding the value of the drug benefit, the total amount of annual premium for the drug benefit and the amount of the annual premium that a beneficiary will be required to pay.

Anthem Recommendation: CMS outlines several approaches for the creditable coverage notice in the preamble, including allowing plans to incorporate these notices into materials routinely disseminated by the plan. We believe that allowing notices to be incorporated into other plan materials is a desirable option. Regarding the format, we believe that employers and health plans need the flexibility to adjust the message as appropriate for the given audience's particular circumstances. Given this, a suggested model seems more appropriate than a standard.

If the requirement to provide individualized information regarding the value and premiums of a retiree drug benefit is implemented, dissemination in routine plan documents becomes very difficult. Employers often vary retiree contribution by years of service. Also, it is not uncommon to have numerous plan designs as companies often have acquired other companies with different retiree health plans and commitments. Additionally, since retirees are almost always enrolled in a health plan that includes both medical and drug benefits, and not a stand alone drug plan, this information would be of little value since they could not purchase the medical and drug benefit separately.

Subpart C – Benefits and Beneficiary Protections

Definitions: Dispensing Fees (§423.100)

Proposed Rule: The Proposed Rule at §423.100 does not include a definition of "dispensing fees."

CMS Request for Comments: CMS requests comments on two issues related to dispensing fees:

1) CMS asks for comments on how to best define dispensing fees, offering three potential options.
2) CMS also invites comments on whether dispensing fees should vary for specific types of drugs, such as vaccines or injectibles.

Issue: The three options currently proposed for defining dispensing fees seem to be absolute, either requiring that the dispensing fee only include activities related to the transfer of possession (Option 1); or requiring that the dispensing include all activities associated with dispensing, supplies/equipment and monitoring (Option 3). While typically dispensing fees for prescription drugs are for the services that are outlined in the CMS Option 1, plans should be given the flexibility to include reimbursement for services beyond that. This type of discretion allows drug plans the flexibility required to effectively manage costs and respond to changes in drug therapies. In addition, this affords plans the ability to vary dispensing fees for specific drugs and other reasons that may be appropriate.

Anthem Recommendation: Allow drug plans to define "dispensing fee". Option 1 should define the minimum requirements for a dispensing fee, but drug plans should have discretion to include other costs within the dispensing fee as they deem appropriate.

Definitions: Treatment of HSA Contributions as Incurred Costs (§423.100)

Proposed Rule: The proposed rule in section 423.100 defines a variety of types of coverage whose payments would not count towards a beneficiary's annual out-of-pocket threshold.

CMS Request for Comments: CMS, in the proposed rule's Preamble C(2)(a) requests comments regarding the treatment of health savings accounts (HSAs) vis-à-vis CMS' definition of "group health plan," insurance or otherwise," and "third party payment arrangements." CMS states that it is their strong preference to not treat HSAs as group health plans, insurance or otherwise, or third party payment arrangements and therefore allow HSA contributions to count toward incurred costs as they see HSA funds as analogous to a beneficiary's bank account.

Issue: While HSAs funds could have been contributed to the HSA by the employer, once the funds are contributed they are controlled by the individual. In addition, we believe that the majority of HSA contributions will be by the individual and not the employer. Given this, we agree with CMS' rationale that HSA funds are analogous to a beneficiary's bank account and should be treated as such.

Anthem Recommendation: Anthem agrees with CMS' rationale and recommends that HSAs should not be treated as group health plans, insurance or otherwise, or third party arrangements. This will allow any payments made with HSA funds to be counted towards the annual out-of-pocket threshold.

Establishment of Prescription Drug Plan Service Areas (§423.112)

Proposed Rule: CMS proposes to establish PDP regions under §423.112 of the Proposed Rule and to publish a list of such regions by January 1, 2005.

Issue: CMS is required to establish no fewer than 10 regions and no more than 50, not including Puerto Rico and territories. The majority of Blue Cross and Blue Shield plans and health plans are state based. Establishing multi-state regions will make it difficult for the majority of plans to participate, particularly in 2006.

Anthem Recommendation: As stated in our letter, Anthem recommends that CMS adopt 50 state-based regions for PDPs and a separate region for Puerto Rico. This approach will maximize the number of heath plans able to participate as PDPs and increase competition and beneficiary choice.

Access to Covered Part D Drugs: Assuring Pharmacy Access (§423.120(a))

Proposed Rule: The Proposed Rule at §423.120(a) provides the requirements for network access for Part D plans.

CMS Request for Comments: CMS has requested comments on whether to impose requirements on drug plans regarding long-term care pharmacies. This ranges from requiring plans to approach some or all long-term care pharmacies in their service area with at least the same terms available under their plans' standard pharmacy contract to requiring all long-term care pharmacies to be included in their network.

Issue: Since long-term care pharmacies are typically the single provider of prescription drugs for beneficiaries residing in long-term care facilities, it is important that they be included in the pharmacy network. However, absent some reasonable limits on what they can charge, a mandate requiring plans to have long-term care pharmacies in the network will inhibit a plan's ability to contract at reasonable rates. A basic premise of the Part D bill is that competition in a variety of different ways will reduce costs. In the case of long-term care pharmacies, we envision this competitive force being the fact that long-term care pharmacies that participate with Part D plans will use this to attract long-term care facilities whose pharmacy does not contract.

Anthem Recommendation: Part D plans should not be required to contract with a particular type of pharmacy, including long-term care pharmacies. It is acceptable to have a requirement for Part D plans to offer long-term care pharmacies their standard pharmacy contract.

Access to Covered Part D Drugs: Formulary Requirements: Limitation on formulary changes prior to the beginning of a contract year: (§423.120(b)(5))

Proposed Rule: The Proposed Rule at §423.120(b)(5) limits formulary changes between the beginning of the annual open enrollment period and 30 days after the beginning of the contract year.

Issue: We understand that CMS has proposed this provision in order to make it easier for a person to compare plans. One issue with this approach is that all formulary changes would then be made during the contract year when a beneficiary usually does not have the ability to change plans. An approach that would appear to be more advantageous to beneficiaries is to allow the

PDP to announce the formulary change for the beginning of the new plan year prior to open enrollment and then market the new formulary during open enrollment..

Anthem Recommendation: CMS should modify the language restricting changes during the period around the beginning of the contract year to allow changes at the beginning of the benefit period. If upcoming changes are announced to current beneficiaries prior to the beginning of an open enrollment period a beneficiary can make an informed decision. In addition, the Part D plan is able to market the new formulary for the upcoming year allowing potential enrollees to also make a more informed decision.

Dissemination of Plan Information: Provision of Specific Information (§423.128(d))

Proposed Rule: The Proposed Rule at §423.128(d) contains provisions related to access to information for current and prospective enrollees including a toll-free customer call center that is open during normal business hours.

CMS Request for Comments: CMS requests comments on whether they should require a more stringent 24/7 standard for customer service in their final regulation.

Issue: Anthem currently manages the drug benefit for more than 7 million people and provides customer service during normal business hours. We have not seen a need for, nor has the market dictated, a 24/7 customer service standard. A portion of our customers are Medicare beneficiaries and their service needs do not require us to offer 24/7 customer service access.

Anthem Recommendation: Anthem supports the current proposed regulation's standard for customer service access during normal business hours.

Subpart D – Cost Control and Quality Improvement Requirements for Prescription Drug Benefits

Dissemination of Plan Information: Claims Information (§423.128(e))

Proposed Rule: The Proposed Rule at §423.128(e) contains provisions related to providing an explanation of benefits (EOB) during any month when prescription drug benefits are provided under this plan. This EOB will list the item or service covered and cumulative, year-to-date total amount of benefits as related to the deductible, initial coverage limit, annual out-of-pocket maximum and the cumulative incurred benefits. In addition, any formulary changes that affect the beneficiary must be contained in this notice.

Issue: EOBs are not typically provided for prescription drug benefits since the transaction is handled at the point of sale. Providing EOBs will add additional administrative cost to the program. In addition, the information about deductibles and cumulative spending that would appear on EOBs is not applicable to full dual-eligibles and some low income beneficiaries.

Anthem Recommendation: Allow the Part D plan to provide information related to the items or services covered and cumulative benefits upon request, including making the information available through electronic means such as an IVR. If CMS does decide to require EOBs in the final regulation, the information required on the EOB should be modified so that it is applicable

to the particular beneficiary's benefit (i.e. accounting for the differences in low-income benefits)..

Issue: The regulation currently states that the EOB should be provided during the month any benefits are provided.

Anthem Recommendation: If CMS decides to require EOBs in the final regulation, the language should be modified to reflect that an EOB is provided following a month in which any benefits are provided. Also CMS should consider a quarterly requirement as opposed to a monthly requirement in order to effectively manage administrative costs.

Issue: The regulation would require the notice of any formulary changes for a particular beneficiary to be contained in the EOB. This may be difficult and costly to accomplish from an administrative perspective.

Anthem Recommendation: Allow plans the flexibility to provide the notice of formulary change in other ways, if a plan desires. For example, allow plans to send individual letters to beneficiaries who will be adversely impacted by the formulary change.

Cost-Effective Drug Utilization Management (§423.153(b))

Proposed Rule: The Proposed Rule at §423.153(b) requires each PDP sponsor or MA organization offering a MA-PD plan to establish a cost effective utilization management program (UM).

CMS Requests for Comments: CMS requests input regarding whether they should look to industry standards for setting UM standards for Part D plans.

Issue: UM techniques continue to evolve and different plans are utilizing different methods to obtain the same result. Establishing standards could inhibit innovation in this rapidly evolving area.

Anthem Recommendation: CMS should retain the current requirement for drug plans to establish cost-effective UM programs without prescribing specific "industry" standards.

Quality Assurance Program (§423.153(c))

Proposed Rule: The Proposed Rule at §423.153(b) requires Part D plans to establish a quality assurance program that includes measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

CMS Requests for Comments: CMS requests input with respect to how error rates be used to compare and evaluate plans.

Issue: Error rates do not seem to be an accurate or appropriate measure for comparing Part D plans. A drug plan's utilization review program will identify certain errors, but this error does not reflect the performance of the drug plan. Rather, it reflects the performance of those prescribing the medications. A drug plan cannot control what a physician prescribes, but it can identify

through its utilization review those prescriptions that appear to be inappropriate based upon FDA approved indications or the manufacturer recommended use.

Anthem Recommendation: An error reporting requirement should not be included in the final regulation.

Medication Therapy Management Program (§423.153(d))

Proposed Rule: The Proposed Rule at §423.153(d) requires Part D plans to establish Medication Therapy Management Programs (MTMP) to assure that drugs prescribed to targeted beneficiaries are appropriately used to optimize clinical outcomes through improved medication use.

CMS Request for Comments: CMS requests input with respect to best practices by MTMPs, essential elements of MTMPs, and appropriate quality assurance requirements for MTMPs.

Issue: MTMP programs are relatively new and are evolving. For this reason, CMS should allow drug plans flexibility to develop programs that address the needs of their specific populations. For instance, a drug plan located in one area of the country may have a high concentration of enrollees with diabetes, while a drug plan in another area may have a concentration of enrollees with HIV/AIDs.

Anthem Recommendation: CMS should allow drug plans the flexibility to develop and refine their MTMP programs to meet the needs of their specific enrolled beneficiaries.

Subpart F -- Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

Submission of bids and related information (§423.265(c))

Proposed Rule: The Proposed Rule at §423.265(c) describes the requirements for the Part D bid. Each bid must reflect the applicant's estimate of its average monthly revenue requirements to provide the qualified prescription drug coverage for a Part D eligible individual with a national average risk profile.

Issue: MMA provides for supplemental coverage for low income beneficiaries and Medicaid dual eligible individuals. The proposed regulation appears to contemplate reimbursement for this supplemental coverage as being a separate reimbursement for the additional benefits in addition to the plan's risk adjusted bid amount. We view the additional benefits being provided under the low-income subsidy (LIS) as being different products that will have cost due to:

- additional benefits
- different utilization due the difference in cost sharing
- additional differences in utilization that are not captured by the medical risk adjuster.

We believe this latter factor will have a material impact on the expected claims cost based on our experience in Medicaid managed care and a review of the limited literature available on this subject.

In the preamble, CMS is seeking comment on a risk adjuster for LIS which we believe is appropriate. However, it is likely that companies will want to adjust their bid to reflect their estimate for the difference in cost for LIS beneficiaries not accounted for by the LIS risk adjuster. While this can be accomplished by including a factor in the claims estimate for a beneficiary with a national average risk profile, the bid becomes very sensitive to the mix of LIS versus non-LIS individuals a plan attracts. We believe a better approach is to allow a plan to submit bids for the various categories of enrollees.

Anthem Recommendation: CMS should modify the final regulation to allow plans to submit bids for the various categories of enrollees reflecting the differences in benefits and utilization not accounted for by the medical risk adjuster.

Rules regarding premiums: Late enrollment penalty amount (§423.286(d)(3))

Proposed Rule: The Proposed Rule at §423. 286(d)(3) describes parameters regarding the determination of the late enrollment penalty amount. In the preamble, CMS has asked for comments regarding the 1% penalty.

Issue: The Part D drug benefit is a voluntary benefit and thus subject to adverse selection. For most people on Medicare, prescription drug expenses are much more predictable than medical expenses. A lot of prescription drugs taken by persons on Medicare are for the treatment of chronic conditions and once a person starts taking the medication they will take it the rest of their life, and these drugs often cost close to $100 a month. This makes it easy for a person to evaluate when Part D becomes a good value to them. The 1% per month penalty, which is close to the amount of the Part B penalty, will likely not be adequate to account for this adverse selection, but given there is no other information on which to base a penalty it appears to be reasonable.

Anthem Recommendation: The 1% per month late penalty should be retained.

Subpart G – Payments to PDP Sponsors and MA Organizations Offering MA-PD Plans for All Medicare Beneficiaries For Qualified Prescription Drug Coverage

Determination of Payment: Health Status Risk Adjustment (§423.329(b))

Proposed Rule: Section 423.329(b) of the Proposed Rule states that CMS will publish an appropriate methodology for adjusting the standard bid amount to take into account variation in costs for basic prescription drug coverage among prescription drug plans and MA-PDs based on differences in the actuarial risk of the enrollees being served. CMS will develop the prescription drug risk adjustment methodology taking into account similar methodologies to risk adjust payments to MA organizations. CMS proposes to develop and publish this risk adjustment methodology in the 45-day notice for the announcement of 2006 MA rates.

Issue: Presently CMS only has medical diagnoses on which to base the risk adjuster. A number of models exist that use prescription drug information to identify medical issues. To our knowledge, little work has been done to do the opposite. Accuracy of the risk adjuster is a critical component of the reimbursement a plan will receive under the program. CMS should use the medical and prescription drug data that it has available under FEHBP, Tricare for Life,

Medicaid and other publicly funded programs to test the validity of the proposed risk adjuster. For 2006, this analysis should be published as far in advance of the official 45 day notice of 2006 MA rates in order to seek comments and refine the methodology before officially publishing it for comment.

Anthem Recommendation: CMS should use data from publicly funded programs or from actuarial consulting firms to develop and test the validity of the risk adjusters. This analysis should be shared for comment prior to the 45 day notice for the announcement of 2006 MA rates to facilitate refinement and the development of 2006 Part D bids.

CMS Request for Comment: CMS asks for comment on the risk adjustment methodology for low-income subsidy (LIS) for individuals. They are concerned that a risk adjustment methodology, coupled with the statutory limitation restricting LIS payments for premiums to amounts at or below the average, could systematically underpay plans with many LIS enrollees.

Anthem Recommendation: Risk adjustment should be implemented in a manner that does not disadvantage plans that enroll a disproportionate number of LIS or any other type of high risk, high cost enrollees. Any risk adjuster for LIS enrollees should account for increased utilization because of less cost sharing as well as potential pent-up demand associated with LIS individuals once they become covered under Part D. In addition, we believe there are additional differences in utilization not captured by medical risk adjusters based on our experience with Medicaid managed care and a review of the limited literature on this subject. The accuracy of this risk adjuster is critical as plans that enter the program in 2006 will likely have a much higher concentration of LIS enrollees in later years of the program. In 2006, dual eligibles that have not enrolled will be randomly assigned to a plan and these people are likely to remain in the assigned plan. If the risk adjuster is not appropriate, these plans will be disadvantaged because they entered the program at the outset. The LIS risk adjustment methodology should be disclosed well in advance of the 45 day notice since it is a critical component of preparing the bid. In addition, CMS should obtain claims data from state Medicaid programs for dual eligible individuals and provide this to potential bidders to assist them in preparing their bid.

Subpart J – Coordination Under Part D Plans with Other Prescription Drug Coverage

General Rule (§423.464(a))

Tracking TrOOP Costs

Proposed Rule: The Proposed Rule at §423.464(a) requires Part D plans to coordinate drug benefits with group health plans, FEHBP, Tricare, State Pharmaceutical Assistance Programs as well as other plans providing prescription drug coverage to Medicare beneficiaries. This coordination is necessary for Part D plans to account for true out-of-pocket (TrOOP) costs as required under the MMA and also to comply with Medicare secondary payer provisions in situations where an employer plan is primary.

CMS Request for Comments: CMS is considering two options for data exchange related to the Part D coordination of benefits and accounting for TrOOP costs. Under the first option, Part D plans would have sole responsibility for tracking TrOOP costs. Under the second option, CMS would contract with a TrOOP facilitation coordinator to establish a single point of contact

between payers. This entity would receive enrollment and claims payment information from all primary and secondary payers, match claims and enrollment data, and send claims files to the appropriate Part D plans.

Issue: Part D plans need an effective and efficient means for collecting the data they need to accurately process claims including payment from other sources. Given the multitude of payers which would need to exchange data, a system where each drug plan facilitates their own data exchange would be extremely inefficient. For instance, a Part D plan would need to build links with any employer whose retiree is enrolled in their plan regardless of where the employer is located. Conversely, a national employer who decides to supplement the Medicare benefit could conceivably have to provide information to every PDP in the country.

Anthem Recommendation: CMS should adopt the second option of contracting with an outside entity that serves as some type of intermediary as this will be more efficient than potentially thousands of independent arrangements.

Subpart L – Effect of Change of Ownership or Leasing of Facilities During Term of Contract (423.551 through §423.553)

Proposed rule: The Proposed Rule at §423.551 through §423.553 addresses a PDP sponsor organizations "change of ownership" (CHOW) or leasing of facilities during a PDP contract term and the steps they must follow if they intend to assign (i.e. novate) their PDP contract or business governing a PDP contract to another entity.

CMS Request for Comments: CMS ask for input of whether they should consider modifications of existing CHOW provisions in order to reduce the administrative burden and to increase the effectiveness of the provisions.

Issue: The proposed novation and lease requirements are very similar to current Medicare Advantage requirements and these requirements are not overly burdensome. One area of possible refinement would be to stipulate in the final regulation that financial and solvency information required by state departments of insurance or similar entities is sufficient documentation for purposes of documents that a plan meets financial and solvency requirements.

Anthem Recommendation: Anthem recommends that the final regulation allow for plans to provide the financial and solvency information submitted to state departments of insurance or similar entities as documentation that a plan meets financial and solvency requirements.

CMS Request for Comments: CMS ask for input on how the CHOW and leasing provisions should be applied to large companies with multiple business units.

Issue: Inter-company arrangements should not be considered a CHOW or a leasing arrangement. Multi-state companies are typically made up of various entities and may be licensed in different states, but certain functions may be centralized in one entity to maximize efficiencies and avoid duplication across the entire organization. In order to make Part D and MA programs successful, multi-state companies need to know that such inter-company arrangement do not constitute CHOW or leasing arrangements. Further, multi-state companies need to be able to delegate such functions to a common subsidiary or related entity as efficiently as possible. Currently, most such inter-company arrangement must be submitted to the applicable state regulatory bodies for

review and approval. This process results in differing agreements and additional administrative cost.

Anthem Recommendations: CMS should explicitly note in the regulation that delegation of PDP functions, in whole or in part, to a commonly owned or affiliated company does not constitute a CHOW or leasing and does not require CMS review unless the applicable legal entity truly intends to novate the agreement or lease its facility to an affiliated company as evidenced by written notice to CMS. In addition, CMS should explicitly preempt state inter-company filing requirements as they relate to PDP, Part D and MA functions and services.

Issue: Under most state laws, HMOs are required to be domiciled in the applicable state in order to obtain an HMO license. This means that when CMS contracts with a multi-state entity, they must execute a contract with each licensed entity that makes up that company. This may also cause consumer confusion in those instances where the HMO or the contracted entity must use the licensed name as compared to the dba or common company name.

Anthem Recommendations: CMS should allow one entity to contract for multi-state regions, provided the entity has affiliated entities in such regions that are compliant with applicable state licensure laws. This requirement should apply to both PDP plans and MA plans.

Subpart M – Grievances, Coverage Determinations, and Appeals

Exceptions Process:Requests for Exceptions to a PDP's Tiered Cost-Sharing Structure (§423.578(a))

Proposed Rule: The Proposed Rule at §423.578(a) requires drug plan sponsors to allow enrollees to request exceptions to tiered cost-sharing requirements under certain circumstances. The Proposed Rule does permit drug plans to request certification from the enrollee's prescribing physician documenting the necessity for the exception. If the exception is granted, enrollees would have access to a covered drug at a lower tier of cost-sharing than normally required by the plan. Denials of exceptions requests are subject to appeal.

Issue: Health plans and PBMs developed 3 tier formularies (and now those with more tiers) to provide an alternative to closed formularies. A basic premise of these formularies is that the person has the alternative to purchase the non-preferred drug if they are willing to participate in additional cost sharing. This provides the consumer with choice, while providing the plan with better leverage when negotiating with drug companies. Anthem recognizes that CMS is limited by the statutory language related to this matter and believes that CMS has taken the right approach in requiring the physician to document the medical need for the exception. It is important that these exceptions only be granted when there is a clinically significant medical need.

While the statutory language does allow for this exception, it is important to note that the language references "preferred" and "non-preferred" drugs. In a three tier formulary the lowest tier is usually for generics, along with some multi-source brand drugs. The industry, drug companies and providers refer to the next tier as the "preferred tier" and tier 3 is referred to as "non-preferred". We do not believe it was the intent of Congress for beneficiaries to obtain non-preferred drugs at the lowest "generic" co-pay tier. If this was the intent Congress would have used language such as the lowest copay or the co-pay applicable to generic drugs.

Anthem Recommendation: Retain the language in the Proposed Rule that permit drug plans to require written certification from the enrollee's prescribing physician documenting why such an exception is needed. Drug plans should be expressly permitted to require physicians, as part of the physician certification process, to provide the following information:

1) A copy of the physician's notes from the patient's medical record that demonstrate based upon previous treatment why the preferred drug(s) or generic drug(s), and all similar drugs on the formulary, are clinically inappropriate for the enrollee or the previous adverse impact such a drug(s) has had for the enrollee; and
2) For cases in which an exception is being requested because of an adverse effect of a preferred drug on the enrollee, a copy of the FDA Medwatch form on which the physician reported the adverse drug event on behalf of the enrollee. This will ensure that the FDA is aware of issues that impact quality.

We further recommend that the Final Rule clarify that the granting of an exception will only result in the application of the preferred "brand" cost-sharing amount and not the generic/lowest cost-sharing amount.

Submitter : Mr. Steven Hitov **Date & Time:** 10/04/2004 08:10:40

Organization : National Health Law Program Inc

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See comments on Subpart M attached.

Submitter : Mr. Amar Vyas **Date & Time:** 10/04/2004 08:10:38

Organization : Mr. Amar Vyas

Category : Academic

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plana??s overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy.

I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. This will adversely affect a pharmacista??s ability to continue to serve patients. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congressa?? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Congress wanted to ensure that patients could continue to use the pharmacy and pharmacist of their choice. Requiring plans to provide patients fair access to their pharmacy was a promise made by Congress that CMS should honor. That will help patients access a local pharmacy for their full benefit. a??Accessa?? isna??t a??accessa?? if patients are forced to use other pharmacies.

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

The Medication Therapy Management MTM) services may prove to be the most significant provision. It has the potential to improve the quality, and to reduce the cost of drug therapy for Medicare.
The current pharmacy education system is preparing pharmacists who capable of performing this role. Additionally, Continuing Education programs have been available to pharmacists to update and prepare them to perform this role. Since this provision has the potential to set the standards for MTM services for other plans, it is important that the program is carried out correctly. It is my concern that leaving the decision of who can provide MTM to the plans may allow plans to choose less qualified
providers to provide MTM services. There are several models, such as the NC Polypharmacy Project in nursing homes which reveal that pharmacists do MTM well, so I urge you to encourage plans to use pharmacists unless they have documented evidence that their alternative approach works as well as having that service provided by a pharmacist.
Many North Carolina pharmacists are providing MTM services in their practice that meet the MTM Services Definition and Program Criteria approved July 27, 2004 by eleven supporting organization in pharmacy. Based on our experience in the Asheville Project, face-to-face interaction between the patient and the provider So we urge CMS to require face-to-face interaction for MTM Services, at least for the initial visit.

Some other concerns to help make this program work appropriately:
Plans must be required to inform beneficiaries when they are eligible for MTMS and inform them about their choices (including their local pharmacy) for obtaining MTMS.
Once a beneficiary becomes eligible for MTMS, the beneficiary should remain eligible for MTMS for the entire year.
CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries.
Pharmacists should be allowed to provide MTMS to non-targeted beneficiaries. Since MTMS is not a covered benefit for nontargeted beneficiaries, pharmacists should be able to bill patients directly for the services.
Plans must be required to pay the same fee for MTMS to all providers. For example, plans should be prohibited from paying pharmacists at non-preferred pharmacies less than pharmacists at preferred pharmacies for the same service.
CMS must carefully evaluate each plana??s application to provide an MTM benefit. CMS must examine whether the fee the plan proposes to pay for the MTM services is high enough to entice pharmacists to provide MTMS.

In conclusion, I urge CMS to revise the regulation: to require plans to meet the TRICARE requirements at the local level; to not allow a plan to have both preferred and non-preferred providers; to only allow price differentials for providing an extended drug supply based on cost of service and not on the differentials in drug costs; require MTMS to be performed by pharmacists unless a plan has evidence their approach works as well as a pharmacist providing MTMS; make sure the proposed payment for MTMS is adequate to encourage pharmacistsa?? participation.

Submitter : Melanie Bella **Date & Time:** 10/04/2004 09:10:53

Organization : Indiana - Medicaid Policy and Planning

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Indiana Medicaid and the State Children?s Health Insurance Program (SCHIP) combined provide comprehensive drug coverage to approximately 784,000 individuals. Of those 784,000 enrollees, approximately 93,000 are full benefit dual eligibles as of June 1, 2004.

In addition to Medicaid and CHIP, Indiana also operates a State Pharmaceutical Assistance Program (SPAP), called HoosierRx. HoosierRx provides financial assistance to seniors up to 135% of the federal poverty level. Current enrollment in HoosierRx is approximately 22,800 individuals. Unlike the new Medicare Part D benefit, HoosierRx has no asset test. We support the requirement that the new Medicare Prescription Drug Plans (PDPs) and Medicare Advantage drug plans (MA-PDPs) coordinate with SPAPs but are concerned about CMS? interpretation of the antidiscrimination language in the law at Sec. 1860D-23(b)(2), which would preclude the use of a preferred PDP.

A significant area of concern to us is the transition of dual eligibles to a PDP or MA-PDP and the potential for a gap in coverage between the effective date of Medicare Part D (January 1, 2006) and the time it takes for a dual eligible individual to either choose a plan or to be auto-enrolled (which will not occur until May 2006). This is a vulnerable population and extra care must be taken to ensure they experience no gap in coverage once Medicaid pharmacy benefits end on January 1, 2006.

We recommend that CMS allow for temporary Medicaid coverage via a continuation of federal financial participation until an individual has either voluntarily chosen a plan or has been auto-enrolled into a plan. We realize CMS may be constrained by the law in this area and would urge CMS to seek modification of the law in this area for the dual eligibles. The negative clinical and financial ramifications of a gap in coverage provide ample rationale for seeking statutory change in this area.

Another major area of concern is the cost of the Medicare Modernization Act (MMA) to states. We are particularly concerned that the ?phasedown state contribution? may not fully recognize the aggressive cost containment measures enacted by states in recent years. While congressional intent was to phase down state contributions, by using a growth factor that overstates cost increases and a rebate number that may not reflect current rebate collection levels, states will likely pay more rather than less for prescription drug coverage for dual eligibles under Medicare Part D. In addition, states, such as Indiana, who receive supplemental rebates, will see a substantial part of their leverage taken away when the dual benefit covered lives leave the Medicaid program (even though the majority of their costs remain through the phasedown), which will result in lower rebates for the states. We urge CMS to exercise the flexibility in the statute to use the most appropriate growth factor that actually is representative of Medicaid program prescription drug cost increases.

States will also incur costs through the administrative functions they are required to assume. And, those costs may increase if CMS requires states to develop a completely separate process for determining eligibility for the low-income subsidy, an issue we will address in greater detail in the comments that follow. Additionally, while we support enrolling those individuals eligible for Medicare cost sharing, it will result in an increase in dual eligible individuals, which will result in additional increased expenditures for states. Lastly, we are concerned that CMS/HHS will not be directly negotiating prescription drug prices for Part D. This, combined with the fact that prices will not be subject to Medicaid best price, leaves states exposed to higher costs that otherwise might be reduced.

Medicare Part D leaves states in the undesirable position of having no control over the spending or management of the benefit yet responsible for the costs.

CMS-4068-P-1282-Attach-1.pdf

CMS-4068-P-1283

Submitter : Ruchi Twiari **Date & Time:** 10/04/2004 08:10:45

Organization : UNC- Chapel Hill

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

RE: CMS-4068-P

Dear Sir or Madam:

I would like thank you for accepting comments in behalf of the MTMS regulations and ask you to consider a perspective on behalf of a future pharmacist and my concerns with the proper implementation of this regulation.

Subpart C: Benefits and Beneficiary Protections

The TRICARE retail pharmacy access standards should be amended to propose that only pharmacies that are on the preferred plan should meet the access requirements.
The current access regulations include preferred pharmacy and non-preferred pharmacies; this presents a burden on beneficiaries and compromises effective therapeutic management.
Beneficiaries should be allowed fair access to all pharmacies. This coerced method of providing care takes away the patient's choice of receiving care from a pharmacist they have previously built a personal and confidential relationship with. Patients should have the option to choose a convenient pharmacy.
Forcing patients to travel distances to receive MTMS will affect patient?s behavior by resulting in an increased disregard of their own therapeutic care as a result of frustrations of traveling inconvenience. Patients will arrive to pharmacies irritated and reluctant to spend adequate time engaged in an active MTMS session with the pharmacist.
The current access requirements also place less incentive for proper contracts with pharmacies. I am afraid many pharmacies will be left out of the plan?s pharmacy network. This compromises and excludes the level of service many pharmacists can provide to this patient population.

Subpart D: Cost Control & Quality Improvement Requirements for
Prescription Drug Plans

Medication Management Services

After four years of graduate training for a Doctor of Pharmacy degree, I will become a drug expert on therapeutic medication management. Four years of training in multiple chronic and acute disease states has prepared pharmacists to make effective therapeutic decisions. With extensive preparation we are competent in providing the following services:

? Patient health assessment
? Creating medication treatment plans
? Managing high-cost ?specialty? medications
? Monitoring response to drug therapy
? Monitoring and adjusting for drug interactions
? Educating and training patients on disease states
? Educating patients on medications related concerns such as proper administration, side-effects, contraindications, precautions, monitoring parameters, etc.
? Managing special patient populations ie. children, pregnant females, geriatric

The great thing about implementing pharmacists as primary providers of MTMS is they have the knowledge to manage a great array of chronic conditions which present in one patient. The average Medicaid/Medicare patient is on 8 prescription drugs. We have the ability to decrease duplications/poly-therapy, thus decreasing costs and providing MTMS in one step. Pharmacists along with therapeutic knowledge have the insight of the remarkably increasing drug costs and the specifics of optimizing the use of an agent that is cost effective yet does not sacrifice efficacy.

If pharmacists were not permitted to be the primary providers of MTMS our education would be a waste of time. Please do not take this opportunity away from us. Medication therapy management is the prime focus of our education and this is the first hope for a shift in our role in the current health-care system to one that is more representative of our training/abilities.

In the hospital system, pharmacists continue to prove their effectiveness and value to America?s current health care system. Clinical trials and studies continue to prove that the approach of integrating a pharmacist on a team of health care professionals, to provide patient care has and continues to reduce costs, reduce adverse

CMS-4068-P-1284

Submitter : Mr. Timothy Schuerch **Date & Time:** 10/04/2004 08:10:07

Organization : Alaska Native Tribal Health Consortium

Category : Hospital

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

Please see attached comments in MS Word

CMS-4068-P-1284-Attach-1.doc

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM
Administrative Offices 4141 Ambassador Drive
Anchorage, Alaska 99508
Telephone: 907-729-1900
Facsimile: 907-729-1901

FILE CODE: CMS-4068-P

Comments To Proposed Medicare Part D Regulations

I. INTRODUCTION: The Alaska Native Tribal Health Consortium

The Alaska Native Tribal Health Consortium (ANTHC) is the largest privately operated Indian health program in America, managing over $125 million annually in IHS program and project funds, and with total revenues in excess of $300 million per year, all of which is devoted exclusively to providing health services to Alaska's 100,000+ Alaska Natives.

We are organized under the Alaska Non-profit Code, and enjoy tax-exempt status under Section 501(c)(3) of the Internal Revenue Code. Our three primary sources of revenue are (1) compacted IHS funds; (2) third party reimbursements, including private insurance, Medicare and Medicaid; and (3) federal grant funds. Our vision is *"a unified Native health system, working with our people, achieving the highest health status in the world."*

Pursuant to our charitable public health mission, we employ over 1,600 staff, including over 600 Indian Health Service (IHS) employees assigned to us under the Intergovernmental Personnel Act (IPA), and over 100 Commissioned Officers of the Public Health Service assigned to us under 42 USC 2004b in accord with 42 USC 215(d).

Our services encompass the Alaska Native Medical Center (ANMC), a JCAHO-accredited 150-bed acute care hospital in Anchorage, which we operate in cooperation with the Southcentral Foundation under the authority of Section 325 of P.L 105-83.

The ANMC Pharmacy is a large I/T/U pharmacy providing an array of services to our customer-owners, including Medicaid covered services, Medicare Part A covered services, Medicare Part B covered services, and Medicare Part D covered services. The ANMC Pharmacy serves many thousands of Medicare Part D eligible AI/AN, a significant percentage of which are subsidy eligible AI/AN.

Thus the treatment of AI/AN under the Medicare Part D regulations, especially AI/AN receiving services from I/T/U pharmacies, will have a significant impact on our third party reimbursements, which we heavily rely upon to support the provision of services to our AI/AN customer-owners.

II. KEY POLICY CONSIDERATIONS

(1) Aligning Part D regulations, as permitted by statute, with the Departmental AI/AN policy goal of narrowing the American Indian/Alaska Native health disparities gap, e.g., by lowering AI/AN barriers to access to pharmacy services.

(2) Consistent with Departmental AI/AN policy goals, and as permitted by statute, maximizing participation of Part D eligible AI/AN in the Part D program by ensuring that AI/AN, and the I/T/U pharmacies serving AI/AN, are consistently and uniformly treated in a manner that reflects Departmental AI/AN policy goals.

(3) Consistent with Departmental AI/AN policy goals, and as permitted by statute, maximizing participation of Part D eligible AI/AN by tailoring the regulations to prospectively avoid Secretarial findings for AI/AN under 42 USC 1860D-11(e)(2)(D)(i), with regard to any PDP, that "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan."

(4) Consistent with Departmental AI/AN policy goals, and as permitted by statute, mitigating the financial burden on I/T/U pharmacies and States resulting from transition of payment for Part D covered services for subsidy eligible AI/AN from 100% FMAP-paid State agencies to the Medicare Part D system, which allocates costs for subsidy eligible AI/AN between I/T/U pharmacies, CMS and States.

(5) Consistent with Departmental AI/AN policy goals, and as permitted by statute, avoiding penalization of I/T/U pharmacies for providing services to AI/AN on an IHS-prepaid basis, without charge to the patient (per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)).

III. COMMENTS

SUBPART A—GENERAL PROVISIONS

(NO COMMENTS)

SUBPART B—ELIGIBILITY AND ENROLLMENT

COMMENT WITH REGARD TO THE SUBPART AS A WHOLE: In order to ensure maximum participation of AI/AN in Part D; in order to ensure that the Part D regulations treat AI/AN and the national network of I/T/U pharmacies serving AI/AN in a uniform manner that is consistent with Departmental AI/AN policy goals; and in order to minimize the likelihood of Secretarial findings for AI/AN under 42 USC 1860D-11(e)(2)(D)(i), with regard to any PDP or MA-PD, that, "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan," **ANTHC feels the Secretary should consider amending the provisions of Subpart B of the proposed regulations to reflect the following comprehensive statutory approach to access and enrollment of AI/AN in PDPs and MA-PDs:**

(1) The Secretary should exercise his statutory discretion under 42 USC §1860D-1(b) and 42 USC §1395w-21(b)(1)(A) to waive, in the case of AI/AN, the requirement that Part D eligible individuals may only enroll in a plan that encompasses that PDP's or MA-PD's geographic region;

(2) Through the bidding and approval processes of 42 USC §1860D-11 (PDPs) and §1854(a) (MA-PDs), the Secretary should establish a small number of PDPs and/or MA-PDs that, in addition to providing coverage for all Part D eligible individuals in their respective PDP or MA-PD area(s) who choose to enroll in that plan, would also provides coverage for AI/AN on a national basis for all Part D eligible AI/AN who choose to enroll in each such plan, as permitted by 42 USC §1860D-11(a)(3).

(3) In preparation for PDP and MA-PD bidding processes, the Secretary should develop and publicize, in close consultation with the CMS Tribal Technical Advisory Group (CMS TTAG), an **AI/AN supplemental information packet**. The packet would solicit PDP sponsors and MA-PD organizations to consider including in their bids one or more plans that would provide coverage for Part D eligible AI/AN on a national basis. It would contain information on Part D eligible AI/AN and the national network of I/T/U pharmacies serving AI/AN, in sufficient detail to allow bidders to fairly assess whether they should include in their bids the information required under 42 USC §1860D-11(b)(2), with regard to any plan(s) in the bid proposing to provide coverage for Part D eligible AI/AN on a national basis. The packet would also set forth any "additional information" that the Secretary (in close consultation with the CMS TTAG) would require to be included in bids containing one or more plans to provide national coverage to Part D eligible AI/AN, as permitted under 42 USC §1860D-11(b)(2)(F). Specific types

of information that the Secretary might consider including in the **AI/AN supplemental information packet** might include general information on AI/AN and AI/AN health issues, as carefully and compellingly set forth in **the National Indian Health Board comments to these regulations.** Consideration should also be given to describing in detail the national network of I/T/U pharmacies serving AI/AN, including:

- who they serve (AI/AN, per 25 USC §1680c);
- the basis on which services are provided (IHS-prepaid without charge to the AI/AN);
- where they are located (in I/T/U facilities near the AI/AN served);
- the way they buy drugs (FSS or 340B programs);
- the way they dispense drugs (with much more patient consultation than in the private sector due to the high risk of culture and/or language barriers impeding instructions);
- the information system used track drug and reimbursement information (RPMS);
- the charitable mission served (providing pharmacy services to a population group and in geographic areas characterized by failure of competitive market dynamics); and
- the way Medicare reimbursements are processed (via a nationally centralized system).

(4) In reviewing and negotiating bids (under 42 USC §1860D-11(d)) that contain one or more plans proposing to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such review and negotiation is conducted in a manner consistent with Departmental AI/AN policy goals.

(5) In approving or disapproving any plan (under 42 USC §1860D-11(e)) that proposes to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such approval or disapproval is made in a manner consistent with Departmental AI/AN policy goals, especially with regard to the requirement of 42 USC §1860D-11(e)(2)(D) that the Secretary approve a plan only if he "does not find that the design of the plan and its benefits (including any formulary or tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan."

(6) The Secretary has already successfully adopted a centralized national model similar to that proposed above for processing Medicare Part A and Part B payments to I/T/U facilities, through the use of a single Carrier for I/T/U providers nationwide. With I/T/U facilities already possessing the capacity to be reimbursed for Part A-covered drugs, and on the verge of gaining the capacity to be reimbursed for Medicare Part B-covered drugs and biologicals under §630 of the MMA, the Secretary may wish to consider the efficiencies and improved coordination of benefits in the administration of the various Medicare drug programs as they apply to I/T/U providers that would likely result from adopting a similarly centralized, national system for processing Part D drug benefit payments to I/T/U facilities. For example, Trailblazer LLC has done a fair job of coordinating Part A and Part B payments to I/T/U facilities since the passage of the BIPA. Organizations like Trailblazer might prove to be efficient and effective sponsors of

PDP or MA-PD plans providing Part D coverage to Part D eligible AI/AN on a national basis.

(Additional Comments to SUBPART B, ELIGIBILITY AND ENROLLMENT):

42 CFR 423.44 DISENROLLMENT BY THE PDP

COMMENT: Because I/T/U pharmacies provide services to AI/AN on an IHS-prepaid basis without charge to the AI/AN, per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)), the financial burden of disenrollment of a Part D eligible AI/AN receiving services from an I/T/U pharmacy will fall squarely on the I/T/U pharmacy, rather than the AI/AN. Moreover, the cost and expense of reenrollment of the Part D eligible, including payment of some or all of the premiums that may be owing, will also fall on the I/T/U pharmacy. Thus ANTHC feels the Secretary should consider adding a new subsection to 42 CFR 423.44 to clarify that in the case AI/AN, the Secretary reserves the discretion to waive or amend the disenrollment and reenrollment provisions of the section.

42 CFR 423.48 INFORMATION ABOUT PART D

COMMENT: This section requires each PDP and MA-PD plan to provide to CMS on an annual basis "the information necessary to enable CMS to provide current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage." For PDP or MA-PD plans providing coverage for Part D eligible AI/AN on a national basis, the Secretary should require this information to also be provided to the CMS TTAG and the IHS for distribution to AI/AN through the national network of I/T/U pharmacies.

42 CFR 423.50 APPROVAL OF MARKETING MATERIALS AND ENROLLMENT FORMS

COMMENT: CMS should consult closely with the CMS TTAG and the IHS in carrying out its review and approval of the marketing materials and enrollment forms of PDP and MA-PD plans providing coverage for Part D eligible AI/AN on a national basis.

42 CFR 423.56 PROCEDURES TO DETERMINE AND DOCUMENT CREDITABLE STATUS OF PRESCRIPTION DRUG COVERAGE

COMMENT: Subsection (a)(9) properly includes as creditable prescription drug coverage "coverage provided by the medical care program of the IHS, Tribe or tribal organization, or urban Indian organization (I/T/U)." However, we feel there are significant administrative burdens and inefficiencies with the approach of the proposed regulations to require, before coverage provided by I/T/U providers may be considered creditable prescription drug coverage, that coverage provided by I/T/U providers must meet the general requirement of subsection (a) that "the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles…." Because I/T/U pharmacies uniformly provide services to AI/AN on an IHS-

prepaid basis, without charge to the AI/AN, and uniformly only scale back services as a last resort when funding falls short, it is highly likely that coverage provided by I/T/U providers will nearly always equal or exceed the actuarial value of standard Medicare Part D prescription drug coverage. And, in those few instances when it may not, it will likely nearly always be because program funding was inadequate, in which case the I/T/U provider providing coverage would especially not be in no position to divert scarce resources away from direct services in order to pay for expensive actuarial analyses. Thus we believe significant public health policy interests weigh in favor of amending this section to waive the actuarial equivalence requirements in the case of coverage provided by I/T/U providers.

SUBPART C—BENEFITS AND BENEFICIARY PROTECTIONS

42 CFR 423.100 DEFINITIONS

Definitions of "INCURRED COSTS" and "INSURANCE OR OTHERWISE:

COMMENT: A bona fide question of statutory interpretation exists with regard to whether (1) amounts up to the annual deductible limit paid by an I/T/U pharmacy on behalf of non-subsidy eligible AI/AN, (2) cost-sharing expenses above the annual deductible limit up to the initial coverage limit waived or absorbed an I/T/U pharmacy on behalf of a non-subsidy eligible AI/AN, and (3) amounts exceeding the initial coverage limit paid by an I/T/U pharmacy on behalf of a non-subsidy eligible AI/AN, should be treated as *"incurred costs"* under 42 USC §1860D-2(b)(4)(C)(ii), and thus be counted by CMS towards the non-subsidy eligible AI/AN Part D enrollee's annual out-of-pocket threshold, which in 2006 will be $3,600.

It is fairly clear that under the preceding subsection at 42 USC §1860D-2(b)(4)(C)(i), all three of these cost categories must be treated consistently, i.e., either all three are "incurred costs" in cases where an I/T/U pharmacy pays or waives them on behalf of a non-subsidy eligible Part D AI/AN enrollee, and thus counted towards the AI/AN's annual out-of-pocket threshold, or all three are "insurance or otherwise," and not counted towards the AI/AN's out-of-pocket threshold.

Given his statutory discretion in this matter, the Secretary may wish to consider the likely, reasonably foreseeable outcomes of the latter, more restrictive of the two interpretations, and determine whether those outcomes are consistent with Departmental AI/AN policy goals.

If in 2006, an I/T/U pharmacy were to provide services to a non-subsidy eligible AI/AN Part D enrollee on an IHS-prepaid basis, without charge to the AI/AN, per its charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)), it would likely want to calculate the costs vs. benefits of paying the $250 deductible on behalf of the AI/AN.

If the AI/AN were to use up $1,250 worth of covered drug benefit in the year, then the I/T/U pharmacy might well decide to pay the $250 deductible, because after it was paid, the PDP or MA-PD would pay 75% of the remaining $1,000 ($750) with the I/T/U pharmacy paying the

remaining 25% ($250). In other words, between the deductible payment and its 25% cost-sharing obligation, the I/T/U pharmacy would pay or waive a total of $500 on behalf of the AI/AN, in return for which it would receive $750 from the PDP or MA-PD, or 60% of the AI/AN's total covered drug costs for the year.

If the AI/AN were to use up $2,250 worth of covered drug benefit in the year, topping out but not exceeding the initial coverage limit for the AI/AN in the year, then the I/T/U pharmacy would get a slightly better deal: it would pay $250 for the deductible, plus waive 25% of the remaining $2,000, for a total cost of $750. In return, it would receive from the PDP or MA-PD 75% of the $2,000 of drug costs in excess of the deductible, or $1,500, or 66.67% of the AI/AN/s total covered Part D drug costs for the year.

If the AI/AN were to use up $3,250 worth of covered drug benefit in the year, then the I/T/U pharmacy's benefit received from the PDP or MA-PD, as a percentage of payment for the AI/AN's total costs for covered Part D drugs for the year, would fall significantly: The I/T/U pharmacy would pay $250 for the deductible ($250), plus bear the cost of waiving the 25% cost-share for next $2,000 worth of covered drug benefit usage ($500), plus bear 100% of the cost of the remaining $1,000, because that is the amount by which the AI/AN's covered drug benefit costs for the year exceed his/her initial coverage limit ($1,000), for a total cost to the I/T/U pharmacy of $1,750, in return for which it would receive from the PDP or MA-PD 75% of the $2,000 ($1,500) of covered drug costs exceeding the deductible amount but less than the initial coverage limit, or 46.15%.

And, to the degree the AI/AN were to use up ever higher amounts of covered drug benefit in the year, the I/T/U pharmacy's benefit received from the PDP or MA-PD, expressed as a percentage of payment for the AI/AN's total costs for covered Part D drugs for the year, would continue to decline ad infinitum, since neither the deductible amounts paid by the I/T/U pharmacy, nor the cost-sharing amounts waived by the I/T/U pharmacy, nor the payment by the I/T/U pharmacy on behalf of the AI/AN of costs in excess of the initial coverage limit would be counted as "incurred costs" for purposes of calculating when that AI/AN's out-of-pocket threshold for that year. In other words, the out-of-pocket threshold amount for that year for that AI/AN would never be reached, nor could the out-of-pocket threshold ever be reached in any year for non-subsidy eligible AI/AN Part D enrollees.

Thus the reasonably foreseeable net effect of treating I/T/U pharmacy payment and waiver amounts as "insurance or otherwise," and not as "incurred costs," is a modest benefit if the AI/AN uses up no more than a few thousand dollars per year in covered Part D drug benefit, but a complete absence of any additional benefit for amounts exceeding the initial coverage limit, which in 2006 will be $2,250. The stop-gap benefits that would normally come into play for amounts of the covered Part D drug benefits in excess of the annual out-of-pocket limit, $3,600 in 2006, would be completely eliminated. In other words, with regard to the significant stop-gap benefits that would otherwise be available to non-AI/AN non-subsidy eligible Part D enrollees, AI/AN non-subsidy eligible Part D enrollees, and the I/T/U pharmacies that serve them, are severely penalized precisely because the I/T/U pharmacy providing services to that AI/AN does

so on an IHS-prepaid basis, without charge to the patient (per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)). **In other words, the proposed regulations, as written, subject AI/AN and the I/T/U pharmacies that serve AI/AN to severe financial penalties in comparison to non-AI/AN and non-I/T/U pharmacies precisely for doing nothing more than fulfilling their public health mission and carrying out the Departmental policy objective of narrowing the AI/AN health disparities gap via, e.g., lowering AI/AN barriers to access to pharmacy services.**

We also agree with and incorporate by reference into these comments the excellent, well-thought-out public health policy discussion regarding these definitions in **the National Indian Health Board comments** to the definitions of "incurred costs" and "insurance or otherwise" in 42 CFR 423.100 of the proposed regulations.

42 CFR 423.100 DEFINITIONS (continued)

Definition of "Network Pharmacy:"

COMMENT: ANTHC feels consideration should be given to amending this definition, or otherwise clarifying in regulation, policy, PDP or MA-PD contract, and/or in "additional information" the Secretary might require of certain plans in their bid documents, that PDP or MA-PD plans that provide coverage for Part D eligible AI/AN on a national basis be required to include as "network pharmacies" all pharmacies in the national I/T/U pharmacy network.

Definition of "Person:"

COMMENT: ANTHC strongly urges the Secretary to amend this definition by adding an additional sentence that affirmatively assures the inclusion of all I/T/U pharmacies, regardless of whether operated by the IHS, a Tribe or tribal organization, or an urban Indian organization. The significance of this definition is that it would clarify that costs paid or waived by I/T/U pharmacies on behalf of AI/AN are "incurred costs" for purposes of calculating the annual out-of-pocket limit for all AI/AN Part D enrollees under 42 USC §1860D-2(b)(4)(B)(ii), including non-subsidy eligible AI/AN.

Definition of "Preferred Pharmacy:"

COMMENT: ANTHC feels consideration should be given to amending this definition, or otherwise clarifying in regulation, policy, PDP or MA-PD contract, and/or in "additional information" the Secretary might require of certain plans in their bid documents, that PDP or MA-PD plans that provide coverage for Part D eligible AI/AN on a national basis be required to treat all I/T/U pharmacies as "preferred pharmacies."

42 CFR 423.112 ESTABLISHMENT OF PRESCRIPTION DRUG PLAN SERVICE AREAS

(NO COMMENTS)

42 CFR 423.120 ACCESS TO COVERED PART D DRUGS

Subsections (a)(1) and (3):

COMMENT: We feel consideration should be given to creating an additional waiver under subsection (a)(3) of the pharmacy access requirements of subsection (a)(1) in the case of the national I/T/U pharmacy network. The national I/T/U pharmacy network has been established by the IHS, Tribes and tribal organizations, and urban Indian organizations for the express purpose of maximizing AI/AN pharmacy access within the constraints of the limited resources available to I/T/U pharmacies. To impose the generally applicable access requirements of (a)(1) on I/T/U pharmacies would be inequitable, costly, and have the effect of penalizing the more remote and underfunded I/T/U pharmacies by creating incentives for PDP and MA-PD plans to de-select them and otherwise attempt to exclude them from their respective networks. In other words, it is precisely because I/T/U pharmacies tend to serve populations and geographic areas characterized by failure that what would normally be generally applicable market assumptions implicit in subsection (a)(1) would not hold true. Again, without such a waiver, PDPs and MA-PDs will in many cases avoid dealing with I/T/U pharmacies, which in turn will result in sub-optimized participation of AI/AN, particularly those in remote or impoverished areas, in the Medicare Part D benefit, contrary to Departmental AI/AN policy goals.

Subsection (a)(5), Discounts for Preferred Pharmacies:

COMMENT: We feel consideration should be given to amending this subsection to clarify that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis must treat all I/T/U pharmacies as "preferred pharmacies," to ensure that in all cases, I/T/U pharmacies will receive the best negotiated PDP or MA-PD reimbursement available, assuring that IHS-funded I/T/U pharmacies, and thus taxpayers, will in all cases be able to take advantage of the financial benefits of the MMA's competition-assurance provisions, as well as assuring that the Department policy goal of narrowing the AI/AN health disparities via lowering AI/AN barriers to access to pharmacy services is well-served.

Subsection (b)(1), Formulary Requirements—Development and Revision By a Pharmacy and Therapeutic Committee:

COMMENT: This provision requires that a PDP sponsor's or MA organization's formulary "must be reviewed by a pharmacy and therapeutic committee" that meets certain requirements. We feel consideration should be given to amending this subsection to require that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis must include on their respective pharmacy and therapeutic committees at least one pharmacist or physician selected by the IHS; at least one pharmacist or

physician selected by Tribes and tribal health organizations; and at least one pharmacist or physician selected by urban Indian organizations.

Subsections (b)(4), (5), and (7), Periodic Evaluation of Protocols; Provisions of Notice Regarding Formulary Changes; Provider and Patient Education:

COMMENT: We feel consideration should be given to clarifying in the regulatory language or in Secretarial policy that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis be required to engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies in the protocol evaluation requirement of subsection (b)(4); the provisions of notice regarding formulary changes requirement of subsection (b)(5); and the provider and patient education requirement of (b)(7).

Subsection (c) Use of Standardized Technology:

COMMENT: We feel consideration should be given to clarifying in the regulatory language or in Secretarial policy that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis be required to engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies in the technology standardization requirements of this subsection.

42 CFR 423.128 DISSEMINATION OF PLAN INFORMATION

COMMENT: We feel consideration should be given to clarifying in the regulatory language or in Secretarial policy that PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis be required to engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies regarding the plan information dissemination requirements of this section.

42 CFR 423.132. PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS

COMMENT: We strongly urge the Secretary to consider amending this section to provide an exception from this requirement in the case of I/T/U pharmacies. I/T/U pharmacies provide services to AI/AN on an IHS-prepaid basis, without charge to the patient, per their charitable public health mission, Departmental AI/AN policy goals, and 42 USC 1320a-7b(b)(3)(G)). Thus it is the I/T/U pharmacies, and not the AI/AN receiving services, that bear the cost of PDP or MA-PD formulary choices, obviating the need for AI/AN receiving services from I/T/U pharmacies to have such price-comparison information.

SUBPART D: …

(NO COMMENTS)

SUBPART F: SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL

COMMENT: COMMENT WITH REGARD TO THE SUBPART AS A WHOLE: In order to ensure maximum participation of AI/AN in Part D; in order to ensure that the Part D regulations treat AI/AN and the national network of I/T/U pharmacies serving AI/AN in a uniform manner that is consistent with Departmental AI/AN policy goals; and in order to minimize the likelihood of Secretarial findings for AI/AN under 42 USC 1860D-11(e)(2)(D)(i), with regard to any PDP or MA-PD, that, "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan," **ANTHC feels the Secretary should consider amending the provisions of Subpart F of the proposed regulations to reflect the following comprehensive statutory approach to access and enrollment of AI/AN in PDPs and MA-PDs:**

(7) The Secretary should exercise his statutory discretion under 42 USC §1860D-1(b) and 42 USC §1395w-21(b)(1)(A) to waive, in the case of AI/AN, the requirement that Part D eligible individuals may only enroll in a plan that encompasses that PDP's or MA-PD's geographic region;

(8) Through the bidding and approval processes of 42 USC §1860D-11 (PDPs) and §1854(a) (MA-PDs), the Secretary should establish a small number of PDPs and/or MA-PDs that, in addition to providing coverage for all Part D eligible individuals in their respective PDP or MA-PD area(s) who choose to enroll in that plan, would also provides coverage for AI/AN on a national basis for all Part D eligible AI/AN who choose to enroll in each such plan, as permitted by 42 USC §1860D-11(a)(3).

(9) In preparation for PDP and MA-PD bidding processes, the Secretary should develop and publicize, in close consultation with the CMS Tribal Technical Advisory Group (CMS TTAG), an **AI/AN supplemental information packet**. The packet would solicit PDP sponsors and MA-PD organizations to consider including in their bids one or more plans that would provide coverage for Part D eligible AI/AN on a national basis. It would contain information on Part D eligible AI/AN and the national network of I/T/U pharmacies serving AI/AN, in sufficient detail to allow bidders to fairly assess whether they should include in their bids the information required under 42 USC §1860D-11(b)(2), with regard to any plan(s) in the bid proposing to provide coverage for Part D eligible AI/AN on a national basis. The packet would also set forth any "additional information" that the Secretary (in close consultation with the CMS TTAG) would require to be included in bids containing one or more plans to provide national coverage to Part D eligible AI/AN, as permitted under 42 USC §1860D-11(b)(2)(F). Specific types of information that the Secretary might consider including in the **AI/AN supplemental information packet** might include general information on AI/AN and AI/AN health issues, as carefully and compellingly set forth in **the National Indian Health Board comments to these regulations.** Consideration should also be given to describing in detail the national network of I/T/U pharmacies serving AI/AN, including:

- who they serve (AI/AN, per 25 USC §1680c);
- the basis on which services are provided (IHS-prepaid without charge to the AI/AN);
- where they are located (in I/T/U facilities near the AI/AN served);
- the way they buy drugs (FSS or 340B programs);
- the way they dispense drugs (with much more patient consultation than in the private sector due to the high risk of culture and/or language barriers impeding instructions);
- the information system used track drug and reimbursement information (RPMS);
- the charitable mission served (providing pharmacy services to a population group and in geographic areas characterized by failure of competitive market dynamics); and
- the way Medicare reimbursements are processed (via a nationally centralized system).

(10) In reviewing and negotiating bids (under 42 USC §1860D-11(d)) that contain one or more plans proposing to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such review and negotiation is conducted in a manner consistent with Departmental AI/AN policy goals.

(11) In approving or disapproving any plan (under 42 USC §1860D-11(e)) that proposes to provide coverage for Part D eligible AI/AN on a national basis, the Secretary should closely consult with the CMS TTAG to ensure such approval or disapproval is made in a manner consistent with Departmental AI/AN policy goals, especially with regard to the requirement of 42 USC §1860D-11(e)(2)(D) that the Secretary approve a plan only if he "does not find that the design of the plan and its benefits (including any formulary or tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan."

The Secretary has already successfully adopted a centralized national model similar to that proposed above for processing Medicare Part A and Part B payments to I/T/U facilities, through the use of a single Carrier for I/T/U providers nationwide. With I/T/U facilities already possessing the capacity to be reimbursed for Part A-covered drugs, and on the verge of gaining the capacity to be reimbursed for Medicare Part B-covered drugs and biologicals under §630 of the MMA, the Secretary may wish to consider the efficiencies and improved coordination of benefits in the administration of the various Medicare drug programs as they apply to I/T/U providers that would likely result from adopting a similarly centralized, national system for processing Part D drug benefit payments to I/T/U facilities. For example, Trailblazer LLC has done a fair job of coordinating Part A and Part B payments to I/T/U facilities since the passage of the BIPA.

SUBPART G: PAYMENT TO PDP SPONSOR AND MA ORGANIZATIONS OFFERING MA-PD PLANS FOR ALL MEDICARE BENEFICIARIES FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

42 CFR §423.329 DETERMINATION OF PAYMENT

Subsection (b), Health Status Risk Adjustment:

COMMENT: We feel that for PDP or MA-PD plans approved by the Secretary to provide coverage of Medicare Part D benefits for eligible AI/AN on a nationwide basis, the Secretary should engage in regular, meaningful consultation with the CMS TTAG, the IHS, and I/T/U pharmacies in the establishment of risk adjustment factors, data collection of risk adjustment factors, development of methodologies to measure risk adjustment factors, and publication of risk adjustment factors as required under this section.

…

SUBPART P: PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

42 CFR 423.772 DEFINITIONS

Definition of "Resources:"

COMMENT: Many AI/AN hold interests in real property that is held in one or more types of trust status by the U.S. Government. Given the statutory restrictions that these real property interests are subject to by definition, we feel consideration should be given to amending this definition to make clear that real property interests of AI/AN individuals held in some form of trust status by the U.S. Government are excluded from this term. **We incorporate by reference the excellent, well-researched National Indian Health Board comments on this definition**.

Definition of "Income:"

COMMENT: Under the MMA, the Secretary has the option to permit a State to make subsidy eligibility determinations using the methodology set out at section 1905(p) of the Act if the Secretary determines that this would not result in any significant difference in the number of individuals who are made eligible for the subsidy. This in turn would permit a State to use the same resource methodologies that it uses to determine Medicaid eligibility for QMBs, SLMBs, and QIs if the Secretary determines that the use of those methodologies would not result in any significant differences in the number of individuals who are made eligible for a subsidy. This includes the less restrictive methodologies a State may use under section 1902(r)(2) of the Act to determine eligibility for QMBs, SLMBs and QIs.

The Secretary has proposed not to exercise this option at all under the proposed regulations, for two reasons: First, allowing States this greater flexibility to establish their own income determination standards would detract from the policy objective of achieving uniformity in the low-income subsidy determination process. Second, allowing States this flexibility would result in significant administrative burdens and complexity in administering the Medicare Part D low-income subsidy eligibility determination process.

Given the Departmental policy goal lowering barriers to access to services to narrow the AN/AI health disparities gap, and given the well-documented barriers of poverty, distance, high incidence of disease experienced by many Medicare-eligible AN/AI, and given the scarce resources and escalating costs experienced by all I/T/U pharmacies, we feel significant public health policy considerations weigh heavily in favor of the Secretary exercising his statutory discretion granted to him at under 42 USC §1860D-14(a)(3)(C)(iv) of the Act to amend this proposed regulatory definition of "income" in a way that would allow States to employ the less restrictive methodologies of 1902(r)(2) in making subsidy eligibility determinations for AI/AN.

The policy interest of maintaining uniformity would still be well-served, because the exception to the rule that would be created would be miniscule in comparison to the entire Part D program; the exception would only apply to a very defined population group; and in creating their own income determination standards under 1902(r)(2), States would still be constrained by the limits inherent in 1902(r)(2) and related statutes.

The policy interests of assuring economy and efficiency and avoiding unnecessary complexity and administrative burdens in carrying out the Part D program would also be well-served because State programs are already quite familiar with AI/AN populations; the I/T/U pharmacies that serve them; and are quite capable of working closely with I/T/U pharmacies to identify AI/AN beneficiaries and appropriately calculate their income for purposes of subsidy eligibility determination in a way that balances the need to control health care costs with the Departmental policy objective of lowering barriers to health services for AI/AN.

It should also be noted that should the Secretary choose to exercise his statutory discretion under the MMA to allow States 1902(r)(2) flexibility with regard to calculation of AI/AN income for purposes of subsidy eligibility determination, that approach would be consistent with the Secretary's exercise of statutory discretion in similar situations, e.g., such as in 2002, when the Secretary exercised his discretion to not subject I/T/U providers to the Medicaid 100% upper payment limit requirements of 42 CFR 447.272.

42 CFR 423.773 REQUIREMENTS FOR ELIGIBILITY

Under Subsection (c)(3), a State agency must notify individuals treated as full benefit dual eligible individuals that they are eligible for a full subsidy of Part D premiums and deductibles. Individuals to receive such notification would include QMBs, SLMBs, and QIs. We feel consideration should be given to providing such notification to the I/T/U pharmacy serving such subsidy-eligible individuals as well.

AI/AN receiving services at an I/T/U pharmacy are likely to include many individuals who are to be treated as full subsidy eligible individuals, all of whom would be receiving care from such

I/T/U pharmacies on an IHS-prepaid basis, with no charges to the individual, pursuant to the public health mission of I/T/U pharmacies.

In these cases, it is the I/T/U pharmacy, rather than the full-subsidy AI/AN that would bear financial responsibility for the payments and waivers that would apply if there were no subsidy. Therefore, we feel consideration should be given to amending subsection (c)(3) to require that in the case of AI/AN served by an I/T/U pharmacy, notice also be given to the I/T/U pharmacy.

42 CFR 423.780 PREMIUM SUBSIDY

Subsections (a) and (b):

I/T/U pharmacies provide services to AI/AN on an IHS-prepaid basis, at no charge to the AI/AN, pursuant to the Departmental public health policy goal of lowering barriers to health services for AI/AN. For this reason, we feel consideration should be given to amending these subsections to expressly clarify that I/T/U pharmacies may pay Part D premium amounts on behalf of the AI/AN that might not be fully covered by the premium subsidy available to full subsidy eligible AI/AN or other low-income subsidy eligible AI/AN. In addition to this, we feel consideration should be given to amending these subsections to make clear that for AI/AN receiving services from I/T/U pharmacies, the I/T/U pharmacies may pay any other unsubsidized premium amounts on behalf of other low-income subsidy eligible AI/AN, as well as on behalf of unsubsidized AI/AN Part D beneficiaries.

We feel this approach would have a significant positive impact on the participation of AI/AN in the Medicare Part D drug benefit.

It should be noted, however, that we feel strongly that such charitable, public health-oriented premium payment amounts (as well as cost-sharing amounts) by I/T/U pharmacies on behalf of AI/AN MUST be counted as "incurred costs," as defined in the proposed regulations at 42 CFR 423.100, as noted at length above in our comments addressed to that section.

42 CFR 423.800 COST-SHARING SUBSIDY:

Subsections (a) and (e):

I/T/U pharmacies provide covered services to low-income subsidy eligible individuals on a IHS-funded, pre-paid basis, with no out-of-pocket charges to the low-income subsidy eligible AI/AN, pursuant to the public health mission of I/T/U pharmacies of reducing barriers to health services for AI/AN, in furtherance of the Departmental AI/AN policy goals.

The Congress has expressly approved this practice in the MMA itself, at Section 101, Part D, Subpart 5, by amending 42 USC 1320a-7b(b)(3) to permit, in the form of a statutory exception to the federal anti-kickback statute,

> "…(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under Part D of Title XVIII, if the conditions described in clauses (i) through (iii) of section 1128A(i)(6)(A) are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1860D-14(a)(3), section 1128A(i)(6)(A) shall be applied without regard to clauses (ii) and (iii) of that section)."

In light of this very recent, unmistakeably clear statutory expression of the Congress, and in light of the compelling public health mission served by I/T/U pharmacies in lowering barriers to access for AI/AN by providing covered Part D drugs to AI/AN on an IHS-funded, pre-paid basis, we believe consideration should be given to amending subsections (a) and (e) to require that in all cases in which an I/T/U pharmacy waives or reduces cost-sharing amounts that would otherwise have been paid as out-of-pocket costs by a low-income subsidy eligible individual, the reimbursement that would otherwise be paid by the individual shall be paid to the I/T/U pharmacy.

42 CFR 423.800 ADMINISTRATION OF SUBSIDY PROGRAM:

Subsections (c) and (d):

Payment to a PDP sponsor or MA organization for cost-sharing subsidies made on a capitated basis may be inappropriate with regard to payments made on behalf of AI/AN to PDP sponsors or MA organizations for PDPs or MA-PDs primarily serving I/T/U pharmacy beneficiaries. Although such a capitated payment system may work well for the private sector, we believe such a payment system inappropriately creates incentives for PDP sponsors or MA organizations to attempt to maximize profits at the expense of reducing the scarce resources necessary for I/T/U pharmacies to carry out the Secretary's stated goal of narrowing the AI/AN health disparities gap.

We would ask that consideration be given to amending these subsections to reflect that PDP sponsors or MA organizations with PDPs or MA-PDs that serve a significant number of AI/AN would not have available to them the option of having the cost-sharing subsidies reimbursed to them on a capitated basis.

SUBPART P: SPECIAL RULES FOR STATES IN MAKING ELIGIBILITY DETERMINATIONS FOR SUBSIDIES

423.902 DEFINITIONS

Definitions of "STATE MEDICAL ASSISTANCE PERCENTAGE," and "PHASED-DOWN STATE CONTRIBUTION PAYMENT"

The proposed regulatory definition of State medical assistance percentage is identical to the statutory definition at section 1935 of the Act: "The proportion equal to 100% minus the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs."

This definition requires the Secretary, in determining each State's medical assistance percentage to first determine "the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs."

Unfortunately, under the Act's FMAP provisions at 42 USC 1396d(b), a State's FMAP can vary.

On the one hand, a State's FMAP for a given fiscal year could be calculated using the default FMAP formula set out in the first paragraph of subsection (b).

On the other hand, the plain language of the 1935 reference to 1396d(b), under well-established principles of statutory interpretation, ould be read more broadly to include ALL of subsection (b), including (b)(1), (b)(2), (b)(3) and (b)(4).

We feel that the correct reading of §1935 should follow well-established principles of statutory interpretation, and in a manner that weighs in favor of achieving the Departmental AI/AN policy goal of narrowing the AI/AN health disparities gap by lowering AI/AN barriers to access to covered Part D drugs, by allowing States to calculate their SMAP for purposes of §1935 by factoring in the 100% FMAP reimbursement amounts received for the applicable year, weighted in proportion equal to that State's overall proportion of 100% FMAP-paid reimbursement in comparison to the overall reimbursement amounts received in that year at otherwise-applicable FMAP percentages.

For example, if New Mexico's established FMAP percentage for a given year were 50%, but 20% of the total value of Medicaid reimbursements paid by the Secretary to New Mexico for that year were paid at 100% FMAP (due to those reimbursements being made for services provided to AI/AN), then 80% of the total value of paid Medicaid claims for that year were reimbursed at 50% FMAP, and 20% of the total value of paid Medicaid claims for that year were reimbursed at 100% FMAP.

So if New Mexico's total value of paid Medicaid claims in a given year were $1 billion, the actual FMAP experienced by New Mexico would be ($800 million x 50% FMAP) = **$400 million + $200 million** ($200 million x 100% FMAP) = $600 million, or 60%, rather than the published FMAP rate of 50%.

This difference, in turn, significantly impacts the amount of New Mexico's phased-down State contribution payment to the Secretary under the statutory formula.

Under the formula, New Mexico's monthly contribution amount is equal to 1/12 of the product of the base year (2003) Medicaid per capital expenditures for covered Part D prescription drugs

for full-benefit dual eligible individuals, multiplied by the State medical assistance percentage (which is the inverse percentage amount of the FMAP percentage), the applicable growth factor, the number of the State's full-benefit dual eligible individuals that month, and the phased-down state contribution factor.

We feel consideration should be given to accepting the plain language of section 1935 on its face, and to assign an FMAP value to each State for each fiscal year using State's FMAP value

As is pointed out in the General Provisions accompanying the proposed regulations at 69 FR 46638, 3rd column:

> "General principles of statutory interpretation require us to reconcile two seemingly conflicting statutory provisions whenever possible, rather than allowing one provision to effectively nullify the other provision. Consequently, when a statutory provision may reasonably interpreted in two ways, we have an obligation to adopt the interpretation that harmonizes and gives full effect to competing provisions of the statute."

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(END OF ANTHC COMMENTS TO PROPOSED PART D REGULATIONS)

Submitter : Mr. Russ McDaid **Date & Time:** 10/04/2004 09:10:36

Organization : PANPHA

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

The following comments on the Centers for Medicare and Medicaid Services proposed rule, ?Medicare Program; Medicare Prescription Drug Benefit?, file code CMS-4068-P, are provided by PANPHA, an association of more than 300 Pennsylvania non-profit senior service providers. PANPHA?s members provide nursing homes, personal care homes (also known as ?assisted living?), continuing care retirement communities, and housing.

Section 423.124(a)(2) Of primary concern is the implementation of the prescription benefit for residents of nursing facilities. We recommend allowing several models to be tested prior to implementing the regulation, including allowing LTC pharmacies to function as ?out-of-network? pharmacies, encouraging PDPs and MA-PDs to contract with LTC pharmacies, as discussed in the regulation summary, as well as other models that may be proposed by other commentors.

As regulations are implemented and our members work through them, we will provide additional comments. Thank you for this opportunity to comment.

Sincerely,

W. Russell McDaid
VP/Chief Public Policy Officer
russ@panpha.org

CMS-4068-P-1286

Submitter : Mr. Leonard S. Holman, Jr., R.Ph. **Date & Time:** 10/04/2004 08:10:25

Organization : Option Care of Northeast Ohio

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see comments in attached word document.

CMS-4068-P-1286-Attach-1.doc

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October 4, 2004

JCAHO *Accredited with Commendation*

Dear Sirs:

Option Care of Northeast Ohio is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P, implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Option Care of Northeast Ohio is a home infusion therapy and specialty injectable pharmaceutical company located in Canfield and North Canton, Ohio. Option Care of Northeast Ohio was founded in 1986 and is part of an Option Care, Inc.'s national franchise. We service patients in 40 counties in Northeastern Ohio, Western Pennsylvania, and Northern West Virginia. We are accredited by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) with full standards compliance, the highest level awarded by JCAHO.

Option Care of Northeast Ohio appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home Infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration includes intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune

Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

- **Dispensing fee option 3** is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit.

The dispensing fee paid to the Home Infusion Pharmacy under option 3 must be split into two parts as follows for this to work for the effective provision of Home Infusion Drug Therapy for Medicare beneficiaries:

A. Payment of daily "per diem" fee specific to the type of therapy and frequency of administration of the drugs employed in the therapy[y for each day or portion there of that the patient receives I.V. therapy.
B. Payment for each intermittent skilled nursing visit that occurs during the course of I.V. Therapy.

CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm http://www.nhianet.org/perdiemfinal.htm> .

* CMS should establish **specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies** to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require **specific standards for home infusion pharmacies** under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the **X12N 837 P billing format** for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should **mandate that prescription drug plans maintain open formularies for infusion drugs** to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Leonard S. Holman, Jr., R.Ph.
President and C.E.O.
Option Care of Northeast Ohio
4137 Boardman-Canfield Road, Suite 7704
Canfield, OH 44406-8087

CMS-4068-P-1287

Submitter : Mrs. Ann Berkey **Date & Time:** 10/04/2004 09:10:11

Organization : McKesson Corporation

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

On behalf of McKesson Corporation, I am pleased to submit comments regarding the proposed rule to create the new Medicare Prescription Drug Benefit.

CMS-4068-P-1287-Attach-1.doc

McKesson Corporation
One Post Street
San Francisco, CA 94104

Ann Richardson Berkey
Vice President
Public Affairs

McKESSON
Empowering Healthcare

October 4, 2004

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: The new Medicare Prescription Drug Benefit as authorized by the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 [CMS-4068-P and CMS-4069-P].

Dear Sir or Madam:

On behalf of McKesson Corporation, I am pleased to submit comments regarding the proposed rule to create the new Medicare Prescription Drug Benefit. We commend CMS for seeking industry input as it begins to implement this landmark legislation to make prescription drugs more affordable to our nation's senior population.

Due to the breadth of our businesses and experiences, we offer a broad and credible perspective on the implementation of this legislation. For the past 170 years, McKesson has led the industry in the delivery of medicines and health care products to drug stores. Today, a Fortune 16 corporation, we deliver vital medicines, medical supplies, and health information technology solutions that touch the lives of more than 100 million patients each day in health care settings that include over 5,000 hospitals, 150,000 physician practices, 10,000 extended care facilities, 700 home care agencies, and 25,000 retail pharmacies. As the world's largest health information technology company, providing technology solutions to 65% of U.S. health systems, McKesson supports the transformation of healthcare from a paper based system to one with electronic solutions that will improve patient safety, reduce cost and variability of care, improve healthcare efficiency, and better manage resources.

McKesson also supplies pharmaceuticals to the entire Department of Veterans' Affairs system, as well as to a significant number of Department of Defense and other government facilities. In addition, we repackage over 1.5 billion doses of drugs annually and provide analytical testing services in support of these operations.

As the largest pharmaceutical supply management company in the world, we leverage our leadership in the distribution business to provide specialty pharmaceutical services for providers and patients with chronic conditions. These high-cost, often injectable bio-pharmaceutical drugs call for special handling, storage, and complex shipping requirements. The services associated with such complex distribution processes expand access to necessary medication treatments, increase cost-effectiveness, and improve the convenience and quality of patient care by enabling the administration of these drugs in a lower cost, outpatient setting.

McKesson has actively supported the use of drug savings cards to help lower the costs of pharmaceuticals through our administration of the successful Together-Rx card and our CMS-endorsed Rx Savings Access card. The Together-Rx card has delivered over $492 million in savings to more than 1.4 million low-income seniors in only two years. McKesson's Rx Savings Access card is providing Medicare beneficiaries with an average savings of 15-25% on the most commonly prescribed medicines and is accepted by over 95% of pharmacies. To date, more than 129,000 Medicare eligible seniors are enrolled in this card and have realized $13 million in savings on their prescription drugs.

McKesson is also an industry leader in providing disease management programs for commercial, Medicaid and Medicare populations where we leverage our experience with patient services, pharmacy management and health care quality improvement activities. In seven states where we provide disease management services to Medicaid patients, physician and patient satisfaction as well as health outcomes have improved. Those states are also saving approximately two dollars for every dollar spent with McKesson. Based on our experiences, we know the benefits that can be achieved through disease management programs and strongly advocate their rapid adoption for the eligible Medicare population.

We welcome the opportunity to share our unique insights into the effective implementation and utilization of the Medicare Prescription Drug Benefit. Our specific comments are detailed by section; however, we want to emphasize and highlight the following provisions as critically important to the success of this benefit across the Medicare population:

- Broad access to and participation of retail pharmacy;
- Medication therapy management programs (MTMPs) that adequately compensate health care professionals and provide needed services to beneficiaries with chronic conditions;
- Optimal integration of MTMPs and chronic care programs;
- Inclusion of drugs acquired through manufacturer-sponsored patient assistance and similar charitable programs as incurred costs;
- Medication error prevention through the promotion of technologies and improved processes, including electronic prescribing; and,

- Ultimately, a "user-friendly" program that is easily understood by Medicare beneficiaries and maximizes access to needed health care services.

Comments on CMS-4068-P

Part II – Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule

II. Provisions of the Proposed Rule

A - General Provisions

A.2.b.iii - Prescription Drug Plan Regions

In order to minimize confusion and provide continuity with existing programs, we encourage CMS to align prescription drug plans (PDP) and MA-PD (Medicare Advantage prescription drug plans) regions with existing Medicare Advantage (MA) regions. Lack of alignment is likely to confuse those beneficiaries currently in MA programs as they try to understand their options during the initial enrollment period for this Medicare Part D benefit.

A.2.d – Financial Relationships between PDP Sponsors, Health Care Professionals and Pharmaceutical Manufacturers

McKesson believes any decisions on formularies and covered pharmaceuticals should be driven by clinical evidence and pharmacoeconomic analysis and should not be influenced by payments made by manufacturers to plan administrators. We urge CMS to provide oversight and auditing to ensure appropriate financial relationships.

B – Eligibility and Enrollment

B.2 – Part D Enrollment Process

As CMS has proposed, McKesson supports an auto-enrollment process for Part D plans, particularly for low-income beneficiaries who will qualify for assistance and will incur no sign up costs. When no MA-PDs are available that meet the premium thresholds, we believe that CMS should allow auto-enrollment of low-income MA members into stand-alone PDPs.

Under auto-enrollment, proper safeguards will have to be established to ensure continuity of pharmaceutical care as beneficiaries are transitioned to new plans with potentially different formulary or other coverage provisions. Further, we recommend that the auto-enrollment process be managed by a single entity rather than by individual states to

simplify the coordination of benefits and minimize any additional administrative burden and associated costs.

To protect the reputation and longevity of the program, we recommend that CMS establish a process to re-evaluate, at periodic time intervals, the ability of a plan sponsor to meet the minimum standard levels within the constraints of the low-income premium subsidy. This process will assure continuity of care for beneficiaries by mitigating the likelihood that a plan sponsor will drop coverage at a later date because they can no longer afford to cover beneficiaries.

B.3.b.v – Special Enrollment Periods; Exceptional Circumstances

A change in control of a PDP that does not result in a material change to a beneficiary's coverage should not result in a special enrollment period (SEP). A SEP would likely result in beneficiary confusion. Furthermore, it would discourage successful and innovative plans from expanding as the program evolves. A plan sponsor may choose to acquire another plan in order to expand the services provided and/or reduce costs, which would be achievable through improved economies of scale, a broader risk pool, and increased negotiating power associated with representing a larger number of enrollees. However, the increased administrative burden and customer service costs associated with providing for a SEP may discourage plan sponsors from acquiring an existing plan sponsor's program. Ultimately, CMS will want to encourage successful plans to continue innovating and growing to minimize costs both to the government and to beneficiaries. Providing a SEP only when there are material changes to a beneficiary's coverage will help to achieve this goal while also maximizing beneficiaries' choice.

B.4.a – Effective Date of Coverage and Change of Coverage; Initial Enrollment Period

Enrollment should become effective as soon as a beneficiary has been processed and approved, and within a 30-day period. Based on our experience administering a Medicare drug discount card, delaying enrollment until the first of the next month is unnecessary and has caused confusion to the beneficiary and commercial partners, particularly when applications are submitted near the end of a month and activation takes longer than 30 days.

B.5 – Coordination of Beneficiary Enrollment and Disenrollment through PDPs

As a Medicare drug discount card sponsor, we recognize that online and telephonic enrollment provides a cost-effective, timely and secure means of enrolling beneficiaries. CMS should encourage PDPs to provide these enrollment methods to capture similar efficiencies.

B.6 – Disenrollment by the PDP

McKesson recommends that plans offering national networks be authorized to operate in each region. We recognize that the statute authorizes the establishment of regional plans; however, a beneficiary's ability to participate in a plan that does not offer national networks could be impacted by logistical issues, such as extensive travel out of the region or residency close to the borders of a region. Authorizing plans with national networks in each region will serve to maintain continuity of care by preventing unnecessary disenrollment (e.g. if a beneficiary is out of the service area for six months) as well as to minimize cost by reducing additional out-of-network expenses.

B.8 – Part D Information that CMS Provides to Beneficiaries

Community pharmacies have demonstrated they are one of the most effective channels for educating and promoting voluntary enrollment in the Medicare drug discount cards. Therefore, we recommend that CMS utilize the expertise and value of local pharmacists to assist in educating those eligible for the Medicare Part D benefit by providing appropriate funding and by designing campaigns that feature pharmacists as an education channel. Since the education and enrollment of patients represents a significant time and resource commitment for pharmacists, we would also urge that pharmacists be appropriately compensated for providing these valuable services.

McKesson fully supports CMS' goal to steer seniors to those plans that provide the best value to each beneficiary. We agree that a price comparison website is effective in helping seniors understand the drug price component of a plan. Recognizing that the value of a plan extends beyond the price of pharmaceuticals to other important plan elements, such as network size, cognitive and therapy management services, formulary and drug utilization rules, we encourage CMS to broaden the plan features compared on its website. These enhancements will allow beneficiaries to make more fully informed decisions. Those most concerned about pricing can make a plan selection on the basis of price. Those who want to consider other elements, such as inclusion of their local pharmacy or the availability and components of a medication therapy management program, will have the necessary information to make an informed decision.

Based on McKesson's experience with the Medicare drug discount cards, we recommend a number of improvements in websites used as resources for beneficiaries:

1. Any ranking of plan designs according to drug pricing should be done according to the lowest *maximum* price a beneficiary would pay at a network pharmacy, and not the lowest *minimum* price. In today's Medicare drug discount card program, when card sponsors present a range of prices available to a beneficiary in a defined service area, the card sponsors are ranked on Medicare's website according to the lowest minimum price within that range. This ranking

methodology creates the potential for beneficiaries to be misled when the lowest minimum price is only available at a small subset of their network, while the pricing more broadly available within network is significantly higher. Utilizing lowest *maximum* price as a ranking methodology will prevent the presentation of misleading information, drive consistently lower prices and allow beneficiaries to more effectively compare available benefits in their region.

2. CMS and PDP websites and resources should provide information on generic equivalents when they publish information on brand versions of multi-source drugs. Additionally, they should allow for queries by generic name. Currently, in today's drug discount card program, generic drugs can only be found by referencing their branded counterpart.

3. CMS should allow more flexibility to plan administrators in highlighting aspects of their benefits, such as network size, availability and components of cognitive and therapy management services, and formulary and drug utilization rules, so that beneficiaries can choose the plan they believe provides the best overall value, not just the lowest price.

B.9 – Approval of Marketing Materials and Enrollment Forms

As pharmacists are recognized as a trusted source of information, particularly for the senior population, we urge CMS to allow pharmacies to provide information about PDPs that offer the best savings and prescription drug coverage for their customers. Pharmacies should also be allowed to collect and submit enrollment forms, particularly on behalf of those Medicare beneficiaries who may not be comfortable completing an application without assistance.

We recommend more stringent monitoring of the marketing behavior of all MA-PDs and PDPs to ensure compliance across the board with regulations. Furthermore, we suggest that those PDPs that have demonstrated consistent compliance with marketing guidelines during the CMS discount card program should obtain streamlined approval under the "File and Use" program.

B.10 – Information Provided to PDP Sponsors and MA Organizations

From our experience as the administrator of a Medicare drug discount card, we believe it would have been more efficient and effective for all card sponsors to have had access to a list of eligible beneficiaries and their mailing addresses. In order to maximize voluntary enrollment, we recommend that CMS provide PDPs with the names and addresses of all eligible beneficiaries in their coverage region. This data would allow plan sponsors to send written educational materials only to eligible beneficiaries and avoid more costly untargeted mailings.

We believe that telephone marketing will lead to confusion and frustration among the beneficiary population and should not be permitted. After enrollment, however, telephone contact should be permitted and encouraged as an important component of medication therapy management and other pharmaceutical care services. Our experience with the drug discount card program suggests that this population relies on direct contact and educational efforts to answer questions and explain benefits. Direct contact will also allow plan sponsors to maximize customer service and satisfaction.

We do not recommend the marketing of additional products and services to beneficiaries that are unrelated to the Medicare Part D benefit. This would violate the intent of other congressional actions to limit direct marketing to peoples' homes (e.g., "do not call lists").

C - Voluntary Prescription Drug Benefit and Beneficiary Protections

C.1.a – Overview and Definitions; Covered Part D Drug

We commend CMS for establishing a clinically focused, patient-centric prescription drug benefit, and endorse provisions providing for close CMS evaluation and oversight of alternative prescription drug coverage and formulary designs. McKesson also concurs with the inclusion of biological products as covered Part D drugs, and we urge CMS to include provisions that ensure appropriate coverage of these products. Noting that these pharmaceutical products are typically not classified or included in traditional formularies, we urge CMS and the United States Pharmacopeia (USP) to establish distinct classifications and provisions that ensure the appropriate coverage and use of these agents. Since these new, lifesaving products are typically expensive and treat small patient populations, we believe beneficiaries using specialty pharmaceuticals are particularly susceptible to benefit design mechanisms which may discourage their enrollment in the Part D benefit. To this end, we strongly endorse proposed CMS measures which stipulate the composition and activities of Pharmacy and Therapeutics committees, and also recommend CMS scrutiny of step therapy, prior authorization and other utilization controls which might discourage the clinically appropriate use of specialty pharmaceuticals.

C.1.b – Dispensing Fees

McKesson recommends that CMS use Option 1 to define the activities covered by the dispensing fee. Dispensing fees are a critical component of the reimbursement formula for pharmacies and have traditionally covered the physical dispensing activity, quality assurance, and cognitive services relating to the dispensing of every prescription drug, such as when and how to take the medication. Given the market's understanding of dispensing fees, expanding the definition to include pharmaceutical therapy could create confusion and deprive the pharmacist of appropriate compensation that should be provided for additional services.

We commend the provisions in the Medicare Modernization Act which promote the value of medication therapy management programs (MTMPs). These services are critical to improving health outcomes and will be marginalized if pharmacists are not appropriately compensated. MTMPs may not be needed for every prescription; by including these important cognitive services in dispensing fees (e.g. Option 3), accountability and visibility are diluted. To that end, we strongly advocate separate payment for MTMP services as detailed in Part D.2.c.

C.2.a - Standard Prescription Drug Coverage

We strongly endorse the proposed CMS classification of pharmaceutical manufacturer contributions to a patient's drug costs through charitable assistance programs as incurred costs that count toward the enrollee's out-of-pocket costs. As the leading administrator of manufacturer-sponsored patient assistance programs (PAPs), McKesson believes that this provision would create a much needed incentive to manufacturers to maintain and enhance their PAPs, which will provide a privately funded mechanism to help the neediest patients pay for their costs in the coverage gap. Without this provision, needy patients may be disincented to participate in manufacturer-sponsored PAPs because it will delay their access to catastrophic coverage; at the same time, manufacturers may be disincented to offer such programs since they will incur significantly increased financial responsibility due to the delayed onset of patients' eligibility for catastrophic coverage. By allowing this provision, CMS will promote continuity of pharmaceutical care for patients who might otherwise interrupt drug therapy, and avoid more costly interventions which can result from patient non-compliance.

We concur with CMS that HSA, FSA, and HRA expenditures should count toward incurred costs because they are analogous to a beneficiary's bank accounts. In addition, price differentials between 90-day prescriptions by mail and 90-day prescriptions at retail should count as incurred costs.

We presume that expenditures for prescription drugs purchased from foreign sources will not count as incurred costs, given that this practice is illegal. To prevent any misunderstanding, CMS may want to explicitly state that drugs purchased through any channel that the FDA has not deemed to be safe will not count toward incurred costs.

C.4.a – Pharmacy Access Standards

We concur with CMS' goal to ensure broad retail access. Most seniors still prefer to obtain their medicines from their local pharmacist. Furthermore, the importance of pharmacists in explaining the Medicare drug benefit program, its benefits and the appropriate use of medication is well documented.

McKesson concurs with the access standards requirements set out in the proposed regulation, namely that 90 percent of Medicare beneficiaries in urban areas have access to

a pharmacy within two miles; 90 percent of Medicare beneficiaries in suburban areas have access to a pharmacy within five miles; and 70 percent of Medicare beneficiaries in rural areas have access to a pharmacy within 15 miles. However, McKesson recommends that access standards be based on traveling distance and not geographic distance. Particularly in rural areas, "line of sight" distances can be deceiving. Mountain ranges, highways, lakes, rivers and other obstacles can substantially increase traveling time to a pharmacy.

McKesson suggests that regulations clearly state that plan sponsors have to meet these access requirements in each of the proposed Medicare regions. The proposed regulations only require plan sponsors to meet this standard on an average basis across all the regions they serve. The unintended consequences of such an interpretation could be high access in one area and substandard access in another. To this end, we strongly urge CMS to ensure that plan sponsors meet the pharmacy access requirements for each *separate* category of population density (e.g. urban, suburban, rural) in each Medicare region.

We concur that pharmacy access requirements should apply to retail pharmacies only and that plans can choose to add other pharmacies to their network as desired. Long-term care pharmacies, specialty pharmacies, mail order pharmacies and Federally Qualified Healthcare Clinics (FQHCs) can be added to the network, but cannot be used to support the access requirements. Otherwise a "closed door" pharmacy for the exclusive use of long-term care facilities in the area could be used to meet an access requirement when in fact patients in the community who are not residents of the contracted long-term care facility do not have access to this pharmacy.

Finally, if the plan sponsor creates a tiered network of preferred and non-preferred pharmacies with a lower co-pay or other benefit associated with the preferred network, access requirements should apply to the preferred networks. Access standards are designed to provide adequate access to drugs and pharmacy services. If access standards apply only to the broader network, but not to the preferred network, some Medicare beneficiaries could be penalized with higher co-pays because they do not have a preferred pharmacy within their area.

C.4.c – Use of Standardized Technology

Fundamental to spurring adoption of standardized technology is the selection of an identifier that is consistent with the requirements for enrollee identification under the e-prescribing provision. If possible, all plan sponsors should have a consistent standard to recognize beneficiaries. In addition, these standards need to provide enough flexibility so that they can keep pace with technological developments and advancements.

C.7 – Public Disclosure of Pharmaceutical Prices for Equivalent Drugs

The pricing comparison should be between the brand name drug and the Maximum Allowable Cost (MAC) price established by that PDP for the generic equivalent to the branded drug. When a brand name drug is prescribed and the prescriber has not given a "Do Not Substitute" order, we recommend that the pharmacy provide the lowest price of the generic version of that drug available at that pharmacy. It is important to note that most pharmacies do not carry multiple generic drug options for the same generic entity.

To ensure that drug pricing information is equally provided, we recommend that mail order pharmacies should also be required to disclose the availability of a less expensive generic at the time the drug is ordered and prior to its delivery.

D: Cost Control and Quality Improvement Requirements for PDPs

D.2.b – Quality Assurance

In outlining the appropriate elements of a quality assurance system, CMS contemplates electronic prescribing, clinical decision support, educational interventions, bar codes, adverse drug event (ADE) reporting systems and provider and patient education systems, and yet anticipates that plans will not implement all of these elements. McKesson believes that, to qualify as a PDP or MA-PD, plans should, in fact, implement all of these technologies and processes. We believe that some form of clinical decision support will be an essential component of an electronic prescribing system, and every such system will have both provider and patient education as a fundamental feature. We endorse the electronic prescribing standards and process that were delineated in the report issued on April 14, 2004 by the eHealth Initiative, entitled *Electronic Prescribing: Towards Maximum Value and Rapid Adoption.*

We believe that error reporting should not be the primary focus of the quality assurance provisions in the proposed regulations; instead, the focus should be on error prevention. CMS needs to ensure that participating plans provide access to sufficient data in electronic form in real-time to permit the electronic prescribing function to consider those variables before a script is produced. Any error that does occur should receive a detailed review to ensure that the system failures that contributed to that error or event are eliminated.

Although ADEs cannot be predicted, they often can be prevented using computerized systems that monitor patients; provide physician ordering capabilities; integrate pharmacy, patient and lab data; and trace the incidence of ADEs. Use of electronic prescribing systems, bar codes and clinical decision support systems can initiate interventions to mitigate the effects and lessen the severity of reactions.

With respect to reporting measures, McKesson supports creating an environment for health care providers to report ADEs where repercussions are not feared. Peer review

protection supports open and honest reporting for system failures, thereby leading to prevention strategies, better patient outcomes and lower health care costs. Costs of ADEs are very high and patients can suffer irreversible injuries that can result in permanent disability or death.

McKesson encourages CMS to foster or create incentives for quality assurance standards including:

- Complete review of patients' medication history and medical records by providers prior to prescribing;
- Evidence of active participation by pharmacists in consultation with prescribers on medication ordering, interpretation, review and monitoring of medication use;
- Use of clinical informatics and technology to promote patient safety;
- Patient safety research dissemination and education;
- Regular assessment of effective working conditions that promote patient safety and incorporate principles of human factors; and
- Error reporting, analysis, and peer review protections to allow enhanced use of data to identify and measure improvements.

D.2.c - Medication Therapy Management Programs

Congress and CMS have recognized the value provided by cognitive services to better manage drug costs, medical costs and outcomes for patients. We commend lawmakers for requiring that each PDP and MA-PD plan include a MTMP for Medicare beneficiaries. Previous studies have shown that as much as 45% of the general population and 88% of the population aged 65 years and older have one or more chronic conditions, and that more than 75% of all U.S. health care expenditures are related to the treatment of chronic conditions (Hoffman C, Rice D, and Sung HY. *Persons with chronic conditions: their prevalence and costs*. JAMA 1995; 276:1473-1479).

Proposed regulations for MTMPs represent an opportunity to advance the nation towards a coherent, effective approach for managing drug regimens more effectively. As drug regimens become more complex and patients take multiple drugs for concomitant diseases, the need for effective therapy services increases. McKesson believes that outpatient and specialty pharmacies, experts in both pharmaceuticals and therapy, are well suited to support therapy management services.

To achieve its goals, regulations for MTMPs need to include more specific standards for eligibility, benefit and compensation.

Eligibility - McKesson recommends that MTMPs should be made available to all patients who are taking two or more drugs on a long-term basis or are suffering from disease states where non-compliance with prescribed medication therapy might lead to

near-term or immediate ADEs. These disease states include, but are not limited to, diabetes, congestive heart failure, hypertension, asthma, chronic obstructive pulmonary disease, coronary artery disease, oncology, hepatitis C, chronic pain, depression, and dementia, and all require active drug therapy management. Beneficiary enrollment should be voluntary; however, plan sponsors should also be able to document on request that MTMP services have been made available to all eligible Medicare beneficiaries in their plan.

Benefit - McKesson believes CMS should define a consistent standard for MTMP services for plan sponsors. The consistent application of MTMPs across the nation will ensure that beneficiaries, regardless of region or plan sponsor, will have access to the same level of care. Pharmacists participating in multiple plans will also benefit because their MTMPs will remain constant for all beneficiaries. In addition, a baseline standard for care will allow CMS to analyze best practices and track improved health outcomes. The MTMPs should promote adherence to prescription medications, evaluate and monitor patient response to drug therapy, provide counseling on potential side effects and refer patients back to physicians for follow-up. The program should provide written materials upon enrollment that establish the parameters of the program and contain health information relevant to the patient and his/her therapy.

Medication therapy management services are individualized patient care services and will need to be focused on each patient's specific needs. We would like to encourage CMS to consider further guidance regarding the proposed services. McKesson supports the *"Medication Therapy Management Services Consensus Document"*, endorsed by eleven national pharmacy professional organizations. The agreement defines critical issues in support of effective medication management, including:

- The need to formulate a patient-specific treatment plan;
- The importance of monitoring therapy and identifying and resolving medication-related problems;
- The importance of educating patients about their therapy;
- The preference for face-to-face interactions between the pharmacist and the patient; and
- The need for adequate reimbursement consistent with contemporary health care provider rates.

MTMPs should be performed by licensed health care professionals, who have an appropriate level of expertise in providing medication therapy services. Our preference would be that all initial consultations between a qualified health care professional and the patient occur face-to-face, although subsequent consultation can be provided using other communication channels. In person communication will permit the necessary dialogue between a health care professional and a senior, and highlight issues that may not be readily apparent from a phone conversation. However, we recognize that other forms of

communication between licensed health care professionals and patients can be utilized effectively to provide medication therapy management services. As one example, medication therapy services for orphan drugs, administered by specialty pharmacies via telephonic or other forms of communication, have been highly successful in educating patients and ensuring compliance with needed therapies.

Compensation - It is important to differentiate the services provided within an MTMP with those associated with simply dispensing a prescription drug. McKesson strongly endorses appropriate compensation to pharmacists or other health professionals for administering MTMPs on a fee-for-service basis or case rate basis. As the value that MTMPs provide is recognized and measured through outcomes analysis, we believe it should be factored into future criteria for establishing appropriate minimum compensation levels.

We also recommend that CMS establish standard methods to bill for MTMP services. The method of payment needs to consider differences in the mechanisms by which claims for prescription drugs and claims for professional services are handled. The NCPDP Telecommunication Standard may adequately accommodate the requirements for proper billing of some services or service components. To the extent necessary, modifications should be made to the NCPDP standard or to the standard currently in use for the specific care setting (for example, ambulatory care setting) to incorporate additional data elements as necessary.

D.4 – Electronic Prescription Program

McKesson applauds the efforts of the National Committee on Vital and Health Statistics (NCVHS) relative to the development of standards and recommends that they be actively involved in any decision to ratify a standard or to alter the timeframe for a pilot program or full implementation.

Comments were requested regarding additional steps to spur adoption of e-prescribing or to overcome obstacles to implementation. Although incremental reimbursement was discussed, McKesson is concerned that there has not been adequate discussion of the structural and workflow challenges that limit electronic prescribing to less than the ten percent of U.S. physicians, as noted by HHS. These challenges arise from many areas:

1. To support effective e-prescribing and quality assurance, it is essential that a minimum data set be electronically accessible to the provider. As an example, plan sponsors currently are not required to supply critical data to the provider regarding a patient's medication history and known medical conditions. A reasonable condition of participation would be that each plan makes such information accessible to both the patient and to any provider authorized by the patient.

2. Each plan should provide such required information in a consistent, standardized manner so that a single provider or application vendor does not have to use multiple access methods to find critical clinical data depending on the PDP or MA-PD.

3. For code sets as with messaging standards, it is essential to identify and address intellectual property issues prior to adoption. Since standards form a natural monopoly, it is preferable that they be publicly owned.

4. All programs for electronic prescribing assume that there is a means for positive identification of the patient or enrollee. A consistent and accurate means for addressing this issue is as critical for successful implementation of electronic prescribing as it is for successful adoption of the electronic health record (EHR). Consistency in approach for these two important initiatives is crucial to the success of these efforts.

While these comments address system or structural issues impacting adoption, McKesson agrees that differential reimbursement will be required to spur adoption. To that end, we would propose a phased implementation of incentives to compensate physicians for increased use of electronic prescribing tools in their practice. We recommend that phased requirements, as advocated by the Bridges to Excellence program Physician Office Link program (www.bridgestoexcellence.org), be considered. Initial adoption should be compensated at a rate that declines over time; a "full" rate should only be maintained over time by achieving certain performance goals for particular classes of patients. Such a plan encourages both initial use and sustained use over time.

We have serious concerns regarding the adoption of e-prescribing as a stand-alone system as opposed to its inclusion as a critical component of a larger electronic health record. Increasingly, hospitals and physicians are adopting integrated solutions that combine e-prescribing with other components of an EHR system. In fact, isolated e-prescribing applications in the ambulatory environment may not even exist by the time these standards are effective in 2009. To that end, we want to ensure that, if providers adopt an integrated EHR system, they will not lose the incentives uniquely applied to the e-prescribing component of that solution, specifically the safe harbor provisions from the Stark anti-fraud and anti-abuse statute that are noted in the Medicare Modernization Act.

G - Payments to PDP Sponsors and MA Organizations

G.4.a - Requirement for Disclosure of Information; Data Submission

We would recommend that the data transmission to CMS for utilization capture be consistent with the NCPDP format for on-line adjudication or the American Society of Automation in Pharmacy (ASAP) format, a telecommunications format for reporting

Controlled Substance use. Such standards are in use today and would cause minimal impact on existing software solutions.

J - Coordination under Part D Plans with other Prescription Drug Coverage

J.6.e - Tracking True-Out-of-Pocket (TrOOP) costs

McKesson supports and recommends a centralized approach to determining and reporting TrOOP information. This centralized approach should include enrollee costs which are incurred across multiple service providers within the PDP network, as well as any out-of-network incurred costs, including costs covered by manufacturer-sponsored patient assistance and similar charitable programs.

The structure of the coordinating body could be based on the "Common Working File" model which is currently in use and is maintained by CMS for beneficiary enrollment, entitlement, and adjudication data. To that end, we prefer Option 2, as outlined, which would establish a TrOOP facilitation contractor as a single point of contact between payers. To avoid conflicts of interest, the facilitation contractor should not be a PDP. Pharmacies do not have the capability to determine and report TrOOP information to the beneficiary, and, therefore, should not be responsible for having to communicate such information.

R - Payments to Sponsors of Retiree Prescription Drug Plans

In line with the stated goals of the Medicare Modernization Act to provide employers with the incentives and flexibility to maintain prescription drug coverage for their retirees, and as a large national employer, we would like to address the following critical concerns:

R.1.a. – Options for Sponsors of Retiree Prescription Programs

McKesson supports the proposal for employers to contract with one regionally qualified PDP that has a national network instead of several different regional PDPs. A national, rather than a regional, approach for large employers would allow for more efficient and effective administration of benefits and would also provide a consolidated data source for timely and accurate reporting to CMS. Additionally, we suggest that CMS encourage employers to elect the wrap-around option by sharing the savings resulting from the lower cost of reinsurance.

R.2 - The Retiree Drug Subsidy Provision - Definitions

Group Health Plan - We recommend that employers who have groups of individuals with differing subsidy formulae have discretion in declaring whether these groups constitute one or several plans. In this way, employers will be encouraged to aggregate

groups in an actuarially equivalent plan and continue coverage with a subsidy. Only those groups with a very low employer subsidy would be identified for transition to a Medicare Part D plan. Otherwise, some employers will not be able to meet actuarial equivalence with any of the coverage they provide to retirees.

Allowable Retiree Costs – Proposed methods for determination of the net cost of a drug as well as calculation and payment of subsidies recognize the inefficiency of repricing costs after point of sale with the application of discounts, rebates, and chargebacks.

We believe it is in the best interests of CMS, employer sponsors and informed consumers to create an electronic process with access to necessary demographic and eligibility data and to all elements of multiple plan provisions at the point of sale. Such a process would provide immediate data for the calculation of participant out-of-pocket costs and the employer subsidy.

The delays in receipt of employer plan subsidies that are inherent in the current proposal could cause employers to reject the employer subsidy option.

R.3.b.1 - Attestation Requirements

Proposed regulations would require an annual attestation of actuarial equivalence by employer plan sponsors. Annual attestation would impose an additional burden on employer sponsors already burdened with requirements such as those under the Federal Accounting Standards (FAS). As long as no material changes have been made in prescription drug coverage or subsidy from one plan year to another, we recommend that the re-determination of actuarial equivalence and attestation be required only once every three to five years. This would relieve employers of burdensome and costly actuarial work, while the lack of material change would preserve the benefits of participants. In lieu of attestation of actuarial equivalence, the employer sponsor would attest to the lack of any material changes in the plan with their application for a subsidy.

R.5.b – Payment Methodology

Assuming that the true cost of a drug can be reflected at the point of sale, we suggest that the subsidy payment be made on a monthly basis for employers who can provide required data electronically. If “net cost of drug” continues to require recalculation at the end of the reporting period, Alternative 3 would be the most favorable option. It would expedite payments to plan sponsors.

III - Medicare Program; Establishment of the Medicare Advantage Program [CMS-4069-P]

D - Quality Improvement Program

D.*2 - Quality Improvement Program*

We strongly recommend that quality performance incentives be utilized to encourage all providers to participate in quality improvement initiatives. These initiatives provide an important means of improving quality of care through adherence to evidence-based national guidelines of care. Performance incentives might include enhanced payment rates and rewards if quality improvements are demonstrated.

We urge CMS to encourage plan sponsors to tie their quality improvement programs to those of local Quality Improvement Organizations (QIOs) efforts to ensure consistency and optimization of state quality initiatives. CMS has a tremendous opportunity to link all quality improvement programs to improve care, health status, outcomes and beneficiary satisfaction for all beneficiaries. Therefore, it is critical that plan sponsors use the same metrics to measure performance, thereby allowing beneficiaries to compare performance across various plans.

D.4 - Quality Improvement Projects

We commend CMS for recognizing the value of chronic care improvement programs and recommend that careful consideration be given to the design and monitoring capabilities of these chronic care programs. McKesson recommends the adoption of the Disease Management Association of America (DMAA) definition of disease management as its definition of Chronic Care Improvement Programs (CCIP). This definition has been adopted by three national accreditation organizations.

> Disease Management is a system of coordinated healthcare interventions and communications for populations with conditions in which patient self-care efforts are significant. Disease management:
>
> - Supports the physician or practitioner/patient relationship and plan of care
> - Emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies, and
> - Evaluates clinical, humanistic, and economic outcomes on an ongoing basis with the goal of improving overall health.

Disease Management Components include:

- Population Identification processes;
- Evidence-based practice guidelines;
- Collaborative practice models to include physician and support-service providers;
- Patient self-management education (may include primary prevention, behavior modification programs, and compliance/surveillance);
- Process and outcomes measurement, evaluation, and management; and
- Routine reporting/feedback loop (may include communication with patient, physician, health plan and ancillary providers, and practice profiling).

McKesson recommends that MA plans offering an MA-CCIP should be accredited by at least one national accrediting body: the National Committee on Quality Assurance (NCQA), the Joint Commission on Accreditation of Health Care Organizations (JCAHO), or the American Accreditation Healthcare Commission (URAC).

We also recommend that CMS encourage MA-CCIP programs for the following conditions: heart failure, chronic obstructive pulmonary disease, diabetes and coronary artery disease. Criteria to evaluate the effectiveness of a chronic care improvement program are necessary to ensure quality of care is impacted. Measurement of program outcomes should include:

- Measurements of quality improvements using clinical variables, such as daily weight monitoring or ACE inhibitor usage for heart failure programs. Health status and functional status measures should also be included;
- Measurements of utilization improvement, such as reductions in emergency room visits and hospital admissions;
- Measurements of beneficiary and provider satisfaction;
- Overall performance and quality improvement evaluation criteria; and
- Measurement of total cost savings, including all direct costs obtained through the use of either pre/post population analyses or prospective cohort analyses.

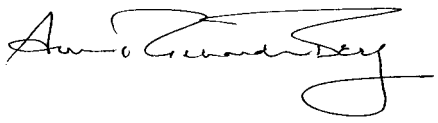
Finally, chronic care improvement programs should address the importance of the physician as a vital member of the care management team. Specific efforts should be made to engage physicians, provide continuing medical education and formulate quality incentive programs to encourage their adherence to evidence-based medicine.

Conclusion

As a major healthcare supply management and information technology company, McKesson appreciates the opportunity to share its views on the proposed regulations to implement the Medicare Prescription Drug Benefit. We applaud the agency's interest in soliciting industry input on these regulations and appreciate your efforts to present realistic and reasonable solutions for consideration. We share your commitment to ensure that these regulations result in a workable and successful program, and we look forward to working with CMS and the Administration on the implementation of the final rule.

Please do not hesitate to contact us with any questions.

Sincerely,



Ann Richardson Berkey
Vice President, Public Affairs

CMS-4068-P-1288

Submitter : Thomas Boudreau **Date & Time:** 10/04/2004 09:10:58

Organization : Express Scripts, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Comment on Title I - Prescription Drug Programs

CMS-4068-P-1288-Attach-1.doc

October 4, 2004

The Honorable Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: File code CMS-4068-P

Dear Dr. McClellan:

Express Scripts appreciates the opportunity to comment on the NPRM for the Medicare Prescription Drug Benefit (CMS-4068-P) that was published in the Federal Register on August 3, 2004.

Express Scripts is one of the largest pharmacy benefit management (PBM) companies in North America, serving thousands of client groups including managed care organizations, insurance carriers, third-party administrators, employers, government and union-sponsored organizations. We currently provide pharmacy benefit services to six million seniors enrolled in a variety of funded retiree health plan arrangements.

Our company strongly supports new federal coverage for prescription drugs to meet the pressing health care needs of the nation's senior and disabled population. We have worked on a bipartisan basis with both the Administration and Congress during the legislative process leading up to passage of the Medicare prescription drug bill. Utilizing a competitive, private sector-based model to administer the new Medicare drug benefit is a sound policy approach to ensure that seniors have access to a choice of high quality, cost effective plans. Express Scripts is currently evaluating a variety of options for participating in the new Medicare drug benefit, including support of our existing employer, government and Medicare Advantage clients. We are also analyzing the requirements associated with bidding to serve the Medicare program as a prescription drug plan (PDP).

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Implementing the new Medicare drug benefit by January of 2006 will present tremendous operational and policy challenges for both the federal government and the private sector. Express Scripts looks forward to working with CMS and other interested parties in refining the draft rule during the coming months to ensure that the new drug benefit is implemented in a way that equitably serves the needs of Medicare beneficiaries, the government, and program contractors.

Express Scripts' comments on the NPRM are divided into two parts: summary comments and recommendations focusing on the structure and implementation of several key elements of the new drug benefit, and more specific comments regarding various technical issues identified in individual sections of the proposed rule (Attachment 1). In addition, we urge consideration of the comments made under separate cover from the Pharmaceutical Care Management Association (PCMA), which is the national trade group for PBMs. The PCMA comments include recommendations on several industry-wide issues contained in the NPRM.

Summary Comments and Recommendations

Express Scripts offers the following summary comments and recommendations regarding the Medicare prescription drug benefit NPRM.

1. Ensure Availability of Pharmacy Benefit Management Tools

Effective cost management of the new Medicare drug benefit necessitates that participating PDP and MA plans be allowed to utilize the full array of pharmacy benefit management tools commonly utilized in the commercial market. In fact, government expenditure estimates regarding the new benefit assume the availability of pharmacy cost management tools as a means to ensure the long term affordability of the benefit, and as a means to promote private sector participation in the offering of risk-based drug plans.

We are encouraged that H.R. 1, and the draft regulation, provides reasonable flexibility to participating entities utilizing various cost management strategies to mitigate unwarranted expenditure growth in the drug benefit and enables the provision of drug plans that are comprehensive and clinically appropriate. While the new Medicare drug benefit limits certain cost management techniques commonly employed in the commercial market, it nonetheless envisions the use of critical pharmacy benefit tools such as formularies, step therapy, prior authorization, pharmacy networks and mail service delivery. We would caution that the imposition of further restrictions on the use of pharmacy benefit tools in the final rule would negatively impact the interest and ability of PBMs and other entities to participate in the program as PDPs.

In particular, Express Scripts believes that the adoption of reasonable and appropriate formulary development guidelines is a critical element of the rulemaking process. We have previously provided separate comments to the United States Pharmacopeia (USP) regarding its proposed Medicare prescription drug model formulary guidelines. It is very important that the final guidelines provide flexibility to PDP and MA plans in the development of clinically appropriate formularies, and to ensure a vigorous competition between drug manufacturers for placement of

prescription products on the formulary. Inclusion of additional drug categories or therapeutic classes in the final USP model guidelines, above the expansive listing already included in the draft, will significantly impair drug plan formulary flexibility, and therefore, negatively impact cost management activities. Creating a reasonable set of formulary guidelines for the Medicare drug benefit will ensure that participating beneficiaries receive a cost effective, safe, and clinically appropriate range of medications.

To effectively manage the drug benefit we also recommend that plan sponsors be provided full flexibility to utilize appropriate step therapy and other utilization management tools at both the Pharmacologic Class and Recommended Subdivision levels. At the Class level, for example, plans should be permitted to implement step therapy programs that permit the use of first line, cost effective therapies prior to the use of second line therapies. For example, at the subdivision level, plan sponsors should be able to ask the prescribing physician to use generic ACE-Inhibitors prior to approving an Angiotensin-II Receptor Blocker, or an NSAID prior to a prescription for a COX-2 agent while allowing the physician to select the second line agent if, in their clinical judgment, the patient should receive the second line agent. Similarly, where appropriate, the plan sponsor should be allowed to ask a prescribing physician to use a first line agent in one category prior to the use of a second line agent in another category yet allowing the physician to select the second line agent if in their clinical judgment it is most appropriate for the patient. We support coupling such utilization management programs with a reasonable exceptions process to ensure the availability of alternative drug therapy regimens when clinically appropriate.

We want to offer our unqualified support and encouragement for another pharmacy benefit tool contained in H.R. 1, and the draft rule, that holds considerable promise to increase patient safety and promote prescription drug compliance—the use of e-prescribing in the Medicare program. E-prescribing is a landmark feature of the Medicare legislation, and in the short term is one of the most important initiatives available to improve the delivery of health care in America.

Express Scripts is encouraged that the National Committee on Vital and Health Statistics (NCVHS) appears to be making good progress in the standards development process for e-prescribing, and that there appears to be broad bipartisan consensus regarding the value of e-prescribing. We encourage continued high level CMS attention to this issue, especially efforts to expedite the implementation timetable for the development of standards and to leverage industry experience in the areas of patient identification, and prescription and benefit information transmission. E-prescribing should be made available to Medicare beneficiaries well in advance of the 2008 statutory deadline.

2. Facilitate/Encourage PDP Stand-Alone Drug Plan Participation

Creation of a viable market of competing private sector PDPs to offer stand-alone drug plans is one of the key challenges involved in implementing H.R. 1. While Express Scripts is exploring possible participation in Medicare as a PDP, there are a number of significant issues/obstacles in the draft rule that could deter interest and participation in this new delivery option. We encourage CMS to take additional measures in the final rule to encourage participation by PBMs in the PDP option, especially in the initial years of the program.

A. Limit Risk Exposure in Startup Years

H.R. 1, and the draft rule, outline the level of insurance/utilization risk that will be borne by full or partial risk PDP vendors interested in offering stand alone drug plans to Medicare beneficiaries. While the federal government will provide subsidies and reinsurance to mitigate potential financial losses incurred by participating PDPs, the level of risk exposure borne by the PDP is potentially significant, which will deter the number of competitive offerings in this option unless the program protects against adverse risk selection.

Given the uncertainties regarding the level of beneficiary participation in the initial years of the benefit, and the lack of data regarding their anticipated level of drug usage, participating PDPs could suffer significant financial losses in the startup years of the program as a result of adverse risk selection unrelated to effective drug plan management efforts. We urge CMS to explore mechanisms to reduce PDP risk exposure in the initial years of the program as a way to encourage the creation of a vibrant PDP market which offers choice to Medicare beneficiaries.

On the critical issue of establishing a workable risk adjustment mechanism for the drug benefit program, CMS should make every effort to spell out and ensure the creation of an average risk pool of beneficiaries for participating PDPs. Drug plans should be rewarded for effective cost and clinical management of their beneficiary population, not on the basis of a favorable draw of lower risk (i.e. lesser utilization) participants. Conversely, PDPs should not be rewarded due to favorable risk selection. Unless the risk adjuster is properly constructed, it is possible that one PDP could do a poor job of effectively managing utilization/cost of their membership, and still benefit financially through a better than average enrollee risk profile, while another plan sponsor could effectively manage their enrolled population but still incur significant financial losses due to adverse selection. Implementation of an effective drug risk adjuster will partially address PDP financial exposure issues. However, PDP and MA plan sponsors must be rewarded for effectively managing the risk, not on the basis of a favorable selection of beneficiaries.

B. PDP Licensure Requirements and Establishment of Regions

The draft rule outlines a process and timetable by which participating PDPs will obtain state insurance licensure and/or a temporary federal waiver regarding licensure and solvency requirements. The NPRM also indicates that a decision will be made by 1/1/05 regarding the establishment of PDP (and MA) contracting regions. Express Scripts believes that these two interrelated activities will be important factors in determining the ability and interest of independent PDPs (i.e. entities not owned or otherwise affiliated with a state licensed insurance entity) to participate in this portion of the program.

The draft rule provides some level of flexibility regarding the requirements for risk bearing PDPs to obtain state insurance licensure in the initial years of the new Medicare drug benefit, and under certain circumstances, requiring initial licensure in only a subset of states in a

region. However, depending on the number of PDP regions established, this flexibility may not be an incentive for PDP participation.

CMS should consider establishing different regions for participating PDP and MA-PD plans. The two offerings have very different characteristics in terms of provider contracts, beneficiary enrollment, and, other substantive operations..

Express Scripts recommends that CMS implement a regional structure that provides PDPs with the flexibility to bid to on either a regional or state specific basis. Under this regional "stacking" approach, CMS would establish multi-state PDP bidding regions. Some of the largest states (e.g. California) may constitute their own region. However, we believe that in certain regions, CMS should allow PDPs the option to bid in only a subset of states in a region. For example, if a mid-atlantic region consisting of New York, New Jersey, Pennsylvania and perhaps several other states is established, PDPs should be given the option of bidding to participate in the entire region or in a subset of states within the region.

This approach would enhance PDP competition, enable entities of differing sizes to determine the level of risk that can be reasonably assumed, and increase the ability of PDPs to aggressively negotiate discounts from other segments of the pharmaceutical chain. In addition, a flexible contracting approach would be consistent and analogous with other provisions of the NPRM that permit local HMOs to submit bids covering only a portion of a state.

Establishment of fifty separate state regions or similar contracting approach for PDPs in the final rule will create a significant problem for PDPs seeking to obtain state licensure or a federal waiver to enable participation in one or more regions. For example, under a regional PDP approach interested PDP entities would be required to obtain upfront licensure (or a federal waiver) in only a subset of states to be served. However, under a fifty region approach state licensure and/or a waiver would be required in each jurisdiction to be served prior to 1/1/06. This would be an extremely difficult task, especially under the tight timeframes required for initiation of the program in 2006.

Express Scripts strongly urges CMS to provide flexibility in the final rule regarding its PDP contracting and licensure requirements.

Attached please find additional technical comments (Attachment 1) on the NPRM. We thank you for the opportunity to comment on these proposed rules and regulations.

Sincerely,

EXPRESS SCRIPTS, INC.
By: /s/ Thomas M. Boudreau
Senior Vice-President and General Counsel

Attachment 1.

Comments on Specific Sections of the NPRM File Code CMS-4068-P

Express Scripts offers the following comments regarding provisions contained within specific sections of the NPRM.

Subsection B – Eligibility and Enrollment

§ 422.50-422.80, §423.34
Auto enrollment of dual eligibles

Comment:

If states and sponsors are to be responsible for auto enrollment of dual eligibles, there must be precise control over the accuracy of the data and explicit operational instructions for sponsors and states. We learned from the discount card experience that marketing and enrollment direct marketing are not efficient and are very expensive. We encourage CMS to early in the process extend auto-enrollment for seniors that are above 150%. The defining point for this group would be adjusted annually as needed but might start at the 300% FPL. This would ensure beneficiaries access a covered drug benefit. It also would assist CMS in controlling Part A and/or Part B costs associated with the lack of drug use/coverage.

Recommendation:

This process should utilize electronic data capture and transfer to be most efficient. A standard process, including file formats, should be established to minimize the requirements for plan sponsors establishing support systems. These auto-enrollment policies and procedures should be standardized for use with other auto-enrollment support services. We would be happy to assist in the formation of the standard process.

Preamble B.5, §423.42
Enrollment mechanisms

Recommendation:

The enrollment process, while supporting paper applications, should include support for technological advances that make data management more accurate and efficient. This should include the use of Internet technologies, appropriate security mechanisms and verifications and confirmations back to the beneficiary of their actions and requests. A system similar to what is in place for FEHBP beneficiaries could be modeled.

Any enrollment system should accommodate those who may need to use alternate forms of communications (through an interpreter or interpretive device), including phone, fax and other forms.

Preamble Section B.6; §423.44, §423.46
Dis-enrollment by the PDP

Comment:

Enrollees should have the primary responsibility for notifying their plan of address changes. This would be consistent with today's processes.

Preamble Section B.8, §423.48
Information CMS provides to beneficiaries

Comment:

While beneficiaries will need information for plan decision making, CMS should ensure that information provided allows for a fair comparison of plans. CMS should specify exactly what plan sponsors should provide when plans will be compared. Lessons from the discount card indicate that a lack of specificity can result in misleading comparisons which results from lack of uniform data submission by plan sponsors.

Preamble Section B.9; § 423.50
Approval of marketing materials and enrollment forms

Comment:

The File and Use process has proved efficient and effective and we support its continued use.

Statute reference 1860D-1(b)(4)(A), Preamble Section B.10
Information provided to PDP sponsors and MA organizations to assist in marketing and outreach.

Comment:

Plan sponsors would benefit from accurate data on Medicare eligibles in the regions they will be servicing. This information should include basic demographics (name, address, city, state, zipcode, DOB, phone number, email address.) This information should be provided to all plan sponsors and not just on request, minimally annually.

Plans should be allowed to specifically designate information that differentiates their plan above and beyond the CMS base standards. Plans should also be allowed to market additional services (e.g. federally approval health-related products and services like HSA products) that plan beneficiaries may be interested in, subject to CMS approval and consistent with the goals and objectives of the Medicare Part D program.

Plans should be allowed to market to existing plan enrollees, including discount card enrollees, via phone, email or direct mail. Beneficiaries may be allowed to select a preferred route of communication.

Plans should be allowed to communicate with existing enrollees without prior CMS approval, within HIPAA guidelines during the 2005 open enrollment period. Drug discount card sponsors should be able to propose Part D drug coverage to beneficiaries who participate in their discount card.

Subsection C – voluntary prescription drug benefit and beneficiary protections

Statute reference 1860D-2(e)(2)(B), Preamble Section C.1.a
Part D versus Part B drug coverage. How can claims be most effectively processed?

Comment:

We understand that a definitive list of Part B drugs is not available and that local coverage decisions may affect coverage determination status. However, PBMs need to process the claim at the point of sale within seconds and the business rules must be clearly defined.

Recommendation:

There needs to be an appropriate set of rules in place to allow the claims routing to identify drugs likely to be covered under Part B versus Part D. A complete list of part B drugs is needed for PDP plans to proceed to prepare for the Part D program. Further, CMS should provide guidance on how it will determine which drugs will be included in Part B and wish drugs will be included in Part D. Any processing rules should be uniform and consistently applied across drug plan sponsors. Pharmacists should be encouraged to solicit from the beneficiary information that will increase the likelihood of the claim being routed to the appropriate plan sponsor. For example, some transplant drugs are only covered when the transplant was Medicare covered. At the point of claims adjudication, today there is no way to know if the transplant was Medicare covered. PBMs can provide specific guidance through messaging.

Statute reference 1860D-2(d)(1)(B); 1860D-15(b)(3)(e)(1)(b). Preamble C.1.b
Dispensing fee defined

Comment

CMS proposes 3 definitions:

1. ingredient cost plus dispensing fee
2. above plus supplies and equipment necessary for the drugs to be administered
3. above plus activities associated with ensuring proper ongoing administration of the drug (nursing visits and clinical pharmacist activities)

The infrastructure today does not allow the claims process to identify that the claim is a home infusion therapy related claim or that the supplies are tied to the medication.

Recommendation:

We support having the dispensing fee include only those activities related to the transfer of possession of the covered part D drug from the pharmacy to the beneficiary (mixing drugs, delivery, overhead). The gaps that exist with home infusion can be covered through an ancillary fee process that is set by the plan sponsor and negotiated with the participating pharmacies.

Preamble Section 2.a
I/T/U pharmacies and HIS beneficiary participation

Comment:

CMS has requested comments on how I/T/U pharmacies and IHS beneficiaries will achieve maximum participation in Part D benefits.

Recommendation:

Allow AI/AN enrollment as with the general population and contract ITU facilities in network as any other retail pharmacy.

Preamble Section C.3.b
Formulary Requirements

Comment:

P&T committee decisions should be binding on the formulary, but the P&T Committee should not be required to be part of tier design, nor should it be required to develop Step Therapy, PA, and generics programs.

Recommendation

CMS should remove the requirement that P&T committees develop UM programs given their ability to handle the workload involved and their level of expertise in program development. It is vital that P&T committees fulfill the role envisions in the Medicare Modernization Act to provide clinical recommendations in developing the formulary. These clinical experts should not be charged with the authority to manage and administer an entire drug benefit plan.

Comment

All members of the P&T Committee should be required to be independent of pharma and have no financial stake in formulary determinations.

Recommendation

We support strengthening the statutory requirement in section 1860D-4(b)(3)(A)(ii) of the Act by requiring all pharmacists and physicians on the P&T committee to be independent and free of conflict. This follows our current business model. To maintain the independence of the P&T committee, their focus should be on the clinical integrity of the formulary. The sponsor has the responsibility to design programs that respect the clinical integrity of the formulary and thus should need to obtain P&T committee approval of the specific programs.

Comment

The determination that a formulary is discriminatory does not sufficiently identify the criteria used to make these determinations. Even plans that follow the USP guidelines could be considered discriminatory based on drugs selected for formulary inclusion.

Recommendation

It is not the structure in and of itself that defines an adequate formulary. It is the application of sound clinical review by independent panels of practicing physicians and pharmacists, commonly referred to as Pharmacy & Therapeutics (P&T) Committees, which results in formularies that meet the needs of plan beneficiaries, while achieving the necessary cost balance to make benefits affordable.

Comment

It appears there is a concern regarding special populations and the drug coverage they will be allowed.

Recommendation

If CMS wishes to increase the number of choices available for certain special populations, they should designate what those populations are and give guidance to PDP plans as to what they determine to be an adequate choice.

Comment

CMS has invited comment on the minimum timeframes for periodic evaluation and analysis of protocols and procedures related to a plan's formulary.

Recommendation

Analysis of treatment protocols should be done as part of an annual update of the formulary to ensure adequate selection of agents to meet the treatment needs of the covered beneficiaries. This reflects current business practices.

Comment

Notification in writing of members and practitioners affected by formulary changes places a large burden on the plan sponsors.

Recommendation

It would be appropriate for plan sponsors to notify beneficiaries in writing if their drug is going off the formulary during the plan year. Professionals should be required to use internet services.

Statute reference 1860D-4(b)(1)(C); Preamble Section C.4.a; § 423.120 Pharmacy Access Standards

Comment

We believe the 'any willing provider' language allows for the participation of all pharmacies in the plan networks.

Recommendation

For a pharmacy to participate as an 'any willing provider" pharmacy, CMS should not require that plans offer anything different from what would be offered to a standard participating pharmacy. Plans should be allowed to negotiate individual terms as the market may dictate. CMS should recognize that there are different services required to meet the needs of enrollees in long term care facilities.

The incentives on both sides would need to be aligned to make it attractive for plans to include infusions pharmacies in the network and sufficient for these pharmacies to want to join.

Preamble Subsection C.4.1
Standard Network contracts

Comment

The pharmacy network inclusion standards must provide adequate access as well as allow for competitive differentiation within the network. We support any means that allows for differentiation in the network with the end result of providing a competitively priced product to the beneficiary.

We would expect any willing provider, at a minimum, to have the ability to process claims electronically using the current standards.

Recommendation

Standard network contracts should not be required to meet 'reasonable and relevant' requirements. Plan sponsors should have the flexibility to craft and be allowed to set the terms of a plan's standard contract. This will create the best network access with the best prices for the beneficiaries.

Statute reference 1860D-4(b)(3)(A); Preamble Subsection C.4.b; § 423.120(b)(1)
Formulary requirements

Comment:

We have submitted comments to the USP. The draft guidelines provide a framework for P&T discussion at the category and class level. Additionally USP's decision to recommend a minimum of one drug from each of the subdivisions mirrors our own approach to formulary development. Any requirement from CMS to alter this recommendation and potentially require more than one drug from each subdivision would hinder our ability to provide a comprehensive and cost-effective formulary.

Plans sponsors should not be precluded from requiring preauthorization, based on sound clinical review and appropriateness, for all listed drugs within individual categories or classes.

Recommendation:

It is very important that the final guidelines provide flexibility to PDP and MA plans in the development of clinically appropriate formularies, and to ensure a vigorous competition between drug manufacturers for placement of prescription products on the formulary. Inclusion of additional drug categories of classes in the final USP model guidelines, above the expansive listing already included in the draft, would significantly impair drug plan formulary flexibility and cost management. Creating a reasonable set of formulary guidelines for the Medicare drug benefit will ensure that participating beneficiaries and the federal government receive the maximum level of discounts

possible as a way to hold down program costs coupled with a clinically appropriate range of medications.

To effectively manage the drug benefit we also recommend that plan sponsors be provided full flexibility to utilize appropriate step therapy and other utilization management tools at both the Pharmacologic Class and Recommended Subdivision levels. At the Class level, for example, plans should be permitted to implement step therapy programs that permit antileukotriene medications to be used only after other more effective and affordable treatments for asthma or allergic rhinitis have been tried. Comparably at the Subdivision level, plan sponsors should be able to promote the use of generic ACE-Inhibitors prior to approving an Angiotensin-II Receptor Blocker, or an OTC NSAID prior to a prescription for a COX-2 agent. We support coupling such utilization management programs with a reasonable exceptions process to ensure the availability of alternative drug therapy regimens when clinically appropriate.

Statute reference 1860D-4(b)(2)(A); Preamble C.4.c; § 423.124
Out of network coverage

Comment:

While we understand the need to provide out of network provisions, cost effective benefits cannot be provided to beneficiaries with paper claims. Additionally, a paper claims process increases the risk associated with not calculating benefit thresholds and may cause a beneficiary to pay more than necessary for medications.

Recommendation:

Minimize the requirements for plan sponsors to retroactively modify claims databases to accommodate paper claims tracking. Should CMS need to require claims modification under specific circumstances, CMS should be specific in the timeline under which these modifications are required, e.g. 60 days.

Preamble Subsection C.5; §423.100, §423.124(b)
Definition of plan allowance

Recommendation:

Agree that out of network pharmacy payment should be reduced to the network contracted rate in order to disincent members from filling scripts at non-participating providers and encourage provider enrollment in the network. This is with the understanding that the enrollee picks up any cost differential. Since the provider has chosen not to participate, any out of network claim would require submission by the member; the member would be responsible for paying any differential owed to the pharmacy.

Subsection C.5, §423.124(b)(2)
Definition of Usual and Customary

Comment:

Standard industry definition - Amount charged cash customers for the prescription exclusive of sales tax or other amounts claimed. CMS would need to retroactively audit

out of network provider's U&C as is currently done with network providers in the commercial business.

Statute reference 1860D-4(k)(1); Preamble Subsection C.7; § 423.132
Public disclosure of pharmaceutical prices for equivalent drugs

Comment:

Information on lowest priced generic drug equivalents provided to enrollees is a valuable means to helping beneficiaries and plans save money.

Recommendation:

This requirement should not be waived for Private Fee for Service (PFFS) plans as there would be many missed opportunities for generic savings.

Subsection D – Eligibility, Election and Enrollment

Subsection D.2.1; §423.153(b)
P&T Committee oversight

Comment:

P&T Oversight for UM programs over the entire drug benefit is a concern based on the workload it would demand of the committee, the resources available and their expertise. There are only limited numbers of P&T committees with limited experts to participate. The current industry standard is to utilize physicians with expertise for specific UM programs and concerns. This alleviates some of the demand on the P&T committee expertise. While some committees pay members for their participation, paying for the additional level of work would significantly increase the costs of the program.

The P&T committee's responsibility with regard to the oversight of UM programs should be limited to the assessment of clinical appropriateness of the tool(s). The operational and policy issues should rest with the plan sponsors.

Recommendation:

The industry standard today is to utilize physicians with expertise to advise on specific UM programs. This process works well and can be facilitated in a variety of practice settings.

The PDP and MA-PD should determine which, if any, of these UM programs are effective.

Subsection D.2.a; §423.153(b)
Prospective utilization review standards

Comments:

OBRA-90 sets forth the standards for a prospective utilization review program in the Medicaid population beyond this there are no clearly defined industry standards.

Recommendation:

We believe the components described in OBRA-90 are adequate to describe the necessary program elements of a cost effective UM program. The choice of which programs should be at the discretion of the plan. How the program is implemented should also be at the discretion of the plan.

Subsection D.2.b
Components and Operation of QA program

Recommendation:

We support an appropriate well defined role for the QIOs, or some outside body, as an oversight body as part of assuring quality across the plan population.

Electronic prescribing as discussed throughout this NPRM is supported in that it would facilitate point-of-service decision making and allow for feedback to the prescriber at the point of care.

Subsection D.2.b
Medication error reporting

Comment:

PBM and plan sponsors have the ability to detect potential medication error and safety issues through the concurrent DUR process. While this process can detect potential drug/age, drug/gender, drug/drug interactions in addition to high dose and ingredient duplication issues there is no ability to detect and report beyond what information is available to the pharmacist at the time of dispensing. Overall, the ability to detect and report medication errors is incomplete. The safety issues are further compounded with "any willing provider' elements since some participants may not meet the standards for detection and reporting of medication errors.

There is a lack of consensus on what constitutes a prescribing error. A paper by Abarca {Abarca, J. *J Am Pharm Assoc. 2004*; 44:136-141} showed there was no consensus between drug interactions as reported in commonly used drug interaction compendia. Given that there is little agreement on what constitutes significant drug interactions, it is premature to report an error rate in prescribing practices without consensus on practice standards.

It is also important to realize that error management systems are encouraged to not be punitive but work toward improving quality. Publishing error rates for a system with good detection versus a system with poor detection would not provide an accurate impression for the consumer.

Recommendation:

Dispensing errors should be under the purview of the state regulatory boards and not the responsibility of the plan sponsor. Without consensus and appropriate supporting systems it is premature to report prescribing errors across plans and error rates should not be published to general consumers.

Statute reference 1860D4(c)(1)(C; Preamble Section D.2.c; § 423.153(d) Medication Therapy Management (MTM) services

Comment:

Because these costs are administrative and must be covered by the plan sponsor in their bid, it is essential that plan sponsors be granted control over who is selected to participate in the program and set the reimbursement rate for activities.

Recommendation:

Considerations such as total cost of therapy, number of drugs and the diseases are the normal ways of targeting today. In the absence of medical claim integration, plan sponsors should be allowed to use drug markers as a surrogate for disease. Plans should be allowed to set the cost trigger for a high-cost beneficiary. Plans should determine the reimbursement rates.

Comment:

There is evidence to suggest that face to face interactions are highly variable and some patients respond better to written information. The literature indicates information preferences (oral, written, other) have been related to education level, age, pharmacy attended and prescription status.

Recommendation:

We believe telephonic and other such means of communicating with individuals- in providing MTM services - are appropriate in many situations and should be supported.

So long as plan sponsors have the flexibility to implement the scope of MTM services, they should have the flexibility to negotiate the costs and reimbursement rates with pharmacy providers.

Comment:

CMS seeks comments on how MTMP services provide through CCIP can be effectively coordinated with MTMP services provided by PDPs.

Recommendation:

Chronic Care Initiative Programs (CCIPs) should take priority over PDP MTMP programs. This may require information sharing from the CCIPs to the PDP sponsors.

Subsection D.2.d; § 423.153(e) Appropriate narcotic prescribing

Comment:

CMS has asked for comments on whether PDP and MA-PD plan sponsors need to determine whether or not physicians are illegally prescribing narcotics.

Recommendation:

Plan sponsors should operate within the law and should not be put in the role of policing prescribing physicians. There should be no repercussions to a plan sponsor for actions taken by a prescriber.

Statute reference 1860D-421(d)(3); Section D.2.e; § 423.153(f)
Prospective drug utilization review

Recommendation:

DUR is an important component of safe and effective use of medication. To exempt PFFS from these programs potentially puts these beneficiaries at risk of drug misadventures.

Statute reference 1850D-4(d); Preamble Section D.3; § 423.156
Consumer satisfaction surveys:

Comment:

We support the centralization of consumer satisfaction surveys as this would facilitate consistency across the survey.

Recommendation:

Plan sponsors should be allowed to conduct their own surveys as deemed necessary by the plan sponsor.

Statute reference 1860D-4(e); Preamble Section D.4; § 423.159
Electronic Prescription drug program

Comment:

We support the NCVHS recommendations which make every effort to acknowledge the industry practices and standards in use today, though also include a number of items which are not yet created or in use and which seek to define improvements for the industry.

We believe that adequate industry experience exists with respect to patient identification, and prescription and benefit information transmission using the RxHub protocols recommended by NCVHS, and therefore no pilot study is necessary.

A key tool in controlling cost is aligning incentives. The real incentives around electronic prescribing should be focusing on changing behavior as it impacts prescribing habits. Stand alone PDPs, as well as MA-PDs, should be allowed to financially incent physicians to participate in electronic prescribing. We support CMS's acknowledgement of incentives that reward 1) formulary compliance, 2) use of lower cost drugs, 3) reduction in adverse drug interactions and 4) efficiencies in filling and refilling prescriptions. Incentives relating only to sending scripts electronically, as opposed to on paper, will not be adequate to drive optimal use of these systems to realize the potential for enhanced quality and cost-savings.

The characterization of the electronic prescribing program inaccurately depicts the true value and goals of the program. We believe that electronic prescribing programs rather than being aimed at providing information to pharmacies, should be aimed at getting the appropriate information to the prescriber at the point of care. Current industry practice already sufficiently deals with providing coverage, benefit and drug-drug interaction information to the pharmacist at the point of dispensing.

Electronic prescribing must ultimately be more than just transcription to pharmacies. The New England Journal of Medicine recently reported the experiences of manual versus electronic prescribing on medication errors. Four Boston clinics were compared for odds of errors in prescribing; two had electronic prescribing, two had pen-and-ink. There were no observable differences among these four practices despite electronic prescribing in two of them. The authors attributed the reason to the fact that the technology only addressed transcription and did not provide any additional decision-support or meaningful information flowing back to the prescribers. The authors estimated that more advanced e-prescribing systems could have prevented 7 of the 20 (35%) of the preventable events, all of which were missed by the minimalist electronic transmission of prescriptions to the pharmacy. (Gandhi, TK. NEJM 2003; 348:1556-64)

While we support the notion that electronic prescribing should not be used to prescribe more frequently or inappropriately steer use to particular drugs, there are instances where electronic prescribing could, and should, be used to appropriately influence medication selection where several choices would be clinically appropriate in terms of therapy, drug selection and/or cost. Plan sponsors should have the ability to share this with the patient and physician at the point of care.

Given the uncertainty of what falls under the provisions of the federal antikickback laws and the physician self-referral laws, industry activities relating to providing incentives for adoption of electronic prescribing will be constrained unless clear safe harbors are promulgated. Without clear safe harbors, any incentive program for physicians involving Medicare providers may be considered risky by industry given the current enforcement environment and the large settlements extracted from providers who find themselves involved in enforcement litigation.

In a number of places, CMS has asked for how to best promote electronic prescribing. The best way to incent adoption is to allow payors (including both PDPs and MA-PD plans) to provide payment differentials, gainsharing programs, and other pay-for-performance plans and incentives so it is financially advantageous for providers to adopt electronic prescribing and deliver the value that it can enable. CMS should also accelerate the acceptance of E-Rxing and infrastructure development through monies to support development and the and establishment of pilot markets as early as 2005.

Subsection F – Submission of bids and monthly beneficiary premiums; plan approval

Determination of 'noncompetitive' and plan evaluation

Recommendation:

CMS should determine a benchmark under which the definition of noncompetitive would open the door for CMS to negotiate with the plan sponsor.

Segmentation of Bid

Comment:

It will be difficult to compare the bids if they are broken up into separate segments

- Administrative costs
- Aggregate costs
- Benefit structure
- Plan management

Would the sponsor need to be competitive in the aggregate or on each element? Plan sponsors have concern regarding the clarity of these elements in the overall evaluation process.

Recommendation:

The bid as a whole should be evaluated for any changes and/or re-negotiation.

Formulary Review

Comment:

CMS has proposed the ability to review formularies for compliance.

Recommendation:

CMS should be aware that any mandated changes to the formularies, other than compliance with the USP guidelines, will affect the plan's ability to control costs through rebates and other price concessions.

§423.286(d)(3)
Rules Regarding Premium

Comment:

A proposed bid penalty of 1% may not be sufficient to control adverse selection. While a 1% penalty may be close to the increases seen in the commercial market, this is a market where there is no adverse selection potential.

Recommendation:

There is no mechanism to risk adjust when adverse selection occurs across all plans in a region therefore there should be some sort of adjustment to address the adverse selection that may occur. One way to adjust this is to match premium to the health status risk of the enrollee who enrolls late.

Late Enrollment Penalties

Recommendation:

Late enrollment penalty payments should be paid upfront as with other premium payments. The plans are taking the risk on these enrollees and should therefore be allowed to collect and receive the late enrollment penalties as soon as they are due.

Subsection G – Payments to PDP sponsors and MA organizations offering MA-PD plans for all Medicare beneficiaries for qualified prescription drug coverage

CMS should provide specific guidance on how payments will be determined and how participants will be counted (e.g. eligibility during the month).

Despite the potential for adverse selection hitting all plans, there is no provision for risk adjustment that would allow CMS to meet the requirement of budget neutrality.

Frequency of data feeds

Recommendation:

Annual submission should be adequate. Plan sponsors could supply additional data on a quarterly basis should there be a need for data conciliation.

Rebate admin fees

Comment:

We believe that admin fees for administering rebates should not be included in assessment of rebate fees.

Recommendation:

The rebate factor that is a reduction of each and every claim to account for the rebate should not include rebate admin fees. This factor could be adjusted as part of the annual bidding process.

Low-income subsidy beneficiaries

Comment:

Risk adjustment methodology has raised concerns over how to account – or not account - for the low income subsidy individuals and the effect on adverse selection.

Recommendation:

These individuals should be serviced in a separate plan with separately determined rates. If they are in the plan, there must be adjustment factors to the degree there is adverse selection brought on to a plan by the low income enrollees.

Subsection I – Compliance with state law

Statute reference 1860D-12(a); Preamble section I.1; § 423.401

Comments:

A requirement for licensure in each state places a tremendous burden on any prospective PDP plans sponsors and potentially the states.

Recommendation:

We support national solvency standards and licensure requirements to more specifically address differences in state laws.

Subsection J – Coordination under Part D with other prescription drug coverage

Statute 1860D-24(c)(1); Subsection J.6; §423.464(e)

SPAP programs

Comment:

A qualified SPAP offering a wrap around program may eliminate the incentive for members to utilize cost effective choices in lower tiers if SPAP wrap coverage reduces beneficiary cost sharing to zero or minimal cost shares.

Recommendation:

State Pharmacy Assistance Program (SPAPs) should be incented to provide more coverage for first tier (specifically generic products) items and limited coverage for second or third tier.

Statute 1860D-23(c)1; Subsection J.6.c
Part D versus Part B POS claims processing

Comment:

The processing of Part D or Part B products at the point of sale is not clearly defined to the point where claims could be accurately adjudicated at the point of sale. To know if a Part B drug should be submitted under Part D would require ICD-9 codes. While this is supported in the 5.1 claim file format, the data must be entered by the pharmacist who must obtain this from the physician.

Recommendation:

CMS should create a clear point-of-sale set of business rules for determining whether a claim is processed to a part B or part D plan. A mechanism should be in place to know if beneficiaries have Part B coverage. We are willing to work with CMS to aid in understanding POS claims processing and help identify pertinent solutions.

Statute 1860D-23(c)1; Subsection J.6.c
Medicare supplier and cross-over claims

Comment:

CMS is suggesting when a Part B claim is denied that it be submitted automatically to the plan sponsor for submission to Part D. DMEs are not equipped to supply this information to third party payors today.

Recommendation:

If the pharmacy receives a reject from a Part B Medicare supplier, the pharmacy should be responsible for re-submitting the claim to the PDP or MA-PD. This a standard practice in the industry today. It is critical for CMS to identify for plan sponsors explicitly what will be covered under Part B now and the criteria for coverage under Part B in the future.

Statute 1860D-2(b)4(C); Subsection J.6.e; §422.106(c)
Options for tracking TrOOP

Comment:

CMS has proposed two options for tracking TrOOP: plans routing and tracking TrOOP on their own or the use of a Troop Facilitation Contractor. Requiring that each PDP

establish connections with all of the appropriate Medicaid plans and other secondary insurance providers would be cost prohibitive.

Recommendation:

A TrOOP Facilitation Contractor would create one central point of contact for the plans and allow for data to be gathered and stored in a consistent format. This process should also include information on the processing priority of all the 'other insurance information' that an enrollee may have. There should be an established set of rules for determining the processing priority to eliminate the need for reversals, re-billings, and recalculations of TrOOP. There should be designated procedures for reversals to foster consistent processes.

Comment:

There are different rules that are needed to determine which dollars are applied to the TrOOP balance and which are not. This determination needs to be reported and explained to members. Therefore, the detail information needs to be available to the PDPs. If the TrOOP facilitator kept the balance information all PDP's would need real-time access to the information for claims adjudication and member calls.

Recommendation:

We recommend the TrOOp facilitator only transfer Post Adjudication claim information from other payors to the PDPs. The PDPs should keep track of the TrOOP balances.

Comment:

There is no current real-time standard to allow the information from a primary or secondary payer to be transmitted back to the PDP. The amount of time needed to develop this standard will not allow it to be available by 2006. However, the NCPDP Post Adjudication Standard is close to completion and could be used. This is a batch standard.

Developing batch processes are cheaper than real-time processes. Since, there is no real incentive for other payors to send the transaction information back to the PDP, the most cost effective method should be chosen.

The main argument for real-time transfer of TrOOP information is to allow the claim to be adjudicated against the most accurate TrOOP balance. However, even in a real-time environment, there are many scenarios in which that would not occur.

a. Up to four claims can be submitted within the same pharmacy transaction. All of these claims are processed by the primary payor before the pharmacy submits them to the secondary payor. Therefore, the information from the secondary payor, even if sent real-time, is not available until after the completion of the total transaction.

b. Even if each claim was submitted separately, first to the primary and then to the secondary, it is possible that the real-time transaction might not

make it back to the primary in time for the processing of the next claim. I would estimate that this would take up to fifteen minutes.

c. Even if the claims were processed in the deliberate manner described above and a sufficient amount of time was left between transactions to ensure the TrOOP balance was up to date, there would still be system outages and communication problems that would affect some portion of these transactions.

There is no situation where it is crucial that the dollars from other payor be applied real-time. Dollars from other payors that would reduce the members TrOOP totals will be applied as they are received. The current indemnity products manage incoming dollars that move the total amounts up and down and across tier boundaries. There is no clear business benefit on receiving secondary dollars in a real-time environment versus batch.

Some of the other payors such as, Worker's Comp and Auto Insurance would be paid using medical processes, which will require the use of paper claims. Therefore, not all of the other payors will be able to respond in a real-time mode, even if the infrastructure was built.

Recommendation:

It is recommended the TrOOP information be transmitted in a batch mode versus real-time using the NCPDP Post Adjudication Standard.

Subsection K – Application procedures and contract with PDP sponsors

Comment:

While we understand the need to assure compliance with the program guidelines and for CMS to understand and hold plans accountable, the expectations of the contracting plan once awarded the contract place a heavy burden on the plan for data provision and reporting. Ultimately this increases the administrative costs of providing the benefit which increases the costs for all involved.

Recommendation:

CMS should establish de minimis threshold for reporting, e.g. reporting set at a dollar or claim threshold.

Comment:

The use of a standard contract to address any willing pharmacy provider could have the adverse effect of raising prices to the beneficiary by shifting the negotiating leverage to the providers from the plans.

Recommendation:

Standard network contracts should not be required to meet 'reasonable and relevant' requirements. Plan sponsors should have the flexibility to craft and be allowed to set the

terms of a plan's standard contract. This will create the best network access with the best prices for the beneficiaries.

We support consistent auditing requirements across PDP and fallback plans.

Subsection M – Grievances, coverage determinations and appeals

Preamble M.5.b; § 423.566(c)
Expedited determinations

Comment:

The preamble of subsection M.4 indicates that the prescribing physician may request expedited determination or an expedited re-determination on behalf of the enrollee and that this physician need not be appointed an authorized representative of the enrollee.

Recommendation:

Today's processes often require information from the physician in order to make the coverage determination. We support that only the enrollee, their authorized representative or the physician may initiate a request. However, it should be recognized that few, if any, of these requests will be administered with enrollee provided information only.

PDPs should be allowed to request or require written or verbal certification from the physician that the drug is medically necessary to treat the enrollee's condition as part of the process in making these determinations. This information should be kept as a part of the medical record.

Partial Fills

Comment:

Regarding "expedited coverage determinations" or authorizations, MA-PDs and PDPs provide call center services for addressing coverage determinations. Some state Medicaid agencies limit partial fills to weekends, when agency/MCO is not open.

Recommendation:

"Expedited coverage determinations" at the point of sale (e.g., retail pharmacy), including partial fills, should be allowed only when the call center is not open within the next 24 hours. The MA-PDs and the PDPs should be allowed to determine any times for which partial fills are to be considered. Our experience suggests that broad authorization for partial fills lowers the effectiveness of formulary and other clinical programs.

Preamble M.5.b
Reconsiderations

Comment:

CMS has requested comments on whether reconsiderations should be automatically referred to the IRE or on request only.

Recommendation:

We agree with CMS's analysis of the cost of coverage determinations (section 6.b) and support that the Independent Review Entity (IRE) reviews occur on request rather than automatically.

Preamble M.5.c; § 423.578(C)(3)
Exception period

Comment:

The preamble indicates that once a beneficiary has an approved exception, they are entitled to continue receiving refills for as long as the physician continues prescribing the drug and for as along as the drug continues to be considered safe and effective for treatment of the enrollee's condition.

Recommendation:

An indefinite exception is not consistent with today's current processes and prevents plans from taking subsequent advantage of cost saving mechanisms and new evidence available. The standard of practice today is to require an annual re-approval.

Preamble M.8; § 423.564
Pre-emption

Comment:

CMS has requested comments on the pre-emption issue and whether specific state grievance requirements that should be incorporated into Federal regulatory requirements.

Recommendation:

Part D plans are federal programs and it is inefficient to operate under federal and state requirements which may vary. Federal law should clearly preempt state law to promote effective operation of the grievance process.

IRE Determinations

Comment:

Plan sponsors may be concerned that determinations of the IRE may become precedent setting for future grievance decisions.

Recommendation:

When creating or advising the IRE with regard to their review process, their review should be limited to whether the plan followed their criteria or did not follow their criteria; IRE's should not be making medical judgments.

Subsection P- Premiums and cost-sharing subsidies for low-income individuals

Statute reference 1860D-14(a)(3)(B)(i); Preamble P.2; § 423.774
Application for Low income subsidy

Comment:

An enrollee can go to the state Medicaid office or the Social Security office to apply for a low income subsidy. This creates the potential that an enrollee would have multiple determinations.

Recommendation:

One group should be responsible for making the final determination even if the ability to apply was allowed at either site.

Statute reference 1860D-14(a)(2)(A); Preamble P.3.b; § 423.46
Sliding scale premiums

Comment:

The process for determining a sliding scale premium for beneficiaries in the >135-150% FPL group should be implemented in a manner that claims processors can easily and effectively implement.

Recommendation:

From an operational perspective, a fixed split of the premium between the beneficiary and CMS would accomplish the same objective and ease the implementation and beneficiary understanding. (For example, 135-140, x%; 141-150, x%). It would be easier to support from a call center and beneficiary support perspective.

Subsection R – Payments to sponsors of retiree prescription drug plans

Preamble R.2.d
Creditable coverage and notification

Recommendation:

A standard language template should be provided that establishes consistency and supports compliance with the provision to provide creditable coverage notification.

The notice should be allowed to be sent with other plan materials to maximize plan efficiency

General considerations for employers

Express Scripts Inc. supports national employers with PBM services and CMS wishes to help employers continue to offer retiree benefits. With this in mind, we wish to echo many of the comments and recommendations from the American Benefits Council in support of our employer clients.

- Swift issuance of guidance for the employer market relating to methodologies and actuarial assumption for determining actuarial equivalence, the process for obtaining waivers, and the allocation of employer and retiree dollars.
- We encourage flexibility for PBMs and PDPs that support employers. We request allowing the waivers to extend to these groups for the purposes of supporting employer plans. For example, a PBM or PDP supporting an employer should be able to elect to solely serve employer groups without also being required to open enrollment to beneficiaries also in the service area but unaffiliated with the employer.

CMS-4068-P-1289

Submitter : Ms. Kathleen Jaeger **Date & Time:** 10/04/2004 09:10:07

Organization : Generic Pharmaceutical Association

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

CMS-4068-P-1290

Submitter : Deanne Birch **Date & Time:** 10/04/2004 09:10:31

Organization : Region D DAC - IV A Team

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4068-P-1290-Attach-1.doc

Region D DMERC Advisory Committee
IV A Team
10480 Perkins Ave. North
Stillwater, MN 55085

October 4, 2005
CMS (Centers for Medicare and Medicaid Services)
Re: Medicare Prescription Drug Improvement and Modernization Act

The Region D DMERC Advisory Committee, (Region D DAC) IV-A Team is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

The Medicare Region D DAC is a nonprofit volunteer organization comprised of HME providers, Home Infusion Providers, State and national associations, manufacturer supporters and industry consultants. The primary function of the DAC is to serve as a communications vehicle between the home medical equipment (HME) industry and CIGNA Healthcare Medicare Administration (CIGNA Medicare), the region D DMERC. **The IV A Team** is representative of a large number of Home Infusion Providers within Region D (17 states) that participate as part of this DAC volunteer organization. This group of professional providers has years of experience and great expertise in the delivery and management of Home Infusion Therapy. A very large portion of our patient population consists of Medicare beneficiaries for those services that have been covered under the Part B DMERC program. Therefore, we feel it is imperative to provide comment to CMS on behalf of this segment of the Region D DAC.

The Region D DAC IV-A Team appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal,

intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients in the PIDD community, this new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

* Dispensing fee option 3 is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it

does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm <http://www.nhianet.org/perdiemfinal.htm> .

* CMS should establish specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies to ensure adequate enrollee access to home infusion therapy under Part D.

* CMS should require specific standards for home infusion pharmacies under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

* CMS should adopt the X12N 837 P billing format for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

* CMS should mandate that prescription drug plans maintain open formularies for infusion drugs to ensure that this population of vulnerable patients has appropriate access to necessary medications.

The Region D DAC IV A Team submits our availability to CMS as a resource for further comment and dialogue on this important issue. Thank you in advance for your consideration of these important issues.

Sincerely,

Region D IV A Team Members
The DMERC Region D Advisory Committee
Mike Hayden – IV A Team Leader
mhayden@alternacare.net
Deanne Birch – Asst... IV A Team Leader
dbirch@infusioninnovations.com

CMS-4068-P-1291

Submitter : sirotkin **Date & Time:** 10/04/2004 09:10:27

Organization : community of Vermont eders

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

see attached document- your first address failed

CMS-4068-P-1291-Attach-2.doc

CMS-4068-P-1291-Attach-1.doc

P.O. Box 1276, 79 River Street, Heritage II, Suite 1, Montpelier, VT 05602
802-229-4731 cove@vermontelders.org www.vermontelders.org

The Community of Vermont Elders (COVE) has been in existence for 25 years and has been continually working on pharmaceutical assistance for Vermont elders since 1986. Over these past 18 years we have seen significant success in raising legislative awareness of the problems low to moderate income seniors have faced in meeting their prescription needs.

For about a decade now, with the help of an 1115 waiver and the federal matching funds it provides, elderly Vermonters below 150% of poverty who do not qualify for traditional Medicaid are entitled to almost full coverage for their prescriptions at a premium of $13/mo or $156 per year;. The cost to those seniors between 150% and 175% of poverty, under the same waiver, is slightly higher at $17/mo, or $204 per year.

Now, with MMA and its proposed regulations, our long evolving state pharmacy programs are being placed in serious jeopardy. It is sadly ironic that a significant percentage of low to moderate income Vermont seniors may be punished by a federal law that clearly designed to help them. This could be a classic case of Vermont being punished for being a leader on the very issue MMA seeks to address.

It is critical that your regulations acknowledge the unique comprehensive prescription drug benefit Vermont (with federal assistance and encouragement) already provides low and moderate income seniors through our 1115 waiver. Vermont's unique circumstances (i.e.already existing full RX coverage with federal matching funds) and MMA's potential impact on these beneficiaries) was not specifically acknowledged or addressed in the legislation. Because of the specific and critical importance of this oversight to Vermont and its pharmacy beneficiaries, we limit our comments to this broad yet crucial concern. We will leave to others the many detailed comments you will no doubt receive on other critical areas of general applicability to seniors nationwide.

The two broad yet critical comments COVE wishes to make are as follows:

1) Continuation of Pharmacy Only 1115 Waiver- the regs should directly state that nothing in the MMA specifically precludes CMS from continuing existing 1115 Rx waivers; and any inconsistencies between existing waivers and the final regulations should be interpreted to do no harm to existing beneficiaries of comprehensive 1115 Rx only waiver programs. Without this provision, it would be hard for the regs to meet the legislative intent of helping seniors with their drug costs in those states that already had significant federal matching pharmacy programs.

2) **Clawback-** The basic concept of the clawback is to mitigate the added costs to the federal government and the potential windfall to the states caused by the federal government essentially taking over the full costs of assistance to dual eligible beneficiaries under part D. Thus, if Vermont's 1115 waiver was allowed to continue as a federally matched wrap around to part D benefits, Vermont's cost under the 1115 waiver would go down (as those drugs covered by Part D would now be 100% federally funded, as opposed to the present 60% federal match under the 1115 waiver). Under these circumstances – increased cost to the feds and decreased cost to Vermont – one might correctly argue that the claw back should apply (even though these beneficiaries are not technically dual eligibles).

HOWEVER, if the waiver is not allowed to continue, then the very basis for a clawback does not exist. In fact, discontinuing Vermont's waiver will save the federal government millions of dollars as an overwhelming majority of our waiver beneficiaries will not be eligible for low income subsidies under Part D. The federal government will be paying far less for these beneficiaries Part D benefits than their present contribution to the full drug coverage these seniors receive under our state waiver programs.

Moreover, no one can seriously argue that Vermont will see any windfall or savings from this group. Indeed, it is likely that without a waiver Vermont will try to hold these seniors harmless by replacing the lost federal matching dollars with state only dollars, causing a major net loss in funds to the state. At the very least Vermont would continue to appropriate the 40% state funds it had been putting into the waiver, so as to minimize the cut in benefits these seniors will face on 1/1/06 (assuming they are then converted from full waiver coverage to the limited coverage under Part D). Under either scenario Vermont's budget would see no net gain from MMA for these beneficiaries.

With the federal contribution decreasing and the state's contribution increasing (or at best staying even), applying the clawback to these particular populations would defy the basic rationale underlying the clawback. It would add insult to injury; and would make it that much harder on the state of Vermont, and ultimately on the seniors these joint federal-state waivers had admirably assisted, to continue the level of assistance previously provided.

Michael Sirotkin, Esq.
COVE Legislative Advocate
Sirotkin & Necrason, PLC
33 Court Street
Montpelier, VT 05602

P.O. Box 1276, 79 River Street, Heritage II, Suite 1, Montpelier, VT 05602
802-229-4731 cove@vermontelders.org www.vermontelders.org

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It is critical that your regulations acknowledge the unique comprehensive prescription drug benefit Vermont (with federal assistance and encouragement) already provides low and moderate income seniors through our 1115 waiver. Vermont's unique circumstances (i.e.already existing full RX coverage with federal matching funds) and MMA's potential impact on these beneficiaries) was not specifically acknowledged or addressed in the legislation. Because of the specific and critical importance of this oversight to Vermont and its pharmacy beneficiaries, we limit our comments to this broad yet crucial concern. We will leave to others the many detailed comments you will no doubt receive on other critical areas of general applicability to seniors nationwide.

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2) **Clawback-** The basic concept of the clawback is to mitigate the added costs to the federal government and the potential windfall to the states caused by the federal government essentially taking over the full costs of assistance to dual eligible beneficiaries under part D. Thus, if Vermont's 1115 waiver was allowed to continue as a federally matched wrap around to part D benefits, Vermont's cost under the 1115 waiver would go down (as those drugs covered by Part D would now be 100% federally funded, as opposed to the present 60% federal match under the 1115 waiver). Under these circumstances – increased cost to the feds and decreased cost to Vermont – one might correctly argue that the claw back should apply (even though these beneficiaries are not technically dual eligibles).

HOWEVER, if the waiver is not allowed to continue, then the very basis for a clawback does not exist. In fact, discontinuing Vermont's waiver will save the federal government millions of dollars as an overwhelming majority of our waiver beneficiaries will not be eligible for low income subsidies under Part D. The federal government will be paying far less for these beneficiaries Part D benefits than their present contribution to the full drug coverage these seniors receive under our state waiver programs.

Moreover, no one can seriously argue that Vermont will see any windfall or savings from this group. Indeed, it is likely that without a waiver Vermont will try to hold these seniors harmless by replacing the lost federal matching dollars with state only dollars, causing a major net loss in funds to the state. At the very least Vermont would continue to appropriate the 40% state funds it had been putting into the waiver, so as to minimize the cut in benefits these seniors will face on 1/1/06 (assuming they are then converted from full waiver coverage to the limited coverage under Part D). Under either scenario Vermont's budget would see no net gain from MMA for these beneficiaries.

With the federal contribution decreasing and the state's contribution increasing (or at best staying even), applying the clawback to these particular populations would defy the basic rationale underlying the clawback. It would add insult to injury; and would make it that much harder on the state of Vermont, and ultimately on the seniors these joint federal-state waivers had admirably assisted, to continue the level of assistance previously provided.

Michael Sirotkin, Esq.
COVE Legislative Advocate
Sirotkin & Necrason, PLC
33 Court Street
Montpelier, VT 05602

CMS-4068-P-1292

Submitter : Valrie Wilbur **Date & Time:** 10/04/2004 09:10:25

Organization : Medicare Policy Coalition

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

National Health Policy Group

Improving Payment and Performance for High-Risk Beneficiaries

October 4, 2004

Center for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

ATTENTION: CMS - 4068- P

Dear Sirs:

The National Health Policy Group appreciates the opportunity to submit comments on the Notice for Proposed Rule Making, which will establish requirements for the Medicare Prescription Drug Program, on behalf of the Medicare Policy Coalition for High Risk Beneficiaries (MPC).

The Medicare Policy Coalition is an alliance of Medicare Advantage Plans and providers that have made a unique commitment to serving high-risk beneficiaries such as the frail elderly and adult disabled. MPC members have a strong interest in the Special Needs Plan designation and other aspects of the Medicare Advantage proposed rule affecting high-risk Medicare beneficiaries as they all currently offer special programs of care for these beneficiaries, many under Medicare demonstrations. Special Needs Plans offer a potential vehicle for the demonstrations to transition to permanent plan status and for non-demonstrations to intensify their focus on targeted beneficiary groups. They also provide a vehicle for more traditional plans and provider networks to develop a specialization in serving special needs beneficiaries.

Thank you for your consideration of our views on the implementation of the Medicare Modernization Act of 2003. If you have any questions regarding the attached comments, please do not hesitate to contact us at 202-264-1508.

Sincerely,

Richard J. Bringewatt Valerie S. Wilbur
President Vice President
Chair, Medicare Policy Coalition Co-chair, Medicare Policy Coalition

801 Pennsylvania Avenue, Suite 245, Washington DC 20004 (202) 624-1516 Fax: (202) 737-6462 www.nhpg.org

CMS-4068-P-1293

Submitter : Mr. Raj Rai **Date & Time:** 10/04/2004 09:10:32

Organization : Option Care, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Pls see attached comments

CMS-4068-P-1293-Attach-1.doc

Option Care Inc. is pleased to submit these comments on the proposed rule to implement the new Medicare Part D prescription drug benefit, as issued in the Federal Register on August 3, 2004. This regulation, CMS-4068-P implements section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) enacted into law on December 8, 2003.

Option Care Inc. is one of the leading providers of Home Infusion Services. We service patients in 33 states through a network of over 120 national pharmacies. Option Care has been in business for over 25 years. We serviced over 100,000 patients last year through our company and franchised locations. Our payor mix reflects reimbursement from various sources such as managed care organizations, insurance companies, self-insured employers and Medicare and Medicaid programs.

Option Care Inc. appreciates the daunting task that CMS confronts in implementing this benefit. We will focus our comments provisions of the proposed regulation that directly affect the ability of the Medicare program to reap the benefits of and ensure meaningful access to home infusion services that are provided in a manner that is consistent with established national quality standards.

We applaud CMS for recognizing the clinical and cost benefits of home infusion therapy and the essential role this area of therapy plays in the private sector health system and in Medicare managed care programs. Home infusion therapy is the administration of parenteral drugs, which are prescription drugs administered through catheters and needles, to a patient in the home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular. It is clear from both the MMA itself and CMS's proposed regulation that home infusion drugs are covered under Part D because they are not currently covered under the Part A or Part B program.

The proposed regulation suggests an interpretation of the Part D benefit to include not only the drugs that can be administered in patients' homes but the essential services, supplies, and equipment that are integral to the provision of home infusion therapy ("dispensing fee option 3" as described in page 46648). If dispensing fee option 3 is adopted in the final regulation, then for the first time, the Medicare fee-for-service program coverage of home infusion drug therapy will be comparable to that of virtually all private sector health plans and Medicare Advantage ("MA") plans. At that point, Medicare finally will be able to realize the significant system-wide savings that come from the provision of home infusion drug therapy in a cost-effective setting that is most convenient for the beneficiaries and their families.

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B *has not resulted in additional access to home IVIG under Medicare.* We see this

as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

In order for the Medicare program to provide meaningful access to home infusion therapies under Part D, we strongly recommend that CMS incorporate the following critical provisions into the final Part D regulations:

- **Dispensing fee option 3** is the only proposed option that will enable Medicare beneficiaries to receive home infusion therapy under the Part D benefit. CMS should follow the well-established home infusion per diem model, encoded using the National HCPCS "S" codes, already used by commercial and Medicare managed care programs. If implemented properly, this model will ensure access and avoid duplication of services-just as it does in the private payer sector. We recommend that CMS reference the National Home Infusion Association National Definition of Per Diem for a list of the products and services included in the home infusion per diem, available at http://www.nhianet.org/perdiemfinal.htm .

- CMS should establish **specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies** to ensure adequate enrollee access to home infusion therapy under Part D.

- CMS should require **specific standards for home infusion pharmacies** under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.

- CMS should adopt the **X12N 837 P billing format** for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.

- CMS should **mandate that prescription drug plans maintain open formularies for infusion drugs** to ensure that this population of vulnerable patients has appropriate access to necessary medications.

Thank you in advance for your consideration of these important issues.

Sincerely,

Raj Rai
CEO
Option Care Inc.

CMS-4068-P-1294

Submitter : Ms. Collin Conway **Date & Time:** 10/04/2004 09:10:46

Organization : student pharmacist

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

COST AND UTILIZATION MANAGEMENT, QUALITY IMPROVEMENT, AND MEDICATION THERAPY MANAGEMENT

As a future pharmacist, Medication Therapy Management will be an exciting part of my practice. The training and education we receive as students make us well trained to provide pharmacy services to elderly patients with multiple chronic disease states.

A couple comments as follows: 1) it would be wonderful if plan providers provided up to date information on patients to all people on the health care team (patient and pharmcist) who are eligible for these services so that we may inform them if they qualify 2) once a patient becomes eligible for services, they should qualitfy for one year so that we may maintain a relationship and allow us to work together to manage their drug therapy

Thank you so much for your consideration of these comments and I look forward to helping my patients in the future. Thank you

CMS-4068-P-1295

Submitter : Mr. Benjamin Loy **Date & Time:** 10/04/2004 09:10:01

Organization : PDX-NHIN-Rx.com

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P Baltimore, MD 21244-8014

Re: CMS-4068-P

Dear Sir or Madam:

PDX, Inc. appreciates the opportunity to submit written comments to the Department of Health and Human Services (HHS) concerning the impact on our companies and our retail pharmacy customers of the proposed HIPAA Privacy Rule changes.

PDX, Inc., a major provider of retail pharmacy software to retail pharmacy, was established in 1985 in Granbury, Texas and was preceded by pc1, Inc., a software application provider primarily directed toward independent pharmacies. PDX is the most widely distributed single code-based pharmacy application used in North America. PDX and its affiliated companies provide pharmacy technology to a customer base of approximately 1,000 independent pharmacies and over 60 chains comprising an additional 9,000 chain pharmacies. PDX has software installations in all 50 states, District of Columbia, Puerto Rico, the U.S. Virgin Islands and most of the provinces of Canada. As such, PDX has a good understanding of the technology issues facing the retail pharmacy industry.

Our comments are provided in an effort to assist HHS in making the implementation of Medicare Part D, the most significant health initiative of recent history, as successful as possible.

Subpart B?Eligibility and Enrollment.
The preamble states that CMS is considering the establishment of the Medicare beneficiary eligibility and other coverage query system using the HIPAA 270/271 eligibility query. Information collected under this section for the purpose of TrOOP application would be available to be queried by pharmacies to facilitate proper billing.

However, since a significant number, if not the majority, of the providers under the Plan D program will be retail pharmacies it is only reasonable that these entities be allowed to use the eligibility standard to which they are accustomed and that is consistent with the HIPAA Final Transactions and Code Sets Rule.

? 162.1202 Standards for eligibility for a health plan.
The Secretary adopts the following standards for the eligibility for a health plan transaction:
(a) Retail pharmacy drugs. The NCPDP Telecommunication Standard Implementation Guide, Version 5 Release 1, September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1 Release 0, February 1, 1996. The implementation specifications are available at the addresses specified in ? 162.920(a)(2).

Therefore, we request that CMS include support for the NCPDP on-line real-time eligibility transaction contained in NCPDP Telecommunication Standard Version 5 Release 1 as this is the most commonly used format for retail pharmacy and that a requirement for retail pharmacy to change to using the X12N-270/271 batch eligibility formats would impose a significant obstacle to the Medicare drug benefit program.

Sincerely,

Benjamin E. (Ben) Loy, R.Ph.
Sr. VP Inudstry Relations

PDX-NHIN-Rx.com

CMS-4068-P-1296

Submitter : Dr. Barbara Manard **Date & Time:** 10/04/2004 09:10:17

Organization : American Association Homes and Services for the Ag

Category : Long-term Care

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

SUBPART AGENERAL PROVISIONS

LTC residentsincluding those in hospital-based facilities--must be able to access LTC pharmacies without paying out of network prices that are higher than in network prices

The proposed rule recognizes that LTC facilities generally contract with specialized pharmacies (LTC pharmacies) that provide important services to LTC residents, enhancing safe pharmacy practices in LTC facilities. A critical question for design of the new Part D program is this: What happens if the LTC pharmacy contracted with by a resident?s LTC facility is not in the network of the enrollee?s Part D plan? In Subpart A, CMS gives four examples of situations when a plan will be required to all an enrollee to use a non-network pharmacy and includes the situation of the out of network LTC pharmacy used by a LTC resident.

AAHSA agrees with this formulation so long as it does not mean that LTC residents will be required to pay the higher prices frequently associated with out of network transactions. Plans must be explicitly prohibited from charging LTC residents out of network prices for using a LTC facility's LTC pharmacy when that pharmacy is not part of the plan's network.

Furthermore, since hospital-based LTC facilities typically get pharmacy services from the affiliated hospital's pharmacy, the definition of LTC pharmacy must be sufficiently inclusive so that residents/patients in hospital-based LTC facilities have the same access to pharmacy services (without paying out of network prices) as residents/patients of free-standing LTC facilities that contract with typical LTC pharmacies.

CMS-4068-P-1296-Attach-1.doc

CMS-4068-P-1296-Attach-2.doc

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 309-G
200 Independence Avenue, SW
Washington, DC 20201
Attn: CMS-4027-P

Re: Comments on Medicare Program; Medicare Prescription Drug Benefit, Proposed Rule, 69 *Federal Register* 46632, August 3, 2004, CMS-4068-P

To Whom It May Concern:

The American Association of Homes and Services for the Aging (AAHSA) appreciates the opportunity to comment on the Proposed Rule, published in the Federal Register on August 3, 2004, to implement a new voluntary Medicare prescription drug benefit (Medicare Part D) as specified in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108-173, signed into law December 8, 2003.

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We recognize the challenge faced by CMS in developing these rules and appreciate the effort of the Administrator and staff to meet this challenge in a timely fashion. We look forward to continuing to work with CMS to better assure smooth implementation of this complex new program for the Medicare beneficiaries served by our members.

INTRODUCTORY COMMENT

Need for a second round of comments before the final rule and access to interim products of the congressionally mandated study of LTC pharmacy issues

The proposed rule leaves a very large number of issues, large and small, either unaddressed or addressed principally as questions to reviewers for guidance**.** We are very concerned that advice and comments offered by us and others, while appropriate given one set of assumptions about a final system, will be substantially off base in terms of a more fully defined system. Failure to obtain public comments on a more fully developed set of rules is very likely to lead to a far greater number of errors and unintended

consequences than if another round of comments before the final rule were permitted. We therefore recommend that CMS issue an interim final rule with opportunity for further comment (even if this is an abbreviated comment period) prior to the final rule.

The problem of inadequate information on which to make decisions about recommendations is particularly grave with respect to rules regarding long term care (LTC) facilities. Recognizing the particular complexities of this sector, about which there is very little research or public information available, Congress directed the Secretary to conduct a thorough study of practice for pharmacy services provided to patients in LTC facilities (MMA, section 107). The results of that study are critical to understanding important issues raised in the proposed rules and developing an appropriate set of final rules. CMS notes in the Statement of Work issued August 25 with the request for quotation (RFQ) for potential bidders on the project that "[t]he goal of the research is to inform the Centers for Medicare and Medicaid Services in its development of Part D policy affecting long-term care pharmacies serving Medicare beneficiaries, as CMS ramps up for the launch of Part D." Further, CMS states "the contractor will … develop a set of options for ways in which the LTC pharmacy system can be smoothly and effectively integrated into Part D, and conduct a critical analysis of the relative pros and cons of each option."

Congress required that this research be completed by June 2005 (eighteen months after enactment) and the work plan outlined in the August 2004 RFQ suggests that that is approximately when the work will be completed, although some helpful interim products are specified in the first few months of the project. This essential study has obviously not been available to those commenting on this proposed set of rules. We therefore request that interim products of this project be made available to the public to the extent that these are prepared prior to the interim final rule we recommend and that the final rule contain an explanation of how the completed study will inform the Part D plan's operation in LTC facilities.

While CMS does not generally make interim study products available to the public, we believe that doing so in this case, coupled with a second round of public comments prior to a final rule, would considerably enhance the chances for a reasonable, equitable, and effective final rule on this complex topic.

SUBPART A—GENERAL PROVISIONS

LTC residents—including those in hospital-based facilities--must be able to access LTC pharmacies without paying out of network prices that are higher than in network prices

The proposed rule recognizes that LTC facilities generally contract with specialized pharmacies ("LTC pharmacies") that provide important services to LTC residents, enhancing safe pharmacy practices in LTC facilities. A critical question for design of the new Part D program is this: What happens if the LTC pharmacy contracted with by a resident's LTC facility is not in the network of the enrollee's Part D plan? In Subpart A,

CMS gives four examples of situations when a plan will be required to all an enrollee to use a non-network pharmacy and includes the situation of the out of network LTC pharmacy used by a LTC resident.

AAHSA agrees with this formulation so long as it does not mean that LTC residents will be required to pay the higher prices frequently associated with out of network transactions. Plans must be explicitly prohibited from charging LTC residents out of network prices for using a LTC facility's LTC pharmacy when that pharmacy is not part of the plan's network.

Furthermore, since hospital-based LTC facilities typically get pharmacy services from the affiliated hospital's pharmacy, the definition of LTC pharmacy must be sufficiently inclusive so that residents/patients in hospital-based LTC facilities have the same access to pharmacy services (without paying out of network prices) as residents/patients of free-standing LTC facilities that contract with typical LTC pharmacies.

SUBPART B—ELIGIBILITY AND ENROLLMENT

The rule allows inadequate time to ensure that all dual eligibles are appropriately enrolled in Part D, thus a delay of the duals' transfer from Medicaid to Medicare or another solution is required.

The proposed rule states that dual eligibles will be automatically enrolled in a PDP or MA-PDP, if they do not enroll themselves, by the end of the initial enrollment period, which, under section 423.36 is November 15, 2005 to May 15, 2006. However, Medicaid's drug benefit for dual eligibles will end on January 1, 2006. This means that duals could face a four and one-half coverage gap.

To enhance the dual's opportunity to select their own plans, we recommend that the transfer of duals be delayed for at least six months. This may require a change in the law and recommend that the Secretary pursue this option.

If it is not possible to delay the transfer, CMS needs to develop a workable alternative that will assure that duals are properly covered in appropriate Part D plans.

The need to develop a workable plan that does not rely on service providers to ensure than all LTC residents and other frail elderly receive the help they need to understand and select an appropriate plan

We are concerned that the proposed rules do not sufficiently specify how special needs populations (cognitively impaired elderly, frail elderly living alone without access to help from family or friends, residents of LTC facilities, and so forth) will obtain the information and help they need to select and sigh up for a plan. AAHSA's experience with the Prescription Drug Card in many settings (senior housing, assisted living, nursing facilities) taught us how difficult it is for even our own computer and Internet savvy staff to understand how to make wise choices. This new program is considerably more

complicated, as CMS is aware. We believe that SHIPS, Area Agencies on Aging, and other similar groups can provide the kind of detailed help needed, but they need additional resources to do the job.

AAHSA is also concerned that CMS not rely on providers of aging services to explain the new program or to help select a plan for the beneficiaries they serve. AAHSA fully intends to assist its members in the same kinds of voluntary educational activities that were undertaken with respect to the Medicare-approved Drug Card. Many of our state affiliates and members across the continuum of aging services worked hard to provide educational materials and forums for the beneficiaries they serve. We expect many to do the same with the new Part D program. But it would be particularly inappropriate, we believe, for providers of aging services to be expected to help beneficiaries actually select a plan.

SUBPART C—BENEFITS AND BENEFICIARY PROTECTIONS

The definition of "long term care facility" needs to assure that residents of facilities that rely on LTC pharmacies continue to have appropriate access to these pharmacies

The proposed rule asks for advice about how the term "LTC facility" shall be defined. The question presumably arises because the law explicitly gives CMS the authority to promulgate rules that include standards with respect to access for enrollees in "long term care facilities," but does not define that term. In the proposed rule, CMS says that it limited the definition to nursing facilities and skilled nursing facilities, based on the agency's understanding that "only those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long term care pharmacies" (69 Fed. Reg. at 46648-49).

There are, however, other types of facilities, notably including "assisted living facilities," that sometimes contract exclusively with LTC pharmacies. Many assisted living facilities serve populations identical to those found in some nursing home: there is substantial overlap among the populations, making the specialized services of LTC pharmacies attractive to a reportedly growing number of assisted living facilities. Therefore, the residents of these facilities need the same kinds of special rules to preserve access to the new Medicare Part D benefit as do residents of nursing facilities, where both are served by contracted LTC pharmacies.

Including assisted living facilities under the definition of "LTC facility" *strictly for the purpose of Part D* may be the only way to accomplish the important goal of assuring access to LTC pharmacies, at no higher (out of network) price, for residents of these facilities, as for those in nursing homes. But if a different way could be found to accomplish the same goal, that would be better. The assisted living movement has worked hard to define its philosophy and services as unique and there is concern that there might be some unintended consequences of defining assisted living as "long term care facilities" in a federal rule. An additional challenge of including assisted living

facilities under the definition of LTC facility is that there is no national definition of assisted living, although most states do define those or similar types of facilities (with definitions varying from state to state).

Letting the market evolve before promulgating a rule regarding plan's contracting with long-term care pharmacies

The proposed rule suggests two possible ways to balance the need to preserve access to LTC pharmacies and appropriate cost containment and asks for comments on which would be best. The two ways suggested are (1) encouraging plans to contract with LTC pharmacies and (2) requiring plans to contract with LTC pharmacies.

CMS expresses concern that LTC pharmacies will be in too strong a negotiating position if plans are required to contract with LTC pharmacies. It is not clear if that would be the case; in fact, it is extremely difficult to determine what the effect of either approach would be.

We therefore recommend that CMS specify that LTC residents who use LTC pharmacies that are out of network may not be charged out of network prices, but leave it to the plans to determine how best to make that work. This is likely tantamount to encouraging plans to contract with LTC pharmacies.

Access to appropriate formularies

The use of formularies is well established in many environments including hospitals, nursing homes, long term care pharmacies, and health plans. They can be tools to promote high quality pharmacy practices and responsible cost containment, or they may be used in ways that actually increase costs over all and/or prevent access to needed and appropriate therapy.

We are therefore reluctant to argue that LTC residents or others must have fully open formularies and recommend instead that CMS require that long term care residents have access to special formularies, meeting at a minimum the requirements set forth by the American Society Consultant Pharmacists for long term care populations.

We also recommend that residents of LTC facilities and others with similarly complex pharmacy needs be given a minimum six month grace period before being transitioned to any new formulary. It will take time to get medications changed, if that needs to happen.

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American Association of Homes and Services for the Aging

October 4, 2004

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Department of Health and Human Services
Hubert H. Humphrey Building, Room 309-G
200 Independence Avenue, SW
Washington, DC 20201
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Vice President
Long term care/Health Strategies
American Association of Homes and Services for the Aging

CMS-4068-P-1297

Submitter : Mr. David Viele **Date & Time:** 10/04/2004 09:10:18

Organization : First Health Serivces Corporation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attached comments

CMS-4068-P-1297-Attach-1.doc

First Health Services Corporation
Comments on the Medicare Prescription Drug Benefit Proposed Rules
October 4, 2004

First Health Services Corporation is submitting comments on the Medicare Prescription Drug Benefit Proposed Rules. These comments are intended to improve the quality of the Medicare Part D program, to limit the disruption to the Medicaid dual eligibles, and enhance the benefits provided to the Part D enrollees. The Part D prescription drug program has been described as following a commercial model, and yet in a number of areas CMS is contemplating dictating how a PDP must operate by creating operational requirements in the rules. First Health Services has spent a considerable amount of time reviewing the proposed rules and hopes that CMS will consider our comments as the rules are finalized. Our comments are intended to be constructive with the goal to provide an effective Medicare Prescription Drug Program in January 2006.

Comments on the Medicare Prescription Drug Benefit Proposed Rules

B. Eligibility and Enrollment (Federal Register page 46637)

2. Part D Enrollment Process (§423.34) (Federal Register page 46638)

In implementing the automatic enrollment process for full benefit dual eligible individuals, we are considering which entity is best suited to perform the automatic and random enrollment function. The options include CMS or the State performing this function, or a contracted entity or entities on their behalf. If we (or a contractor on our behalf) performed the auto assignment, we would expect consistent, clear oversight of the process, thus making the process uniform nationally; this might also reduce the need to transmit data from CMS to the States. However, this would be highly dependent on receiving timely, accurate Medicaid eligibility data from States and would also make us responsible for a new national workload of indeterminate size.

An alternative is for States (or their contracted entities) to be responsible for performing the automatic enrollment. This approach may be appropriate because States have experience with random assignments through their Medicaid programs and have more immediate access to changes in Medicaid eligibility. We would define random assignment; establish standards for notification, and so forth, to ensure consistency. If we were to pursue this option, we could consider this function as necessary for the proper and efficient administration of the State plan. We would need to provide States with accurate and timely Part D data. States could be compensated for this effort through Federal financial participation (FFP) in their administrative expenses or through contractual or other arrangements. We invite comment on the most appropriate method of performing automatic assignment of dual eligibles and the appropriate entity to do so.

Comment: CMS has solicited comment on the question of whether the federal government (CMS or its contractor) or the States (or their contracted entities)

should have responsibility for administering the "random" automatic enrollment process for full benefit dual-eligible individuals who do not otherwise enroll in an MA-PD or PDP. *See* 69 Fed. Reg. 46,639 (Aug. 3, 2004). CMS suggests that State responsibility for this function might be appropriate because they have more immediate access to Medicaid eligibility changes and experience with random assignments through their Medicaid programs.

First Health Services opposes imposing this additional administrative burden, which CMS accurately describes in the Federal Register as "a new national workload of indeterminate size," on the States. As a threshold matter, the governing legislation is clear that this responsibility should fall upon the federal government. Section 1860D-1(b)(1)(C) of the Act unambiguously directs that, if there is more than one prescription drug plan available to a full-benefit dual eligible individual who has failed to enroll in a PDP or MA-PD plan, "*[t]he Secretary shall enroll* such an individual on a random basis among all such plans in the PDP region" (emphasis added).

Given this express designation of responsibility, neither the Secretary nor CMS has authority, by administrative regulation, to impose responsibility for the auto-enrollment function on the States. The preamble to the proposed rule suggests that administrative costs of auto-enrollment activities by the States might have to be borne, at least in some substantial part, by the States themselves. Moreover, even if administrative costs of carrying out this function were to be fully federally reimbursed (as would be more appropriate, given that the Part D program falls within the federal Medicare program, not the joint state/federal Medicaid program), it would nevertheless constitute a substantial, additional administrative burden on the States that they are not equipped to perform.

As the preamble to the proposed regulation acknowledges, CMS' assumption of the auto-enrollment responsibility will further the goals of national uniformity in, and facilitate federal oversight over, the process. Auto-enrollment will require accurate and timely information flow between CMS and the States in any event. There is no reason to assume that transmission of accurate Medicaid eligibility data from the States to CMS would be inherently any more problematic than transmission of accurate and timely Part D data from CMS to the States. Accordingly, First Health Services believes there is no legitimate rationale for transferring to the States an administrative responsibility that Congress clearly indicated should fall upon the federal government.

4. Coordination of Beneficiary Enrollment and Disenrollment through PDPs (§ 423.42) (Federal Register page 46641)

— Section 1860D–1(b)(1)(A) of the Act authorizes us to establish a process for enrollment in and disenrollment from prescription drug plans. We have outlined the coordination of enrollment and disenrollment through PDP organizations in the regulations at §423.42. A Part D eligible individual who wishes to make, change, or

discontinue an enrollment during applicable enrollment periods may do so by filing an enrollment with the PDP directly. We envision a paper enrollment form process and recognize the opportunity for other possible mechanisms that may prove secure, convenient for beneficiaries, and valuable to the efficient administration of the program. We request comments on other possible enrollment mechanisms that address data security and integrity, privacy and confidentiality, authentication, and other pertinent issues.

Comment: In order to ensure that as many beneficiaries as possible enroll in a PDP prior to implementation of a random, auto-enrollment process, we believe it is strongly advisable to facilitate the participation of the SPAPs [and other state agencies] in assisting beneficiaries with their enrollment in a PDP. While we believe that it would be inappropriate to require States to assume responsibility for the random auto-enrollment of all full benefit dual-eligible individuals, States should be permitted to voluntarily assist their residents, including dual eligibles, with the enrollment process. Such voluntary participation in the enrollment process by States will provide SPAPs with greater ability to facilitate the smooth transition of their populations into the Part D program. It will also ease the burden on the federal government of carrying out the auto-enrollment function under § 423.34, by diminishing the number of individuals who need to be auto-enrolled.

Medicare's experience with the drug discount card has demonstrated that seniors and other vulnerable populations often will not enroll on their own initiative in a program such as the Part D benefit, despite the advantages of the benefit being offered. The statute authorizes the random auto-enrollment of full-benefit dual-eligibles in a Part D program, but does not include the wider population of potential Part D beneficiaries in this provision. Accordingly, States should be given broad authority to create their own mechanisms to support the enrollment process and to assist individuals enroll in Part D benefits.

In order to achieve widespread beneficiary access to the current drug discount card, it has been necessary for SPAPs to execute applications for their members (with opt-out procedures, instead of affirmative actions required by beneficiaries to obtain the card). Similarly, SPAPs should be authorized to assist the beneficiaries they serve by completing PDP applications for their beneficiaries, as long as each beneficiary is fully informed of the enrollment assistance being provided by the SPAP, and his or her right to decline or opt out of that service prior to the start of the Medicare Part D benefit. While the First Health Services believes that CMS should bear responsibility for implementing the random auto-enrollment of dual-eligibles, mandated by Congress in the event such individuals are not otherwise enrolled in a Part D plan, First Health Services believes that SPAPs [and other State entities] should be given express authority – to the extent they have the resources and desire to do so – to assist in the enrollment of *any* of their qualified Part D beneficiaries prior to CMS' auto-enrollment.

Accordingly, we seek amendment to both § 423.34(b) and § 423.42(a) in order to clarify that a State may assist an individual with completion of the individual's PDP

application, including executing the application on the individual's behalf, or may otherwise assist an individual in the Part D enrollment process, as long as the individual is provided an opportunity to decline this assistance or "opt-out" of any available PDP.

6. Disenrollment by the PDP (§ 423.44) (Federal Register page 46641)

We are particularly interested in receiving comments about the requirement to disenroll individuals from a PDP if they no longer reside in the service area. Under the MA rules at 42 CFR 422.74, individuals who are out of the service area for more than 6 months will be disenrolled, unless the MA plan offers visitor or traveler benefits. We recognize the inherent difference between PDPs and MA plans (in particular, the range of services each provides) and that it may not be reasonable to apply the disenrollment requirements established under MA in the same way for PDPs. For example, while we have a limit on the length of time an MA enrollee may be out of the service area, this limit may not be necessary as long as there are specific assurances from the PDP that individuals will have access to PDP benefits while out of the area (provided the individual remains in the United States). For example, a regional PDP may either have a corporate or other relationship with a PDP in another region or have a network of pharmacies in other regions (or nationwide) that would provide access to prescription drugs outside of the region on the same basis as in-network pharmacies within the enrollee's region of residence. We would appreciate any comments on this area.

Comment: PDP's need the ability to disenroll an individual from their plan if the individual no longer resides in the service area, in the same manner as MA plans currently disenroll individuals. The disenrollment requirements should be the same for PDP's and MA plans. Since the PDP regions are not yet known, a PDP's relationship with pharmacies outside of the contracted region is unknown. PDP's may not be working in contiguous regions and may only have contracts with pharmacies within the region, therefore they will not have the capability of providing pharmacy coverage on the same basis as they have with in region pharmacies. If a state is a region, a larger number of PDP's will be in a position to provide services to the region. Not all PDP's may be able to provide the same access to drugs outside of the region. Pharmacy contracts are specific to a distinct geographical area, and discounts can vary between regions.

We plan to establish re-enrollment guidelines under the MA program for optional disenrollment for nonpayment of premium and disruptive behavior. We recognize, however, that this policy may not be appropriate for PDPs. If the individual is prohibited from re-enrolling in each of the MA plans available in an area, original Medicare is always available to provide and deliver services to that that individual. Under the PDP infrastructure, if the individual was prohibited from re-enrolling in each PDP available, there is no other option available. We would appreciate comments regarding the applicability of prohibiting re-enrollment in a PDP.

Comment: PDP's need the ability to disenroll an individual for non payment of premiums. PDP's are less concerned about disruptive behavior, since the PDP is only providing a pharmacy benefit. PDP's rely on all sources of revenue to be able to provide the pharmacy benefit. Without payment of premiums, one of the fund sources is removed, and the PDP's plan loses actuarial soundness. A process could be established where an individual would be re-enrolled upon payment of back premiums, and an agreement signed by the beneficiary for automatic payment of premiums through an EFT process.

8. Part D Information that CMS Provides to Beneficiaries (§ 423.48) (Federal Register page 46642)

We propose building on our experience in implementing the drug discount card price comparison Web site as we develop requirements for the Part D price comparison Web site, and we are seeking comments on how to provide information in the drug benefit to help achieve maximum drug savings.

Comment: In the Medicare Discount Drug card Program, the guidelines for the production of the price files has been unclear and thus interpreted differently by sponsors in the program. Our interpretation has been that these price files reflect our negotiated discount with our pharmacy network members. Others in the program have interpreted this to also include rebate discounts. With this kind of variance, prices on the Price File Comparison web site have been misleading for the member.

The multiple step process that is required and the lack of clarity make it difficult if not impossible to get through these screens successfully. Members have indicated that this process is confusing and have therefore not taken advantage of the comparison process.

The complexity of drug pricing and the negotiated rates and rebate discounts do not lend themselves to this type of inquiry – it has lead to confusion and concern for members. Production and publication of formularies with all drugs, their associated price and generic equivalents would appear to be less confusing.

The process of providing rebates at the point of sale is not a standard practice in the industry and has caused problems – adopting a similar model to that of Medicaid or even a commercial plan seems to make more sense and still serves to discount the cost of the drug to the member, if administered correctly. This way the network discount is applied at the point of sale, drug claims are submitted to the manufacturers retrospectively, rebates are returned to the sponsor and in our recommended case these rebates are then returned to the plan for use in reducing the cost of coverage. The usefulness of a pricing website is questionable without specific guidance from CMS on what the site is to contain.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections (Federal Register page 46646)

1. Overview and Definitions (§ 423.100) (Federal Register page 46646)

a. Covered Part D Drug (Federal Register page 46646)

— We are concerned that the aforementioned exclusion of outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer (or its designee) as a condition of sale (item 7 above) may prove too narrow to address inappropriate tying arrangements. We may consider expanding this exclusion and solicit public comments on how to reduce the risk of abusive tying arrangements.

We intend to ensure that the Part D benefit ''wraps around'' Part B drug benefits to the greatest extent possible. For example, Part D would cover immunosuppressive drugs furnished to Medicare beneficiaries who did not have their transplant paid for by Medicare (e.g., a beneficiary who had his or her transplant paid for by a private insurer when he or was employed, and the beneficiary has now enrolled in Part B). Part D could pay for these immunosuppressive drugs for these beneficiaries since Part B is prohibited by statute from paying for them. Therefore, we are soliciting comments concerning any drugs that may require specific guidance with regard to their coverage under Part D, and any gaps that may exist in the combined ''Part D & B'' coverage package.

Comment: There are concerns with CMS attempting to mandate the interactions between the PDP and the drug manufacturers. In a majority of instances, PDP's have the flexibility to obtain drugs in the same categories or classifications from multiple manufacturers. Tying arrangements are an issue between the PDP and the manufacturers, and not CMS. As long as the PDP complies with the formula requirements developed by the USP and adopted by CMS, the issue of which drugs are covered by the PDP can not be controlled by CMS. The Medicare Part D prescription drug benefit requires the establishment of formularies, in order for the PDP to operate successfully within the capitation rates created by CMS. Specific guidance on what drugs should be covered by Part D providers is not necessary.

b. Dispensing Fee (Federal Register page 46647)

— Because the statute is ambiguous on the meaning of ''dispensing fee,'' in this proposed rule we are not proposing a specific definition of ''dispensing fee,'' but instead are offering three different options we believe would be reasonable, permissible definitions of the term. We invite comments on each of the definitions proposed below.

Option 1: The dispensing fee would include only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including

charges associated with mixing drugs, delivery, and overhead. The dispensing fee would not include any activities beyond the point of sale (that is, pharmacy follow-up phone calls) or any activities for entities other than the pharmacy. Option 1 would differentiate between ''dispensing'' a covered Part D drug and ''administering'' one in order to restrict the scope of these fees to include only those charges for pharmacy services related to the preparation and delivery of a covered Part D drug. Under option 1, the dispensing fee could not include any charges associated with administering the drug once the drug has already been transferred to the beneficiary. Thus, for example, the fee would not include any professional fees (such as skilled nursing services), durable medical equipment (such as an external infusion pump or an IV pole), supplies (such as tubes and dressings), or even follow-up telephone calls from the pharmacy to the patient to check on the patient's progress with the drug.

Comment: First Health Services prefers this definition of dispensing fee as it is consistent with the definition used by NCPDP and is standard practice in the industry.

Option 2: The dispensing fee would include the activities included in Option 1, but in addition would include amounts for the supplies and equipment necessary for the drugs to be provided in a state in which they can be effectively administered.

Comment: The interpretation of this option is that it includes things such as the preparation of a compound drug. Typically a compound drug will have a variable dispensing fee for the complexity that is involved in its preparation. First Health Services does not see this as a replacement for option one but rather a variant that should be used for these compounded drugs that require more in the way of preparation and supplies in the pharmacy.

Option 3: The dispensing fee would include the activities in Option 2, but in addition would include activities associated with ensuring proper ongoing administration of the drugs, such as the professional services of skilled nursing visits and ongoing monitoring by a clinical pharmacist.

Comment: NCPDP has already provided for this type of pricing over and above the standard dispensing fee. Systems and transactions are available and used for the pricing and payment of professional services for the pharmacy in the preparation of drugs and the administration of drugs. In addition there are also professional services fees already in existence for use by nursing services care givers for the actual administration of drugs – we do not feel that this should be part of a dispensing fee in pharmacy.

However, we also recognize that options 2 or 3 would eliminate current gaps in coverage relative to home infused drugs. We have limited options 2 and 3 to cases of home infusion because this is the only circumstance we know of where the additional services associated with administering the drug would not already be covered under Medicare Part

A or B and would be necessary to ensure effective delivery of the drug. (For example, infusion therapy provided in a hospital outpatient setting or in a physician office could be covered under Part B. Infusion therapy by a hospice could be covered as part of the hospice benefit, if a patient meets the conditions for hospice care.) However, there may be related issues with respect to the administration of other drugs (for example, vaccines and inject able long-acting antipsychotic drugs), and we solicit comments regarding any implications for our proposed options

Comment: The point of sale systems in place today can and do support multiple variations of dispensing fees based on the drug or the amount of effort that is required to prepare and possibly administer the medication. Provider participation agreements can and are structured to support this multiple tier fee structure already. Once defined, these agreements can be executed and administered within the POS systems through the process of building rules for each instance. Then at the time the drug is requested and dispensed the pharmacists identify the scenario and the system handles the pricing. In addition the POS system can handle specialty care – such as home infusion. In our system a pharmacy, group of pharmacies or whatever set of providers can be identified and credentialed to handle specialty drugs such as home infusion, oncology drugs and so forth. Systems can handle the process as long as it meets NCPDP standards and the logic can be entered into the system.

2. Requirements Related to Qualified Prescription Drug Coverage (§ 423.104) (Federal Register page 46649)

a. Standard Prescription Drug Coverage (Federal Register page 46649)

We request comments regarding the treatment of health savings account (HSAs) vis-a`-vis our definition of ‘‘group health plan,’’ ‘‘insurance or otherwise,’’ and ‘‘third party payment arrangements.’’ Our strong preference is not to treat HSAs as group health plans, insurance or otherwise, or third party payment arrangements and therefore to allow HSA contributions to count toward incurred costs, since we see these funds as essentially analogous to a beneficiary’s bank account. We also seek comments on how to treat FSAs, health reimbursement accounts (HRAs), and Medicare savings accounts (MSAs), relative to our definitions of group health plan, insurance or otherwise, and third party payment arrangements.

Comment: All three types of savings accounts should be treated the same, and not be treated as an insurance plan. The HSA’s , FSA’s and HRA’s are created using the beneficiaries own funds. How the beneficiary uses these funds is up to him or her. Using the accounts to purchase prescription drugs should not be treated differently than if the drugs were used to pay for physician visits. CMS should not count these accounts as health insurance.

a). Pharmacy Access Standards (Federal Register page 46655)

We are interpreting the access standard under § 423.120(a)(1) such that a prescription drug plan or regional MA–PD plan would have to meet or exceed the access standards across each region in which it operates, and a local–MA–PD plan would have to meet or exceed the access standards in its local service area. In other words, a prescription drug plan or regional MA–PD that operates in a multi-region or national service area could not meet the access standards proposed in § 423.120(a)(1) by applying them across the entire geographic area serviced by the plan; instead, it would have to meet the standards in each region of its multi-region or national service area. We believe that such an interpretation maximizes plan flexibility while assuring the best possible access to pharmacies for Part D enrollees, and we request comments on our proposed approach.

Comment: Consideration should be given to the access standards for adjacent regions, as border pharmacies will serve more than one region. Without counting these pharmacies across multi-regions the access these pharmacies provide is not recognized. PDP's should be able to identify pharmacies outside of the region that will provide access within the region in which they have applied as a sponsor. Medicare beneficiaries are loyal customers to their pharmacies, they will continue to use their border pharmacies, as they have learned to trust the advice of their pharmacist. In some rural states, the access standards may have to be relaxed, as the TRICARE rural access standard may not be possible to meet due to a lack of pharmacies.

1. Overview and Definitions (423.100) (Federal Register page 46646)

c. Long-Term Care Facility (Federal Register page 46648)

We request comments regarding our definition of the term long-term care facility in § 423.100, which we have interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act, or a nursing facility, as defined in section 1919(a) of the Act. We are particularly interested in whether intermediate care facilities for the mentally retarded or related conditions (ICF/MRs), described in § 440.150, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. It is our understanding that there may be individuals residing in these facilities who are dually eligible for Medicaid and Medicare. Given that payment for covered Part D drugs formerly covered by Medicaid will shift to Part D of Medicare, individuals at these facilities will need to be assured access to covered Part D drugs. Our proposed definition limits our definition to skilled nursing and nursing facilities because it is our understanding that only those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies. However, to the extent that ICF/MRs and other types of facilities exclusively contract with long-term care pharmacies in a manner similar to skilled nursing and nursing facilities, we would consider modifying this definition.

Comment: As a result of the Olmstead decision, states have been moving seniors and persons with SSI benefits from institutions into less restrictive placements.

These placements include ICF/MR facilities for the disabled, community care, and assisted living facilities for the aged. In addition to these less restrictive institutional settings, states have implemented waiver programs for home and community based care as an alternative to placement in a nursing home. Medicare beneficiaries spend down their assets until they are forced into nursing homes. These alternatives provide Medicare eligible beneficiaries with a choice of placement. Exclusive contracts with a long term care pharmacy should not be the deciding factor on whether or not to extend the definition of long term care facility to other forms of housing other than traditional nursing homes; the beneficiaries' qualification for Medicare and their placement should be the deciding factor. States can identify Medicare eligible individuals who were institutionalized, and can also identify those individuals that, if it were not for the Olmstead decision or an 1115 waiver, would be institutionalized. These individuals are low income Medicare beneficiaries; having a Medicare prescription benefit at no cost will allow their income to be used for daily living expenses and not on prescriptions.

2. Requirements Related to Qualified Prescription Drug Coverage (423.104) (Federal Register page 46649)

a. Standard Prescription Drug Coverage (Federal Register page 46649)

We seek comments on how I/T/U pharmacies and IHS beneficiaries will achieve maximized participation in Part D benefits.

Comment: IHS beneficiaries will be eligible for the Medicare Part D benefit and the PDP must provide access, at a minimum, to the beneficiaries in accordance with TRICARE standards. Many of the IHS beneficiaries use I/T/U pharmacies, however many of these I/T/U pharmacies do not provide the wide range of drugs often found on the formulary of a PDP. PDP's will need to contract with I/T/U pharmacies in order to provide access to the IHS beneficiaries, and will need to encourage the I/T/U pharmacy to expand the number of drugs provided. PDP's will need to work with these pharmacies to provide outreach and education materials, and encourage the pharmacy to assist in enrolling IHS beneficiaries into Medicare Part D.

We are considering allowing prescription drug plans and MA–PD plans to count I/T/U pharmacies toward their network access requirements, provided: (1) Such pharmacies are under contract with the plan; and (2) it would be impossible or impracticable for the plan to meet the access standard in rural areas of its service area without the inclusion of an I/T/U pharmacy (or pharmacies) in that count because there is not a sufficient number of non-I/T/U pharmacies in those areas willing or able to contract with the PDP sponsor or MA organization in accordance with its terms and conditions. We invite comments on this proposed exception to our pharmacy access rules, including any impact it might have on pharmacy access for non-AI/AN Part D enrollees residing in those areas.

Comments: I/T/U pharmacies should be counted toward the network access standards as long as they are under contract with the PDP. Since these pharmacies serve a portion of the Medicare population, their absence in the access standards would skew the results. All pharmacies under contract serving the Medicare population should be included in the access standard calculation. Since these pharmacies can only serve the IHS populations, the pharmacy and the population they serve could be removed from the access standard calculation. Typically, commercial pharmacies exist for non IHS populations in the same communities that have I/T/U pharmacies.

— However, it is our goal to balance convenient access to long-term care pharmacies with appropriate payment for dispensing fees of efficient facilities. To the extent that we require plans to contract with long-term care pharmacies, it is our goal to assure that long-term care pharmacies charge reasonable dispensing fees to plans (and indirectly to CMS through the direct subsidy paid to prescription drug plans and MA–PD plans). We welcome comments regarding how to balance convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies under the provisions of the MMA.

Alternatively, we would not require that plans contract with long-term care pharmacies and would, instead, strongly encourage PDP sponsors and MA organizations offering MA–PD plans to negotiate with and include long-term care pharmacies in their plans' pharmacy networks. We seek public comment regarding the advantages and disadvantages of these two approaches.

Comments: Long Term Care pharmacies serve a target group of Medicare beneficiaries living in nursing homes. There are 5-6 national long term care pharmacy chains that serve nearly 80% of the nursing home industry. PDP's need the ability to negotiate with these pharmacies without the requirement from CMS that PDP's must contract with them. Publishing the fact that PDP's must contract with the LTC pharmacies will place the PDP at a disadvantage. PDP's will need the LTC pharmacies to meet the access standards; this need will encourage the PDPs to contract with the LTC's. Allowing the LTC pharmacies to count toward the access standards provides a benefit to the PDP to contract with the LTC pharmacies.

Similarly, we are considering two options for assuring access to I/T/U pharmacies by AI/AN Part D enrollees per the provisions of section 1860D–4(b)(1)(C)(iv) of the Act.

Another option for assuring access to I/T/U pharmacies under Part D would be not to require that plans contract with I/T/U pharmacies and, instead, to strongly encourage PDP sponsors and MA organizations offering MA–PD plans to negotiate with and include I/T/U pharmacies in their plans' pharmacy networks. We are concerned, however, that—in the absence of a contracting requirement—plans may make assumptions regarding the

administrative costs (whether real or perceived) of contracting with I/T/U pharmacies and may not actively solicit the inclusion of these pharmacies in their networks. It is our understanding that I/T/U pharmacies are not currently well integrated in commercial pharmacy networks. The lack of I/T/U pharmacies in Part D plan networks would render enrollment in Part D of little use to AI/AN beneficiaries who rely primarily on I/T/U facilities for their health care. We encourage comments regarding these two approaches, their advantages and disadvantages, and their ramifications for AI/enrollees who are eligible to enroll in Part D.

Comment: By allowing a PDP to consider the I/T/U pharmacy as part of their pharmacy access requirement, the PDP will have an incentive to contract with I/T/U pharmacies. PDP's will have an incentive to include I/T/U pharmacies in their network in order to gain access to the potential enrollees. There would be negative ramifications if PDP's did not contract with I/T/U pharmacies as a large majority of AI/AN beneficiaries utilize I/T/U pharmacies.

We seek comments on how I/T/U pharmacies and IHS beneficiaries will achieve maximized participation in Part D benefits.

Comments: IHS beneficiaries will be eligible for the Medicare Part D benefit, and the PDP must provide access to the beneficiaries in accordance with TRICARE standards at a minimum. Many of the IHS beneficiaries use I/T/U pharmacies, however many of these I/T/U pharmacies do not provide the wide range of drugs often found on the formulary of a PDP. PDP's will need to contract with I/T/U pharmacies in order to provide access to the IHS beneficiaries, and will need to encourage the I/T/U pharmacy to expand the number of drugs provided. PDP's will need to work with the I/T/U pharmacies to understand their role as a provider, and to understand the reliance by IHS beneficiaries on these pharmacies. PDP's will also need to work with these pharmacies to provide outreach and education materials, and encourage the pharmacy to assist in enrolling IHS beneficiaries into Medicare Part D.

3. Establishment of Prescription Drug Plan Service Areas (423.112) (Federal Register page 46655)

— Section 1860D–11(a)(1) of the Act requires that a prescription drug plan's service area encompass an entire PDP region, as established by us under § 423.112(b), and § 423.112(a) of our proposed rule codifies that requirement. However, as provided under § 423.112(e) of our proposed rule, a prescription drug plan can be offered in more than one PDP region (provided the plan encompasses the entire PDP region for each region where offered), as well as nationally.

Section 1860D–11(a)(2) of the Act provides us with the authority to establish PDP regions, and such PDP regions must be established in a manner that is consistent with the establishment of MA regions under 42 CFR 422.445 of our proposed rule. Section

1860D–11(a)(2)(B) stipulates that PDP regions must be, to the extent practicable, consistent with MA regions as established under section 1858(a)(2) of the Act. As provided under § 423.112(b)(2), however, if we determine that access to Part D benefits would be improved by establishing PDP regions that are different than MA regions, we may establish PDP regions that vary from MA regions. Section 423.112(d) of our proposed rule would continue to receive federal Medicaid grants under section 1108 of the Act to compensate them for drug coverage provided to Part D eligible individuals under specific conditions.

We intend to initially designate both PDP and MA regions by January 1, 2005. In accordance with section 1858(a)(2)(C)(i) of the Act, there will be between 10 and 50 PDP regions within the 50 States and the District of Columbia and at least one PDP region covering the United States territories. The PDP regions, like the MA regions, will become operational in January 2006.

We conducted a public meeting on July 21, 2004, in order to obtain broad public comment on the methodology we should use in establishing both the PDP regions and MA regions for MA regional plans, which would operate as preferred provider organizations (PPOs).

Comment: First Health Services believes that the establishment of PDP regions consistent with MA regions (as described in proposed § 422.55) is of far less importance than establishing PDP regions that are defined by individual State boundaries. It is critical to a number of operational aspects of Part D benefits administration that each State should be a separate PDP region. As the Proposed Rule seems to acknowledge, existing SPAPs will play a critical role in coordinating benefits with the PDPs for the most vulnerable populations to be served under the Part D program, as well as in providing "wrap-around" coverage for beneficiaries within these populations. The administrative complexities and burden of effectuating these goals will be enormously – and unnecessarily – increased to the extent that the boundaries of PDP regions are not consistent with the State boundaries defining the relevant SPAP service areas.

For example, it will be difficult for a PDP sponsor to effectively tailor its benefits and formulary so as best to serve individuals transitioning from an SPAP to a PDP, if the PDP must coordinate its program and benefits with multiple SPAPs that have differing formularies and benefit structures in place. Similarly, other aspects of the establishment and operations of PDPs, (e.g., compliance with State licensure requirements under § 423.401(a)(1)) would be substantially more complex if PDP regions were to be established to encompass service areas in more than one State.

First Health Services also believes that creating a separate PDP service area for each State will promote beneficial competition between potential PDP sponsors. In fact, the establishment of large, multi-State regions would be anti-competitive because only a small number of potential, corporate PDP sponsors would be of sufficient size to be able to bid for such large, multi-State service areas. However, if

separate PDP services areas are designated for smaller States, a greater range of potential PDP sponsors will realistically be able to bid on a service area contract and offer services.

First Health Services therefore urges CMS to amend § 423.112(b)(2) to clarify that the boundaries of MA regions will not be adopted to determine PDP regions except where such MA regions are defined by individual State boundaries. This proposal amendment fully complies with the statutory language authorizing the Secretary to establish PDP regions which differ from MA regions if the establishment of such different regions "would improve access to benefits under this part." *See* Section 1860D-11(a)(2) of the Act. Coordinating the efforts of the PDPs and the SPAPs, and increasing competition between PDPs, will ultimately improve beneficiary access to Part D benefits.

b. Formulary Requirements (Federal Register page 46659)

— To the extent that a PDP sponsor or MA organization uses a formulary to provide qualified prescription drug coverage to Part D enrollees, it would be required to meet the requirements of § 423.120(b)(1) and section 1860D–4(b)(3)(A) of the Act to use a pharmaceutical and therapeutic (P&T) committee to develop and review that formulary. As a note of clarification, we interpret the requirement at section 1860D–4(b)(3)(A) of the Act that a formulary be ''developed and reviewed'' by a P&T committee as requiring that a P&T committee's decisions regarding the plan's formulary be binding on the plan. However, we request comments on this interpretation. In addition, it is our expectation that P&T committees will be involved in designing formulary tiers and any clinical programs implemented to encourage the use of preferred drugs (e.g., prior authorization, step therapy, generics programs).

Comment: In issuing its proposed regulations, CMS has asked for commentary on the coordination between SPAPs and PDPs and suggestions of additional areas in which such coordination would be beneficial for the individuals to be served under Medicare Part D. First Health Services believes that effective coordination between the SPAPs and PDPs will be central to ensuring that uninsured and low-income individuals receive the assistance they need from both State programs and Medicare Part D, and urges CMS to more explicitly authorize and facilitate such coordination in the key area of establishing formularies.

Continuity of pharmaceutical treatment is of great importance to effective disease management and appropriate healthcare. As the proposed regulations themselves seem to acknowledge, PDP formularies must be developed with appropriate consideration of the point that – especially for older individuals – it is often therapeutically counter-productive, or even dangerous, to abruptly change medications. Accordingly, we believe that coordination of formulary development between SPAPs and PDPs is especially important and should be expressly encouraged by the Part D rules. It must be anticipated that a large number of

individuals will be transferring from state pharmaceutical assistance to Part D coverage through a PDP, with the likelihood that the SPAP will prospectively be providing those individuals with "wrap-around" benefits. In such cases, PDP development of formularies that are different from the formularies offered by the SPAPs serving the same beneficiaries could create a situation that would be confusing and potentially highly detrimental to beneficiaries' care.

To resolve these problems, First Health Services urges the Secretary to revise the regulatory provisions with respect to formulary development in two ways. First, the regulations should make clear that formulary development is one area in which SPAPs and PDPs are encouraged to closely coordinate their activities. Second, we strongly urge the Secretary to include in the regulations a provision that would permit a PDP to be deemed in compliance with the formulary requirements under § 423.120(b)(1) and (b)(2), upon appropriate certification by the PDP and an SPAP with which it is coordinating on benefits issues, that the PDP is adopting the SPAPs formulary and that the SPAP's formulary substantially meets the requirements of § 423.120(b)(1) and (b)(2). Such a regulatory change would provide PDPs with the flexibility that will be required in order to fully coordinate with an SPAP regarding formulary composition, thereby ensuring a smooth transition for beneficiaries whose primary drug coverage is transferred from an SPAP to a PDP.

As PDPs and MA-PDs coordinate benefits with secondary payers such as SPAPs, or when drug plans include in their networks certain pharmacies, such as 340B entities, we recognize that a duplicate rebate problem may arise; *i.e.*, a manufacturer may be expected to pay both a rebate negotiated with a Part D drug plan and an additional rebate negotiated or required under a different state or federal program. The risk of manufacturers paying duplicate rebates on the same drug is inevitable if CMS is successful in encouraging supplemental drug coverage by secondary payers, such as wrap-around coverage by SPAPs. [69 Fed. Reg. 46,633 (Aug. 3, 2004)]. However, while the drug industry's concern about duplicate discount arrangements is justified, we do not believe that it is the role of the Secretary to address this problem. The Medicare prescription drug benefit relies on market forces to set drug prices, and we believe that market forces will ensure that the matter of duplicate rebates is handled appropriately. Furthermore, we do not believe that the MMA provides CMS with the authority to prohibit duplicate rebate arrangements, and we believe that an attempt by CMS to do so would prove ineffective due to the complex interrelationships of multiple state and federal drug discount programs.

Drug manufacturers, as they negotiate rebates with PDPs and MA-PDs, can take the matter of duplicate rebates into account in their discussions with Part D drug programs, and undoubtedly will do so. Drug companies are in the best position to assess the unique facts surrounding potential duplicate discount arrangements, and to determine the level of risk involved and how best to address the problem. Manufacturers are knowledgeable regarding what rebates and discounts are already being offered to entities such as SPAPs, other federal payers such as

TRICARE or the Federal Employee Health Benefit Program (FEHBP), and 340B provider pharmacies. If the manufacturers choose to provide PDPs or MA-PDs with rebates that supplement these other rebates and discounts, they are free to do so. Alternatively, if manufacturers want to limit payment of rebates to PDPs and MA-PDs, they have this option too. Ultimately, market forces will lead to a solution that is acceptable to all parties.

The government has taken this non-regulated approach to the duplicate discount issue in comparable situations. In the context of interfaces between the Medicaid program and the 340B drug discount program, federal administrative mechanisms that otherwise protect manufacturers from being required to give duplicative discounts to Medicaid and 340B entities are lifted when a State chooses to outsource administration of its Medicaid drug benefit to a private party, typically a health maintenance organization that is paid on a capitated basis. Because the government considers payment of manufacturer rebates to such HMOs to be "voluntary" (as they will be for PDPs and MA-PDs under Part D), the drug manufacturer and HMO are left to resolve the potential duplicate discount problem through private negotiation.

Furthermore, we do not believe that CMS has the legal authority to promulgate a regulation that prohibits duplicate rebate arrangements. There is no statutory provision that provides authority for such a regulation and, indeed, such an action is precluded by section 1860D-11(i) of the Social Security Act, which states that "the Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors." This statutory provision effectively prohibits CMS from promulgating a rule regulating the amount of rebates between Part D drug plans and manufacturers, even in order to avoid duplicate rebates. Instead, in accordance with the clear legislative intent of this noninterference provision, CMS must leave the matter of duplicate rebates to the manufacturers and the drug plans.

It is also worth noting that, even if CMS had the authority to promulgate a regulation designed to avoid duplicate discount problems, no provision could adequately address the intricacies of the many state and federal rebate and discount arrangements that are potentially affected. CMS would have to anticipate every potential secondary rebate or discount, and would have to craft a solution that is specific to each rebate or discount scenario. For example, one federal law mandates that drug manufacturers not sell above a discounted price to 340B entities, while a different federal statute (administered by a different federal agency) dictates the discount under the TRICARE program. A CMS regulation would have to be reconcilable with both statutes. Discounts or rebates offered to SPAPs, on the other hand, are often governed by state laws. While we recognize that in the MMA Congress has generally preempted state laws governing PDPs and MA-PDs (*see* Sections 1856(b)(3) and 1860D-12(g) of the Social Security Act), there is no such authority to preempt state laws governing drug manufacturers and SPAPs. Accordingly, CMS may not regulate what rebates or discounts SPAPs obtain from drug manufacturers. As this small sample of considerations suggests, it would be

virtually impossible to draft a duplicate-discount rule adequately addressing the peculiarities of every state and federal drug discount program.

a).Pharmacy Access Standards (Federal Register page 46655)

We are interpreting the access standard under § 423.120(a)(1) such that a prescription drug plan or regional MA–PD plan would have to meet or exceed the access standards across each region in which it operates, and a local–MA–PD plan would have to meet or exceed the access standards in its local service area. In other words, a prescription drug plan or regional MA–PD that operates in a multi-region or national service area could not meet the access standards proposed in § 423.120(a)(1) by applying them across the entire geographic area serviced by the plan; instead, it would have to meet the standards in each region of its multi-region or national service area. We believe that such an interpretation maximizes plan flexibility while assuring the best possible access to pharmacies for Part D enrollees, and we request comments on our proposed approach.

Comments: Consideration should be given to the access standards for adjacent regions, as border pharmacies will serve more than one region. Without counting these pharmacies across multi-regions the access these pharmacies provide is not recognized. PDP's should be able to identify pharmacies outside of the region that will provide access within the region in which they have applied as a sponsor. Medicare beneficiaries are loyal customers to their pharmacies, they will continue to use their border pharmacies, as they have learned to trust the advice of their pharmacist. In some rural states, the access standards may have to be relaxed, as the TRICARE rural access standard may not be met due to a lack of pharmacies.

We invite comments as to minimum timeframes for periodic evaluation and analysis of protocols and procedures related to a plan's formulary by PDP plans and MA organizations offering MA–PD plans (for example, quarterly, annually

Comment: Since a PDP can only change their formulary at the start of each year, the minimum time frame for reviewing a plan's formulary should be annually.

5. Special Rules for Access to Covered Part D Drugs at Out-of-Network Pharmacies (§ 423.124) (Federal Register page 46662)

— Section 1860D–4(b)(1)(C)(iii) of the Act requires us to establish pharmacy access standards that include rules for adequate emergency access to covered drugs. Section 1860D–4(b)(2)(B)(i) of the Act mandates that we develop, adopt, or recognize standards relating to a standardized format for a card or other technology for accessing negotiated prices to covered Part D drugs by Part D enrollees. We reviewed the definition of an ''emergency medical condition'' (see § 422.113(b)(1)(i) of our proposed rule) under the MA program to determine whether the ''prudent layperson'' standard was an appropriate

standard for ascertaining whether the need for a covered Part D drug constitutes an emergency. However, we do not believe that the definition of an emergency medical condition, or a variation thereof, is entirely appropriate to prescription drugs. To the extent that a physician (or other prescriber) prescribes a covered Part D drug, we consider that covered Part D drug to likely be medically necessary. The issue of urgency or emergency is difficult to determine from a clinical perspective, however.

Comment: There are many categories and classes of drugs with multi-source drugs available to treat the same symptoms. To mandate that a prescription by a physician must be filled with the drug he or she prescribes removes flexibility from the PDP. While a drug prescribed by a physician should be medically necessary, physicians can not be given the authority to prescribe whatever drug they wish, and the PDP expected to cover that drug in its formulary. Authority of this level would undermine the entire formulary process. A PDP should be required to provide a drug in the category the physician is prescribing from, and not a specific drug.

We believe that enrollees under the aforementioned circumstances could not reasonably be expected to access a network pharmacy and must therefore be assured access to an out-of-network pharmacy as provided under § 423.124(a) of our proposed rule. We request comments on our proposed out-of-network access requirements. We are aware that routine access to out-of-network pharmacies by Part D enrollees may undermine a plan's cost-savings incentives. However, provided adequate access is assured under § 423.124(a), PDP sponsors and MA organizations offering MA–PD plans would have some flexibility to design their out-of-network coverage policies. PDP sponsors and MA organizations offering MA–PD plans may therefore

Comment: First Health Services believes that when a PDP meets or exceeds the TRICARE standards for access there should be no reason for a beneficiary to access an out of network pharmacy. These standards would easily provide emergency access to a beneficiaries needs. The only exception that should be allowed would be for prescriptions needed after an emergency room visit, when local pharmacies are closed. In that case the beneficiary would be allowed to access the drug from the hospital pharmacy. Other than this situation, beneficiaries must be expected to use network pharmacies. Since CMS is requiring PDP's to meet the TRICARE standards, CMS is setting access standards that provide adequate access to prescription drugs for all beneficiaries. PDP's must have the flexibility to restrict the use of out of network pharmacies.

Section 423.124(b)(1) of our proposed rule would require that the Part D enrollee be liable for any cost-sharing, including a deductible, that would have otherwise applied had the covered Part D drug been obtained at a network pharmacy. Such cost-sharing would be applied relative to the plan allowance for that covered Part D drug, which we propose defining in § 423.100 as the amount prescription drug plans and MA–PD plans use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at out-of-network pharmacies in accordance with the requirements of proposed

§ 423.124(b). We request comments on how to further define the term ''plan allowance.'' Our understanding is that it is current industry practice to define the plan allowance as the lowest of the contractual discount offered to pharmacies in a plan's standard contract (as described above, we are soliciting public comment regarding whether we should require PDP sponsors and MA organizations to offer a standard contract to all pharmacies), maximum allowable cost (MAC), or the pharmacy's usual and customary price (described below).

Comment: In our experience, standard practice is to contract with network pharmacies using the lesser of usual and customary, network discount percent, or in the case of a generic, the FUL or MAC.

In an instance when a member used an out of network pharmacy, they would pay the reverse of the above – we typically see that they are charged the greater of U&C, the pharmacy discount, or the FUL/MAC price.

In addition to this cost-sharing, and as provided under proposed § 423.124(b)(2), the enrollee would be responsible for any difference in price between the out-of-network pharmacy's usual and customary (U&C) price and the plan allowance for that covered Part D drug. The term ''usual and customary price'' refers to the price that a pharmacy would charge a customer who does not have any form of prescription drug coverage.

We request public comments regarding our definition of usual and customary price. We are concerned that, given our proposed out-of-network access policy, pharmacies may increase their U&C prices to increase their total reimbursement. This would be prejudicial not only to beneficiaries in need of out-of-network access, but also to uninsured individuals purchasing drugs at retail pharmacies, and we seek feedback on permissible ways to prevent such an outcome.

Comment: First Health Services agrees with the definition used for usual and customary. The only way that this can be established and monitored is to periodically review the dispensing practices of pharmacies both in and out of network. This is currently standard practice to determine suspected fraudulent behavior and is quite easy to determine by evaluating trends in dispensing for in network and out of network both prior to start up of the program and then periodically throughout the life of the program.

— When an enrollee purchases a covered Part D drug at an out-of-network pharmacy consistent with § 423.124(a) of our proposed rule, the cost-sharing he or she pays relative to the plan allowance ($22.50 in the example above) counts as an incurred cost against his or her annual out-of-pocket threshold because such out-of-network access to a covered part D drug is a covered benefit under those circumstances. As with the price differential that a beneficiary could incur by purchasing an extended supply (for example, 90-day) of covered Part D drugs purchased at a retail pharmacy rather than a mail-order

pharmacy (discussed in section II.C.4.a of this preamble), the price differential between out-of-network pharmacies' U&C costs and the plan allowance would also be counted as an incurred cost against a beneficiary's annual out- of-pocket threshold. We seek comments on our proposal that this price differential be counted as an incurred cost against the out-of-pocket threshold consistent with the definition of ''incurred cost'' in § 423.100 of the proposed rule. Under this approach, plans would be required to explicitly account for such price differentials in the actuarial valuation of their coinsurance in their bids. In addition, any such differential would also count toward the deductible for covered Part D expenditures between $0 and the plan's deductible. We welcome public comments regarding our proposed payment rules for covered Part D drugs obtained at out-of-network pharmacies when enrollees cannot reasonably obtain those drugs at a network pharmacy.

Comment: The cases in which a beneficiary "cannot reasonably obtain" drugs at a network pharmacy will be very limited. Since PDPs must meet the TRICARE standards for access, urban beneficiaries will have a pharmacy within 3 miles of their home, and suburban beneficiaries will have a pharmacy within 5 miles of their home. With this level of accessibility, beneficiaries should be restricted to obtaining their medications at network pharmacies only. Only in a case of an emergency when network pharmacies are unavailable should a beneficiary be allowed to go to an out of network pharmacy and have their expenditures counted as out of pocket expenses. It will be extremely difficult to incorporate the actuarial valuation of out of network expenditures in bids, since there isn't anyway to determine what level of out of network purchases will be made if CMS allows the proposed level of flexibility in the rules.

6. Coordination of Benefits with Other Providers of Prescription Drug Coverage (Federal Register page 46700)

a. Coordination with SPAPs

— We do not know how SPAPs will actually choose to coordinate with Medicare drug plans, and we welcome comment in this regard—particularly from States. We would like to better understand what SPAPs plan to do in 2006 relative to Part D interaction (such as in payment of premiums or claim-specific wrap-around), and how Medicare can assist State preferences in this regard. Our goal is to make the coordination of benefits process as functional for the beneficiary, pharmacy, and States as possible.

We assume that some SPAPS will pay Part D plans' premiums on behalf of enrollees. For SPAPs that choose to wrap-around coverage rather than paying premiums, we propose to include SPAP information in a coordination of benefits system described below. In this way, pharmacies will know that a claim should be sent to the SPAP following adjudication by the Part D plan.

We request comment on this proposed approach, including the feasibility of the approach for SPAPs and the ease of administration for pharmacies. We also request comment on whether or not SPAPs that choose to coordinate benefits on a wrap-around basis should

be required to provide feedback on how much of the remainder of the claim they have actually paid. Since SPAP payments count as true out-of-pocket spending toward catastrophic coverage, the Part D plans could simply assume that any amounts not paid by the Part D plan and sent to an SPAP for reimbursement would count toward calculating TrOOP. We are concerned that we may need information from SPAPs to determine more precisely the SPAP contribution or payment. But we are also mindful of systems implications for States and would appreciate comments in this regard, particularly from SPAPs

Comment: First Health Services believes that the proposed regulation presently designated § 423.464(e)(1)(ii) is inconsistent with the underlying statutory provision it purports to implement, and that its promulgation in final form would therefore be *ultra vires* and invalid. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") contains an "anti-discrimination" provision that is incorporated into the definition of State Pharmacy Assistance Program ("SPAP") within the meaning of Part D of the Medicare Act. See Section 1860D-23(b)(2) of the Social Security Act, as amended, 42 U.S.C. § 1395w-133(b)(2). Specifically, under the statutory provision, a qualifying SPAP must be one "which, *in determining eligibility and the amount of assistance to Part D eligible individuals under the Program*, provides assistance to such individuals in all Part D plans and does not discriminate based upon the Part D plan in which the individual is enrolled." (Emphasis added).

The plain meaning of the statute is that an SPAP – in order to be accorded "qualified" status under the Medicare Part D Program – may not "discriminate based upon the Part D plan in which the individual is enrolled" in the specific context of "determining eligibility and the amount of assistance to Part D individuals." The words of the statute limit the applicability of the "non-discrimination" requirement to that particular context – determinations of eligibility and amount of benefits – and do not extend to "discrimination" or preferential treatment in any other matters. Thus, the statutory provision may be construed to prohibit a qualifying SPAP from promoting individuals' enrollment in a "preferred" PDP by restricting an individual's eligibility for SPAP assistance or affording the individual a lesser amount of assistance as a consequence of the individual's enrollment in a different PDP. The language enacted by Congress makes no reference to, and does *not* restrict, "discrimination" based upon the plan an individual enrolls in, as long as the disparate treatment of an individual or particular pharmacy plan pertains to some activity or matter other than determinations of beneficiaries' eligibility and/or amounts of assistance.

The proposed regulation, by contrast, would expand this clearly limited non-discrimination provision well beyond the words employed by Congress. The proposed definition of an SPAP states that a State program will be considered an SPAP for Part D purposes only if it "[p]rovides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls." See 69 Fed. Reg. 46,832 (Aug. 3, 2004), proposed to be

codified at 42 C.F.R. § 423.464(e)(1)(ii). In other words, the regulation entirely ignores the statutory limitation of the referenced "discrimination" to differential treatment relative to "determinations of eligibility and amount of benefits," and instead appears to prohibit qualifying SPAPs from engaging in "discrimination" of any kind based on the PDP in which a beneficiary enrolls. Indeed, the preamble to the proposed Part D regulations appears to go even further, by stating flatly that an SPAP "may not steer beneficiaries to one plan or another through benefit design *or otherwise*." 69 Fed. Reg. at 46,697 (emphasis added). Thus, the proposed regulation sets out an exceptionally broad rule, far beyond that contained in the governing statute. Under this administrative interpretation of the law, there would appear to be no permissible means of implementing an SPAP's preference for a particular PDP to facilitate "wrap-around coverage" and minimize confusion for seniors and pharmacists under any circumstances.

First Health Services believes the putative non-discrimination rule that appears in the Proposed Rule and its preamble is incorrect and invalid as a matter of law. It is well established that an administrative regulation is invalid to the extent that it is inconsistent with the statutory provision it seeks to implement. See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837, 843-44, 104 S. Ct. 2778, 2782-83 (1984), ("Chevron") and other authorities cited at note 12 therein. It is equally well established that a statute may not properly be construed by simply ignoring the inclusion of certain words in the legislation. See, e.g., Alaska Department of Environmental Conservation v. EPA, _____ U.S. _____, _____ n.13, 124 S. Ct. 983, 1002 n.13. (2004) (Reiterating that it is a "cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.") See also TRW, Inc. v. Andrews, 534 U.S. 19, 31, 122 S. Ct. 441, 449 (2001); Bennett v. Spear, 520 U.S. 154, 173, 117 S. Ct. 1154, 1166 (1997).

The interpretation of the non-discrimination provision set forth in the Proposed Rule and its preamble gives no effect at all to the words "in determining eligibility and the amount of assistance to Part D eligible individuals under the Program." This critical limitation on the type of "discrimination" Congress expressly intended to prevent has impermissibly been read out of the statute altogether. The resulting, much broader formulation of a non-discrimination rule applicable to qualifying SPAPs is contrary to the plain meaning of the governing statute, and therefore invalid. Importantly, this revision of the statutory standard cannot be styled as the responsible agency simply "filling in the gaps" left by Congress in its legislation. It is often permissible, of course, for an agency responsible for a statutory scheme to resolve ambiguities in the legislation and "fill in" certain "gaps" in areas as to which Congress chose to be silent and explicitly or implicitly delegated authority to the agency to further elucidate a provision of the statute by regulation. See Chevron at 2782, citing Morton v. Ruiz, 415 U.S. 199, 231, 94 S. Ct. 1055, 1072 (1974). This is permissible, however, only where Congress has not spoken to the precise matter at issue. See Chevron at 2781 (where "Congress has directly spoken to the precise

question at issue" the agency "must give effect to the unambiguously expressed intent of Congress.") In the MMA, Congress has directly spoken to the definition of an SPAP and explicitly defined the type of "discrimination" in which a qualifying SPAP may not engage. There is no "gap" to fill in this regard. As the Supreme Court has observed, "[t]here is a basic difference between filling a gap left by Congress' silence and rewriting rules that Congress has affirmatively and specifically enacted." Mobil Oil Corporation v. Higginbotham, 436 U.S. 618, 625, 98 S. Ct. 2010, 2015 (1978).

In summary, the proposed regulation portrays a much broader and very different non-discrimination rule than is contained in the statute, and is inconsistent with the express statutory language establishing limitations on that rule Under the statute's express language, a qualifying SPAP would quite plainly be permitted to encourage beneficiaries to enroll in a "preferred" PDP by any otherwise legal means that does not constitute disparate treatment of individuals in respect to determinations of eligibility for, or the amount of, assistance. In other words, while a Part D qualifying SPAP would be required to provide the same amount of "wrap-around" coverage to an individual in an alternative plan as would be provided to the individual if enrolled in a "preferred" PDP designated by the SPAP, this would not prevent the SPAP from implementing a preference for a given PDP through other means. CMS, in its proposed regulations, has rewritten this statutory rule so as apparently to prohibit *any* kind of SPAP activity that might grant preference to a given PDP or steer beneficiaries to a particular PDP; the law does not permit this substitution of agency policy for clearly expressed legislative intent.

The final regulations should include a revision of Section 423.464(e)(1)(ii) so that the rule conforms to the express language and intent of Congress in prohibiting qualifying Part D SPAPs from employing determinations of beneficiaries' eligibility or amount of benefits to favor one PDP over another; but the CMS regulations may not validly expand this statutory rule to preclude any preferential treatment of a PDP by an SPAP.

As PDPs and MA-PDs coordinate benefits with secondary payers such as SPAPs, or when drug plans include in their networks certain pharmacies, such as 340B entities, we recognize that a duplicate rebate problem may arise; *i.e.*, a manufacturer may be expected to pay both a rebate negotiated with a Part D drug plan and an additional rebate negotiated or required under a different state or federal program. The risk of manufacturers paying duplicate rebates on the same drug is inevitable if CMS is successful in encouraging supplemental drug coverage by secondary payers, such as wrap-around coverage by SPAPs. 69 Fed. Reg. 46,633 (Aug. 3, 2004). However, while the drug industry's concern about duplicate discount arrangements is justified, we do not believe that it is the role of the Secretary to address this problem. The Medicare prescription drug benefit relies on market forces to set drug prices, and we believe that market forces will ensure that the matter of duplicate rebates is handled appropriately. Furthermore, we do not believe that the MMA provides CMS with the authority to prohibit duplicate rebate

arrangements, and we believe that an attempt by CMS to do so would prove ineffective due to the complex interrelationships of multiple state and federal drug discount programs.

Drug manufacturers, as they negotiate rebates with PDPs and MA-PDs, can take the matter of duplicate rebates into account in their discussions with Part D drug programs, and undoubtedly will do so. Drug companies are in the best position to assess the unique facts surrounding potential duplicate discount arrangements, and to determine the level of risk involved and how best to address the problem. Manufacturers are knowledgeable regarding what rebates and discounts are already being offered to entities such as SPAPs, other federal payers such as TRICARE or the Federal Employee Health Benefit Program (FEHBP), and 340B provider pharmacies. If the manufacturers choose to provide PDPs or MA-PDs with rebates that supplement these other rebates and discounts, they are free to do so. Alternatively, if manufacturers want to limit payment of rebates to PDPs and MA-PDs, they have this option too. Ultimately, market forces will lead to a solution that is acceptable to all parties.

The government has taken this non-regulated approach to the duplicate discount issue in comparable situations. In the context of interfaces between the Medicaid program and the 340B drug discount program, federal administrative mechanisms that otherwise protect manufacturers from being required to give duplicative discounts to Medicaid and 340B entities are lifted when a State chooses to outsource administration of its Medicaid drug benefit to a private party, typically a health maintenance organization that is paid on a capitated basis. Because the government considers payment of manufacturer rebates to such HMOs to be "voluntary" (as they will be for PDPs and MA-PDs under Part D), the drug manufacturer and HMO are left to resolve the potential duplicate discount problem through private negotiation.

Furthermore, we do not believe that CMS has the legal authority to promulgate a regulation that prohibits duplicate rebate arrangements. There is no statutory provision that provides authority for such a regulation and, indeed, such an action is precluded by section 1860D-11(i) of the Social Security Act, which states that "the Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors." This statutory provision effectively prohibits CMS from promulgating a rule regulating the amount of rebates between Part D drug plans and manufacturers, even in order to avoid duplicate rebates. Instead, in accordance with the clear legislative intent of this noninterference provision, CMS must leave the matter of duplicate rebates to the manufacturers and the drug plans.

It is also worth noting that, even if CMS had the authority to promulgate a regulation designed to avoid duplicate discount problems, no provision could adequately address the intricacies of the many state and federal rebate and discount arrangements that are potentially affected. CMS would have to anticipate every potential secondary rebate or discount, and would have to craft a solution that is

specific to each rebate or discount scenario. For example, one federal law mandates that drug manufacturers not sell above a discounted price to 340B entities, while a different federal statute (administered by a different federal agency) dictates the discount under the TRICARE program. A CMS regulation would have to be reconcilable with both statutes. Discounts or rebates offered to SPAPs, on the other hand, are often governed by state laws. While we recognize that in the MMA Congress has generally preempted state laws governing PDPs and MA-PDs (*see* Sections 1856(b)(3) and 1860D-12(g) of the Social Security Act), there is no such authority to preempt state laws governing drug manufacturers and SPAPs. Accordingly, CMS may not regulate what rebates or discounts SPAPs obtain from drug manufacturers. As this small sample of considerations suggests, it would be virtually impossible to draft a duplicate-discount rule adequately addressing the peculiarities of every state and federal drug discount program.

Separate Qualifications of an SPAP Component (Proposed 423.4640)

Under the proposed rule, in order for a State program to qualify as a SPAP for purposes of Medicare Part D, the State program must satisfy the criteria set forth at 42 C.F.R. § 423.464(e)(1).

Comment: States often use SPAPs to cover significantly varying populations (the regulations also encourage the creation of new SPAPs as a means of facilitating "wrap-around" coverage). For example, the needs of a very low-income beneficiary may be significantly different than the needs of a non-Medicare, non-Medicaid individual who is at 200% of the federal poverty level ("FPL"). States must take such differences into account when designing SPAP programs. As a result, some States may have established or may develop SPAP programs with different "components" that offer significantly different benefits to different populations.

First Health Services believes that the proposed regulations should be amended to clarify that an SPAP may have both "qualifying" and "non-qualifying" components for purposes of meeting the Medicare Part D definition of an SPAP. For example, a State program may have a component dedicated to providing supplemental care to dual-eligibles, a separate component for coverage of individuals between 135% and 150% of the FPL, and a component for individuals above 150% of the FPL. These components might be operated separately, with different enrollment mechanisms and rules. If one component does not meet one of the criteria set forth at 42 C.F.R. § 423.464(e)(1), this should not disqualify the remaining components that meet the definition of an SPAP for purposes of Medicare Part D.

There is precedent for such a model in the concept of a "hybrid entity" under regulations implementing the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). *See* 45 C.F.R. § 164.103. Under HIPAA, a single entity may designate both "covered" and "non-covered" components, so that the entire entity is

not inappropriately and unfairly constrained by the requirements of the HIPAA regulations. We believe a similar model should be developed under the Part D regulations to accommodate the varying needs of SPAPs.

Changes to Formulary (Proposed 423.120)

Under the proposed regulations, a PDP sponsor or MA organization generally may not alter the therapeutic categories and classes of its formulary other that at the beginning of each plan year (§ 423.120(b)(3)). Additionally, such an entity may not remove a drug from its formulary, or make a change in the preferred or tiered cost-sharing status of a drug, without providing at least 30 days notice to CMS, affected enrollees, authorized prescribers, pharmacies, and pharmacists (§ 423.120(b)(5)). Finally, a PDP sponsor or MA organization may not remove a drug from its formulary, or make a change in the preferred or tiered cost-sharing status of a drug, between the beneficiary election period and 30 days after the beginning of the contract year (§ 423.120(b)(6)).

Comment: First Health Services believes that the regulations should be amended to clarify that the above restrictions do not preclude a PDP sponsor or MA organization from adjusting its formulary after the time of its bid (on or before March 1, 2005) and before the initial enrollment period for beneficiaries (November 15, 2005), as long as such adjustments do not have the effect of violating other applicable requirements respecting formularies. Such adjustments may be necessary in order to achieve the coordination between an SPAP and a PDP sufficient to ensure that disruptive transitions in drug therapies are avoided for the SPAP's beneficiaries.

Accordingly, the regulations should be clarified to state that, as long as 30 days notice is provided to CMS, such a formulary change is permissible. Specifically, since any such changes would occur prior to the benefit year (*e.g.*, before January 1, 2006), and prior to the beneficiary election period (*e.g.*, proper to November 15, 2005), it should be made clear that no notice would be required for affected enrollees, authorized prescribers, pharmacies, and pharmacists (since the plan would not yet be in effect).

7. Public Disclosure of Pharmaceutical Prices for Equivalent Drugs (§ 423.132) (Federal Register page 46665)

— Finally, as provided in § 423.132(c)(5) of our proposed rule, we propose waiving the public disclosure requirement in § 423.132(a) under such circumstances as we deem to be impossible or impracticable. We request comments on the appropriateness of the circumstances we have proposed for waiver of the requirements in § 423.132(c), as well as any additional circumstances we may wish to consider. We note that a similar public disclosure requirement was waived for endorsed discount card sponsors under the

Medicare Prescription Drug Discount Card (42 CFR 403 and 408) for covered discount card drugs dispensed under several of the same circumstances as those described above.

— In § 423.132(d)(1) of our proposed rule, we propose waiving the requirement that information on differential prices between a covered Part D drug and generic equivalent covered Part D drugs be made available to prescription drug plan and MA–PD plan enrollees at the point of sale when prescription drug plan enrollees obtain covered Part D drugs in long-term care pharmacies. Long-term care pharmacies generally provide drugs directly to the skilled nursing facilities and nursing facilities where the patient resides, not directly to the patient, under a medical benefit. They also engage in a significant coordination of benefits effort that would require that at least some claims be processed off-line, and not in real time. Given the manner in which long-term care pharmacies provide prescription drugs to residents of long-term care facilities, as well as the way in which they process claims, it would be impracticable for these pharmacies to provide beneficiaries with information regarding covered Part D drug price differentials at the point of sale. Although long-term care network pharmacies would be exempt from the requirement that information about lower-priced generic alternatives be provided at the point of sale, they would not be exempt from the public disclosure requirement in § 423.132(a) altogether. We request comments regarding appropriate standards with regard to the timing of such disclosure by long-term care pharmacies to the institutionalized Part D enrollees they service. We note, as well, that under § 423.132(d)(2) of our proposed rule, we may modify the timing of the public disclosure requirement under such other circumstances as we deem compliance with that requirement to be impossible or impracticable.

Comment: Since beneficiaries in LTC facilities have no out of pocket costs, CMS should waive the public disclosure requirement for LTC pharmacies. PDP's will be contracting with LTC pharmacies for discounts and the best price available. Requiring the LTC pharmacies to comply with the public disclosure requirement does not seem to satisfy any purpose, as most LTC beneficiaries do not have a choice of pharmacies.

(Federal Register page 46666)

2. Cost and Utilization Management Programs, Quality Assurance Programs, Medication Therapy Management Programs (MTMP), and Programs to Control Fraud, Abuse, and Waste(§ 423.153)

a. Cost Effective Drug Utilization Management (Federal Register page 46666)

— We believe that a cost-effective drug utilization management program could also employ the use of prior authorization, step therapy, tiered cost-sharing, and other tools to manage utilization. We are aware that these are tools commonly used today to manage pharmacy benefit costs for many commercial and State programs. We believe that the competitive bidding and premium setting processes, combined with the requirements for transparency and information availability, provide powerful incentives for plans to innovate and adopt the best techniques available. We invite comment on whether there

are industry standards for cost effective drug utilization management and whether CMS should adopt any of these standards for PDPs and MA–PDs.

Comment: There are no industry standards that must be followed. The Pharmacy Benefit Management industry and government programs all have utilization management tools. The use of prior authorization, while used in both commercial and government programs, is constantly under attack by the pharmacy manufacturing industry. This is especially true in government programs. CMS should not establish and require a standard for the PDP's. This regulation goes beyond the authority of CMS, as it directs how a PDP must operate a portion of its business.

Although we have not included proposed regulations, we are considering for the final rule a requirement that these tools should be under the direction and oversight of a Pharmacy and Therapeutics Committee to ensure an appropriate balance between clinical efficacy and cost effectiveness. We seek comments on this issue. We also seek comments on requiring the direct involvement of a Pharmacy and Therapeutics Committee not only with cost containment measures, but also with other areas of quality assurance and medication therapy management. Again, although we have not included proposed regulations requiring this standard, we are considering this standard for our final rule.

Comment: P&T committees should focus on the clinical and therapeutic value of the drugs on the PDP formulary. P&T committees are not full time commitments as physicians and pharmacists typically do not work for the PDP. Requiring the P&T committee to be responsible for cost containment measures is outside the realm of what a P&T committee sees as their primary responsibility. The PDP is responsible for cost containment measures, as these measures are necessary for the PDP to operate within its bid. Quality assurance is also a responsibility of the PDP and not the P&T committee. P&T committees could assist the PDP in developing the medication therapy management programs, but the day to day operations of the program is the responsibility of the PDP. The P&T committee is an advisory committee to the PDP.

b. Quality Assurance (Federal Register page 46667)

—We note that the MMA does not define or explain the term ''medication error.'' Nevertheless, we believe a common definition is important. In the future, we may require quality reporting that includes error rates. We could use this information to evaluate plans. In addition, we may publish this information for enrollees to use when comparing and choosing their individual plans. Therefore, we particularly invite comments on how we could evaluate PDPs and MA–PDs based on the types of quality assurance measures and systems they have in place, how error rates can be used to compare and evaluate plans, and how this information could best be provided to beneficiaries to assist them in making their choices among plans.

Medication error reduction programs and requirements have been discussed in many venues and various definitions of ''medication error'' have been used. For example, in its proposed rule requiring bar codes on most human drug products, the Food and Drug Administration adopted the following definition of a medication error:

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (See 68 FR 12500 (March 14, 2003)). This definition of ''medication error'' is identical to that used by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). (See National Coordinating Council for Medication Error Reporting and Prevention, ''What is a Medication Error?'' (Undated)).

We are citing this definition in this preamble as one that we would use initially in interpretive guidance. We believe that this definition could be applied to, and include, adverse drug events and interactions as they pertain to quality assurance. As the state of industry practice evolves, we may, from time to time, update this definition by manual issuance. We invite comments on this definition.

Comment: Use of the POS/ProDUR capability of most pharmacy systems has built in edits and controls, both clinical and financial, that looks for such errors. If used, the POS/ProDUR systems can look for adverse drug to drug, drug to diagnosis, drug to gender, drug to age, and various other interactions when one drug is being administered and another is added to the therapy regimen. If used appropriately, the system will tell the pharmacist that there is a possible reaction or interaction that should be evaluated further by the dispensing pharmacist of the physician prescribing the medicine. First Health Services' experience has shown that many potential medication errors are avoided when the system is set up and used properly. Contributors to this problem have been documented as unclear handwriting on the part of the physician, transposition of information into the pharmacy system, unclear understanding on the part of the member.

Systems and processes have been put in place over the past several years to handle these errors and reduce the possibility of them occurring. Implementation of practice management systems that automatically print out a prescription rather than relying on the physician to hand write have improved legibility. A recent implementation of Eprescribing in the doctor's office has shown, in Florida Medicaid, that errors can be further reduced if the physicians have access to the ProDUR edits and rules in their office through use of a hand held PDA device. Subsequent automated distribution of these electronic scripts directly to the pharmacy can further reduce the risk of error.

Implementation of clinical management programs are a must where clinicians for the pharmacy benefit manager review dispensing and prescription trends for physicians and pharmacies and follow up with educational interventions when problems with dispensing or prescribing are seen.

5. Quality Improvement Organizations (QIO) Activities (§ 423.162) (Federal Register page 46672)

— We have been consulting, on an individual, organization by organization basis, with representatives from pharmacy benefit managers, managed care organizations, programs that have monitored drug utilization, and others who have utilized pharmacy claims data. We welcome comments related to the collection and use of information for providing quality improvement assistance related to Part D.

Comment: First Health Services uses this process in our normal business processes. Claims utilization data are reviewed by clinical pharmacy staff to determine appropriateness of prescribing practices, dispensing practices and many other areas. This data is used to show if there are education or other initiatives that need to be taken with the member population, the pharmacy providers who dispense drugs or the physicians who prescribe drugs. Intervention with these parties takes the form of letters stating any problems seen with practice; recommendations for change and can possibly result in face to face educational sessions.

There are two ways to perform this function – make the PDP responsible for conduct and reporting, or request data to be sent. If data is to be sent, then the request must take advantage of standard data definitions so that accurate comparisons can be made between data and sponsors.

This process is similar to the currently implemented Retrospective DUR process performed in Medicaid and many other commercial health plans.

F. Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation (Federal Register page 46674)

2. Requirements for Submission of Bids and Related Information (Federal Register page 46674)

— We are interested in providing information to potential bidders to help eliminate the uncertainty of drug trend for Medicare beneficiaries and in delaying the submission of pricing information as long as we can under the law and consistent with our need to inform beneficiaries. We solicit comment on the nature of any additional information needed to prepare bids and suggestions for any other methods that the bid submission process could be structured to provide for later pricing data submission.

Comment: PDP's need information on drug expenditures for seniors. While there is no central collection point for this information, a number of Medicare managed care plans provide prescription drug coverage. The sharing of expenditure information for non-Medicaid seniors will prove beneficial in the preparation of bids. PDP's need the final Part D final rules by January 1, 2005 so bid preparation can begin. CMS could allow the PDP's to submit their applications without the pricing information by the June 6, 2005 deadline. CMS could then begin the review and approval process of the non-financial information. Negotiations between CMS and PDP's must be completed on an expedited basis. In order to educate beneficiaries and to allow sufficient time for outreach efforts by PDP's, contracts should be awarded by mid August 2005.

7. National Average Monthly Bid Amount (Federal Register page 46683)

We welcome comments on the existence of regional price variation in drug prices and on any factors that could lead to that variation. As part of carrying out the Congress' requirement that our geographic adjustment methodology be ''appropriate,'' we believe the method would first require gathering data from PDPs and MA–PDs on regional drug prices. Therefore, we may not implement a geographic adjuster for the first few years of the program unless we have acquired sufficient information on pricing to accurately characterize that variation. If we were to determine that there is significant geographic variation in prices, we anticipate that we would announce the adjustment factors in advance of the bidding process for any year in which geographic adjustment would be applied to bids in the calculation.

Comment: Certain areas of the United States require geographical adjustments in the first year of PDP operation. Alaska and Hawaii, at a minimum, would require a geographical adjustment. Such and adjustment could initially be calculated by comparing spending for Medicaid fee-for-service dual eligibles in those States to that of other States.

8. Rules Regarding Premiums (Federal Register page 46684)

— We note that achieving very high (indeed, virtually universal) access to prescription drug coverage for beneficiaries who participate in Part D was a key Congressional consideration in enacting MMA. We would encourage comments from insurers, actuaries, and others with experience, data, or expertise in this area. We are particularly interested in receiving comments on the most appropriate level for the late enrollment penalty, the likelihood of whether a $.36 per month of delay penalty (that is, 1 percent for each month of delayed enrollment) constitutes an adequate safeguard against selection bias, and the importance of strongly encouraging widespread enrollment to maximize the affordability and stability of Part D premiums.''

Comment: A late penalty of 1% or an estimated penalty of $.36 per month will not constitute safeguard against selection bias, and is not enough of a penalty to encourage enrollment into a PDP. While widespread enrollment is a major goal of congress, there are alternate ways to develop wide spread enrollment. The Part D program encourages the coordination of benefits between SPAP's and PDP's. This coordination would be greatly enhanced by allowing SPAP's to auto enroll their members into a PDP. The auto enrollment process proved to be beneficial to the Medicare prescription drug card program. Seniors as a group will not enroll in health care programs without encouragement, this will be especially true for enrollees in SPAP's. Auto enrollment would also eliminate the potential of late enrollments for this sizable group of seniors.

G. Payments to PDP Sponsors and MA Organizations Offering MA-PD Plans for All Medicare Beneficiaries for Qualified Prescription Drug Coverage (Federal Register page 46685)

4. Requirements for Disclosure of Information (§ 423.322) (Federal Register page 46686)

a. Data Submission (Federal Register page 46686)

— As provided under sections 1860D–15(c)(1)(C), 1860D–15(d)(2) and 1860D–15(f) of the Act and in § 423.322 of our proposed regulations, we would condition program participation and payment upon the disclosure and provision of information needed to carry out the payment provisions. Such information would encompass the quantity, type, and costs of pharmaceutical prescriptions filled by enrollees that can be linked to individual enrollee data in our systems; that is, linked to the Medicare beneficiary identification number (HIC#). We would appreciate comments on the content, format and optimal frequency of data feeds. We believe that more frequent feeds than annually (weekly, monthly, quarterly) would allow us to identify and resolve data issues and assist the various payment processes. We are evaluating our minimum data requirements with regard to prescription drug claims. Our goal would be to determine the least burdensome data submission requirements necessary to acquire the data needed for purposes of accurate payment and appropriate program oversight. Our view is that we will need at least the following data items for 100 percent of prescription drug claims for the processes discussed below:

- Beneficiary name (first, middle initial, last).
- Beneficiary HIC#.
- Beneficiary birth-date.
- Eleven-digit NDC code.
- Quantity dispensed.
- Prescription drug cost before co-payment (ingredient cost, dispensing fee, sales tax amount).
- Beneficiary co-payment amount, and

- Date prescription filled.

Comment: PDP's have the capability of submitting prescription utilization data to CMS on a monthly basis, and in any format required. The PDP point of sale system, coupled with the enrollment information, will contain sufficient information to allow payments to be made on a beneficiary basis by CMS. All of the information listed above is included in the point of sale system. Submitting data on these time frames will allow CMS to complete the risk corridor evaluations and re-insurance subsidy calculations and payments on an ongoing basis rather than months after the close of the year. Similarly, PDP's can provide prescription utilization on a daily basis for persons with low income subsidies. Daily utilization for these groups of beneficiaries will allow the low income subsidy program to function as a fee for service program. The Medicare drug discount card currently operates on a fee for service program, where sponsors submit utilization daily to CMS for repayment of the drug claim. CMS pays the sponsor for the cost of the program within 24 hours. This process has worked well for the discount card program and sponsors. Without a fee for service reimbursement system, PDP's will be advancing millions of dollars to pharmacies for the payment of prescription drugs while waiting for reimbursement from CMS. The PDP point of sale system will have all of the information needed to implement a fee for service type program for the low income subsidy beneficiaries

We assume that ingredient cost and dispensing fee reflect point of sale price concessions in accordance with purchase contracts between plans (or their agents, such as PBM's) and pharmacies, but do not reflect subsequent price concessions from manufacturers, such as rebates. We anticipate that we will need similar data on prescription drug claims for appropriate risk-adjustment, reconciliation of reinsurance subsidies, and calculation of risk sharing payments or savings, and program auditing. Data will also be required for assessing and improving quality of care. We will welcome comments on the nature and format of data submission requirements for the following processes:

- Risk adjustment process would require 100 percent of drug claims in order to develop and calibrate the weights for the model for this new benefit. Consequently, PDP sponsors and MA organizations offering MA–PD plans would be required to submit 100 percent of prescription drug claims for Part D enrollees for the coverage year. Risk adjustment would require the submission of prescription drug agent identifying information, such as NDC codes and quantity, in order to allow the standardized pricing of benefits in the model. Because we would use standardized pricing, cost data on each prescription is not a requirement for risk adjustment, although it is needed for other purposes.

- The reinsurance subsidy payment process would require 100 percent of claims for each enrollee for whom the plan claimed allowable reinsurance costs. (Although reconciliation of the reinsurance subsidy does not require NDC codes or quantities, it does require member, cost and date of service data.) All claims for enrollees with expenses in excess of the out-of-pocket limit would be necessary to verify that the costs were allowable because the totality and order in which the claims are incurred

would define which claims would be eligible for reinsurance payments. While the start of reinsurance payments begins with claims after the out-of-pocket threshold has been reached, which is $5,100 in total spending (2006) for defined standard coverage, it may be associated with a higher dollar total spending amount under alternative coverage. Whatever the level, we would need to receive all claims by date of service including the amount of beneficiary cost sharing in order to determine the occurrence of the out-of-pocket threshold. Any plan-incurred costs for claims for supplemental benefits cannot be included in determining whether the out-of-pocket threshold has been met.

- The risk sharing process would require 100 percent of claims for all enrollees for the calculation of total allowable risk corridor costs. The plan would need to segregate costs attributable to supplemental benefits from those attributable to basic benefits since supplemental benefit costs are not subject to the risk corridor provisions. Again, all claims would be necessary to verify that the costs were allowable because the order in which the claims were incurred would help determine whether the claims were solely for basic coverage. For instance, a claim processed between a beneficiary's deductible and initial coverage limit (in standard coverage) would count towards risk sharing, but another claim (processed identically but immediately after the initial coverage limit has been reached) would not. Unlike the reinsurance subsidy, which is limited to individuals with expenses in excess of the out-of-pocket threshold, risk sharing involves costs (net of discounts, chargeback's and rebates, and administrative costs) for all enrollees for basic coverage, but only those costs that are actually paid by the sponsor or organization. Because all plans participate in risk sharing, potentially all claims for all Part D enrollees in all plans must be reviewed. Like the reinsurance reconciliation, risk sharing does not require NDC codes or quantities, but does require member, cost, and date of service data.

- The program audit process would require at least a statistically valid random sample of all Part D drug claims. We believe that several points of reference including HIC#, cost, date of service, and NDC code would be required for unique identification of individual claims in any random sample drawn from the population. If we receive 100 percent claims to support the payment processes, this sample could be drawn from our records. We believe it would be useful to obtain the prescribing physician's National Provider Identifier (NPI) number, as required by the administrative simplification provisions of HIPAA, in the elements of collected data for purposes of fraud control once it is available. Prior to May 2007 when the NPI is expected to be used, we would be interested in alternative means for identifying the physician prescriber. (Nothing in this data collection discussion should be construed as limiting OIG authority to conduct any audits and evaluations necessary for carrying out our proposed regulations.)

Comment: The Medicare drug discount card program has shown that this level of information is available in the sponsors' POS and enrollment systems. The only item that would be a problem is the provider's NPI number on the claims. This is not information currently collected unless the prescription is for a narcotic drug.

Other than the NPI number for each claim, the rest of the data can be provided to CMS on regularly scheduled basis.

b. Allowable Costs (Federal Register page 46687)

— Section 1860D–15(b)(2) and 1860D–15(e)(1)(B) of the Act and § 423.308 of our proposed regulations, specify that to determine ‘‘allowable costs’’ for purposes of both the reinsurance and risk corridor payments, only the net costs actually paid after discounts, chargeback's, and average percentage rebates, as well as administrative costs, are to be counted. We encourage comments on appropriate methodologies and data sources that can be used in making these adjustments. For example, we would like to receive comments on how price concessions (discounts, chargeback's, rebates, or any other periodic financial remuneration) would be most accurately and efficiently applied to prescription drug claims data to satisfy this requirement. We would also be interested in any information or data on the effect on costs such adjustments can be expected to yield. We are particularly interested in how data would be appropriately allocated and applied to the reinsurance subsidy tied to individual expenses in excess of the out-of-pocket limit.

Comment: Point of Sale systems are designed to handle pharmacy network discounts, deductibles, co-pays and other prescription related services and fees. They have historically not been used to provide a rebate to the member in a distinct and discreet way at the point of sale. Use of a standard Medicaid or commercial model for the negotiation, tracking and collection of rebates is preferred, as these models have proven track records. This provides for a process of applying negotiated rebate rates to the claims retrospectively, then submitting them to the manufacturer for payment and finally returning these rebates to the plan sponsor for use in covering the cost of administering the plan and providing coverage for members. This process is simpler to administer and does not modify the industry standard transaction data sets.

First Health Services does subscribe to the philosophy that these rebates should be returned to the plan sponsor rather than being retained by the PDP. The PDP should only receive an administrative fee for the handling of the rebates.

c. Coverage Year (Federal Register page 46687)

— In § 423.308 we propose that the term ‘‘coverage year’’ would mean a calendar year in which covered Part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than 3 months after the end of the year. In other words, drug

claims paid past the close of the 3-month period would not be considered part of that coverage year (or the next), and would not be used to calculate that year's payments or in reconciling risk adjustment payments for the year.

This limit would be imposed in order to provide timely closure for payment determination processes such as reinsurance, risk corridors and employer subsidies. While the period of 3 months would be significantly less than the fee-for-service Medicare medical claims standard of 18 months, we believe that a shorter period is warranted due to the highly automated and point of sale nature of prescription drug claim processing. We understand that the vast majority of prescriptions are not filled without the claim being simultaneously processed and therefore, there is a much shorter claims lag to be considered. We believe that the number and value of drug claims that would potentially be missed would be immaterial, consisting primarily of paper claims. The 3-month close-out window would not limit the liability of the plan or its claims processing contractor for reimbursing any lagging claims, but would simply establish a timely cut-off for finalizing payments. Any rebates for the coverage year not reflected in the fourth quarter data (sent to close out the year) must be credited against future payments. Although we are closing the year for claims purposes, the plan must account for all rebates that occur throughout the coverage year and send us all the data.

A shorter period would allow for payment processes that are dependent on the knowledge of total allowable costs for each coverage year to be concluded on approximately the same schedule as other reconciliations involving enrollment or risk adjustment data. On this schedule, calculations of risk sharing could begin as soon as five to six months after the close of the payment year. If the claims submission standard were a longer period, final reconciliations would be significantly delayed. We are interested in receiving comments on this timetable, specifically whether we should adopt a shorter or longer period than 3 months, and including data with which to estimate the proportion and value of drug claims that could be excluded with a 3-month close-out window.

Comment: The majority of claims are submitted and paid within the 90 day window described in this rule. From a processor viewpoint, there is very little reason for any longer period of time. It is the pharmacy and the member that determine when a claim is processed. If all parties know of the amount of time limitation then we see no problem with a 90 day rule.

5. Determination of Payment (§ 423.329) (Federal Register page 46688)

b. Risk Adjustment (Federal Register page 46688)

— Any risk adjustment methodology we adopt should adequately account for low-income subsidy (LIS) individuals (and whether such individuals incur higher or lower-than average drug costs). Our risk adjustment methodology should provide neither an incentive nor a disincentive to enrolling LIS individuals, and we request comments on this concern and suggestions on how we might address this issue.

Our particular concern is that a risk adjustment methodology, coupled with the statutory limitation restricting low-income subsidy (LIS) payments for premiums to amounts at or below the average, could systematically underpay plans with many LIS enrollees (assuming LIS enrollees have higher costs than average enrollees). If the risk-adjustor fails to fully compensate for the higher costs associated with LIS recipients, an efficient plan that attracts a disproportionate share of LIS eligible individuals would experience higher costs to the extent the actual costs of the LIS beneficiaries are greater than the risk-adjustment compensation. Failing to discourage enrollment by LIS beneficiaries in 2006, the plan would experience higher than expected costs in that year and presumably be driven to reflect these higher costs (due to adverse selection, not efficiency) in its bid for 2007. In this hypothetical, plans would have a disincentive to attracting a disproportionate share of LIS beneficiaries. One possible solution would be to assure that the initial risk-adjustment system, which will be budget neutral across all Part D enrollees, does not under compensate plans for enrolling LIS beneficiaries. In fact, to the extent that an initial risk-adjustor might at the margin tend to overcompensate for LIS beneficiaries, plans would have a strong incentive to disproportionately attract such beneficiaries. Plans could attract LIS beneficiaries both by designing features that would be attractive to such beneficiaries but also by bidding low. We would appreciate comments on this concern and suggestions on how we might address this potential problem.

Comment: PDP plans should first be compensated for premium underpayment for LIS enrollees when actual plan expenditures exceed the plan's target amount. After this initial level of reimbursement (when required), risk corridor computations should be applied as usual.

d. Reinsurance Subsidies (Federal Register page 46689)

ii. Payment of Reinsurance Subsidy (Federal Register page 46689)

— Since allowable reinsurance costs can only be fully known after all costs have been incurred for the payment year, we would propose to make payments on an incurred basis to assist PDP sponsors and MA organizations with cash flow. Under § 423.329(c)(2)(i), we would provide for payments of reinsurance amounts based on plan actual reinsurance-eligible allowable costs with a one-month lag period. In other words, no payments would be made until enrollees reached the true out-of-pocket threshold. This would require timely submission of drug claim data. In this approach rebates would be recognized in the month after they were received and would be offset against the previous month's actual costs.

Alternatively, we could consider payments of reinsurance amounts on a monthly prospective basis based on the reinsurance assumptions submitted and negotiated with each plan's approved bid. We would take these assumptions into account in developing either a plan-specific or program-wide approach. We note that any program-wide approach involving some kind of average of the amounts included in the bids would have

to adjust for the fact that plans providing enhanced alternative benefits would incur lower reinsurance costs. We are also aware that allowable reinsurance costs would be predominantly incurred in the latter parts of the coverage year and are considering the most appropriate methodology for distributing interim payments. One possible approach would require the submission of a schedule of the estimated timing of incurred allowable reinsurance costs along with the bid. For example, we might take schedules from each plan or we could propose an incremental schedule (X% of the total in January, Y% in February, etc.). We are aware that the prospective payment of estimated costs would create an incentive to overstate reinsurance, however, and are interested in ensuring that payments are not excessive. Since equal payments would be most compatible with our systems, in the first two years of the program (and for the first two years of new plans thereafter) we could also consider another approach paying 1.12th of the net present value of estimated allowable reinsurance costs in each month of the coverage year. The net present value would be calculated on the basis of all estimated reinsurance payments due at the end of the year and discounted by the most recently available rate for one-year Treasury bills. We would welcome comments on these approaches and on the appropriate treatment of interest in such a system.

Comment: PDP plans will be required to track actual enrollee spending on a daily basis. As such, plans will be aware on a daily basis of their reinsurance-related expenditures. To limit plan funding of reinsurance expenses and to avoid advance CMS payment for such expenses, it is recommended that plans invoice CMS daily (similarly to the way Medicare Discount Card transitional assistance is paid) and CMS reimburse plans within 48 hours.

6. Low-Income Cost-Sharing Subsidy Interim Payments (Federal Register page 46690)

— We are aware that low-income cost sharing would not necessarily be incurred evenly throughout the coverage year and are considering the most appropriate methodology for distributing interim payments. Since equal payments would be most compatible with our systems, in the first two years of the program (and for the first two years of new plans thereafter) we are considering an approach paying 1.12th of the net present value of estimated low-income cost sharing in each month of the coverage year. The net present value would be calculated on the basis of all estimated costs due at the end of the year and discounted by the most recently available rate for one-year Treasury bills. An alternative approach would require the submission of a schedule of the estimated timing of incurred low-income cost sharing along with the plan bid. For example, we might take schedules from each plan or we could propose an incremental schedule (X% of the total in January, Y% in February, etc.). We are aware that the prospective payment of estimated costs creates an incentive to overstate low-income cost sharing, and are interested in ensuring that our interim payments are not excessive. We would welcome comments on these approaches and on the appropriate treatment of interest in any methodology. For subsequent years of the program, we are considering an approach of paying 1.12th of the two-year prior year's actual expenses. Such an approach would need

to be trended forward by an appropriate index to account for expected growth in plan costs. In other words, in 2008 the interim payments would be based on actual reconciled low-income cost sharing subsidy payments for 2006 trended forward by an estimated two-year growth factor. Again, any reconciliation at the end of the year would need to be based on the sponsor providing adequate information in order to determine the subsidy amounts for the year. If the sponsor could not provide such information, interim payments would be recovered. In addition, the low-income payments would be subject to the same inspection and audit provisions applying to the other payments made under section 1860D–15 of the Act.

Comment: PDP plans will be required to track actual enrollee spending on a daily basis. As such, plans will be aware on a daily basis of their low-income subsidy-related expenditures. To limit plan funding of subsidy expenses and to avoid advance CMS payment for such expenses, it is recommended that plans invoice CMS daily (similarly to the way Medicare Discount Card transitional assistance is paid) and CMS reimburse plans within 48 hours.

8. Retroactive Adjustments and Reconciliation (§ 423.343) (Federal Register page 46693)

— We also request comment on the remedy that should be imposed in the event a PDP sponsor or MA organization offering an MA–PD plan fails to provide us with adequate information regarding risk-sharing arrangements. In the case of risk corridor costs, the organization or sponsor may owe the government money if, for example, prepayments exceed adjusted allowable risk corridor costs. In this case, failure to provide information could result in a shortfall to the government, since the entity would not have the information necessary for the Secretary to establish the proper amount owed. Although we have not proposed regulations on this issue, some of the remedies we are considering for the final rule are: (1) Assume that the sponsor's or organization's adjusted allowable risk corridor costs are 50% of the target amount; (2) assume that the sponsor's or organization's adjusted allowable risk corridor costs are the same percentage of the target amount as the mean (or median) percentage achieved by all PDPs or MA–PDs whose costs are lower than the target amount; (3) assume that the sponsor's or organization's adjusted allowable risk corridor costs are the same percentage of the target amount as the mean (or median) percentage achieved by all PDPs or MA–PDs (whose costs are both higher and lower than the target amount). We use a 50% threshold for option (a) because we believe this threshold would constitute a lower limit; and it would be unlikely for any organization or sponsor to have costs lower than 50% of their total payments. We request comments on these options, as well as proposals of other options that would allow us to recoup risk-sharing payments in the event a sponsor fails to provide us the adequate information necessary to determine appropriate risk-sharing payments.

Comment: Per the MMA rules, PDP's must submit year end utilization data for every individual enrolled in each region. CMS should be able to perform a match of PDP utilization against CMS enrollment files to determine if a PDP is reporting

utilization for all enrollees. While beneficiary expenditures that hit the risk corridors and reinsurance corridor will be known on a daily basis, beneficiaries who spend under the risk corridors will not be known until the end of the year. CMS will be unable to make an adjustment to the corridor for low spenders since they could have high utilization at the end of the year.

J. Coordination Under Part D Plans with Other Prescription Drug Coverage (Federal Register page 46696)

6. Coordination of Benefits with Other Providers of Prescription Drug Coverage (Federal Register page 46700)

— On rare occasions Part D plans would also be required to coordinate benefits with other Part D plans. In the event that a beneficiary disenrolled from one plan mid-year and enrolled in another, the two plans would be required to exchange information sufficient to allow the beneficiaries' claims to be processed as if there had been no break in enrollment. Specifically, the second plan would need to obtain the enrollee's claim data and adjust its claims processing system accumulators to reflect that a certain level of expenditures and out-of-pocket costs had already been incurred in order that the correct sequence of claims processing could be maintained. This is not to say that the second plan could claim the first plan's costs as their own allowable costs, but that their systems would process future claims as if the earlier costs had been incurred by the second plan. We solicit comments on any other issues that may be involved in coordination of benefits between Part D plans.

We solicit comment on how we can ensure that wrap-around coverage offered by SPAPs and other insurers does not undermine or eliminate the cost management tools established by Part D plans. We also request comment on the most effective way to administer this provision without creating undue administrative burden on either Part D plans or the SPAPs and other insurers that might choose to provide wrap-around coverage for eligible individuals.

Comment: Under the proposed rule, in order for a State program to qualify as a SPAP for purposes of Medicare Part D, the State program must satisfy the criteria set forth at 42 C.F.R. § 423.464(e)(1).

States often use SPAPs to cover significantly varying populations (the regulations also encourage the creation of new SPAPs as a means of facilitating "wrap-around" coverage). For example, the needs of a very low-income beneficiary may be significantly different than the needs of a non-Medicare, non-Medicaid individual who is at 200% of the federal poverty level ("FPL"). States must take such differences into account when designing SPAP programs. As a result, some States may have established or may develop SPAP programs with different "components" that offer significantly different benefits to different populations.

First Health Services believes that the proposed regulations should be amended to clarify that an SPAP may have both "qualifying" and "non-qualifying" components for purposes of meeting the Medicare Part D definition of an SPAP. For example, a State program may have a component dedicated to providing supplemental care to dual-eligibles, a separate component for coverage of individuals between 135% and 150% of the FPL, and a component for individuals above 150% of the FPL. These components might be operated separately, with different enrollment mechanisms and rules. If one component does not meet one of the criteria set forth at 42 C.F.R. § 423.464(e)(1), this should not disqualify the remaining components that meet the definition of an SPAP for purposes of Medicare Part D.

There is precedent for such a model in the concept of a "hybrid entity" under regulations implementing the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). See 45 C.F.R. § 164.103. Under HIPAA, a single entity may designate both "covered" and "non-covered" components, so that the entire entity is not inappropriately and unfairly constrained by the requirements of the HIPAA regulations. We believe a similar model should be developed under the Part D regulations to accommodate the varying needs of SPAPs. SPAP's would treat each PDP equally in providing wrap around services.

a. Coordination with SPAPs

— We do not know how SPAPs will actually choose to coordinate with Medicare drug plans, and we welcome comment in this regard—particularly from States. We would like to better understand what SPAPs plan to do in 2006 relative to Part D interaction (such as in payment of premiums or claim-specific wrap-around), and how Medicare can assist State preferences in this regard. Our goal is to make the coordination of benefits process as functional for the beneficiary, pharmacy, and States as possible.

We assume that some SPAPS will pay Part D plans' premiums on behalf of enrollees. For SPAPs that choose to wrap-around coverage rather than paying premiums, we propose to include SPAP information in a coordination of benefits system described below. In this way, pharmacies will know that a claim should be sent to the SPAP following adjudication by the Part D plan.

We request comment on this proposed approach, including the feasibility of the approach for SPAPs and the ease of administration for pharmacies. We also request comment on whether or not SPAPs that choose to coordinate benefits on a wrap-around basis should be required to provide feedback on how much of the remainder of the claim they have actually paid. Since SPAP payments count as true out-of-pocket spending toward catastrophic coverage, the Part D plans could simply assume that any amounts not paid by the Part D plan and sent to an SPAP for reimbursement would count toward calculating TrOOP. We are concerned that we may need information from SPAPs to determine more precisely the SPAP contribution or payment. But we are also mindful of systems implications for States and would appreciate comments in this regard, particularly from SPAPs.

Comment: In issuing its proposed regulations, CMS has asked for commentary on the coordination between SPAPs and PDPs and suggestions of additional areas in which such coordination would be beneficial for the individuals to be served under Medicare Part D. First Health Services believes that effective coordination between the SPAPs and PDPs will be central to ensuring that uninsured and low-income individuals receive the assistance they need from both State programs and Medicare Part D, and urges CMS to more explicitly authorize and facilitate such coordination in the key area of establishing formularies.

Continuity of pharmaceutical treatment can be of great importance to effective disease management and appropriate healthcare. As the proposed regulations themselves seem to acknowledge, PDP formularies must be developed with appropriate consideration of the point that – especially for older individuals – it is often therapeutically counter-productive, or even dangerous, to abruptly change medications. Accordingly, we believe that one area in which coordination between SPAPs and PDPs is especially important and should be expressly encouraged by the Part D rules is that of formulary development. It must be anticipated that a large number of individuals will be transferring from state pharmaceutical assistance to Part D coverage through a PDP, with the likelihood that the SPAP will prospectively be providing those individuals with "wrap-around" benefits. In such cases, PDP development of formularies that are different from the formularies offered by the SPAPs serving the same beneficiaries could create a situation that would be not only confusing but potentially highly detrimental to beneficiaries' care.

To ameliorate these problems, First Health Services urges the Secretary to revise the regulatory provisions with respect to formulary development in two ways. First, the regulations should make clear that formulary development is one area in which SPAPs and PDPs are encouraged to closely coordinate their activities. Second, we strongly urge the Secretary to include in the regulations a provision that would permit a PDP to be deemed in compliance with the formulary requirements under § 423.120(b)(1) and (b)(2), upon appropriate certification by the PDP, and an SPAP with which it is coordinating on benefits issues, that the PDP is adopting the SPAPs formulary and that the SPAP's formulary substantially comports with the requirements of § 423.120(b)(1) and (b)(2). Such a regulatory change would provide PDPs with the flexibility that will be required in order to fully coordinate with an SPAP regarding formulary composition, thereby ensuring a smooth transition for beneficiaries whose primary drug coverage is transferred from an SPAP to a PDP.

Sub Part K. Proposed Application Procedures and Contracts With PDP Sponsors (Federal Register page 46707.

6. General Provisions

— Section 1860D–4(b)(1)(A) of the Act assures pharmacy access by requiring a PDP sponsor to permit the participation of any pharmacy that meets the terms and conditions under the plan. Based on this requirement, we are considering adding the following language to the contract provisions: The PDP sponsor would agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any

willing pharmacy may access the standard contract and participate as a network pharmacy. We are interested in public comment on the inclusion of such a provision.

Comment: PDP's will create a pharmacy network within each region that will meet the TRICARE standards as required by the MMA. PDP's will welcome all interested pharmacies, however the pharmacy must agree to provisions of the PDP's contract. CMS should not become involved in contracting issues between PDP's and pharmacies.

M. Alternatives Considered (Federal Register page 46801)

1. Designation of Regions

— The MMA requires that we establish between 10 to 50 PDP regions within the 50 States and District of Columbia and at least one PDP Region covering the territories. These regions will define PDP service areas. PDPs that provide service in a particular region must cover that region entirely. PDPs can submit bids to provide services in anywhere from one to all regions.

The MMA stipulates that, to the extent practicable, PDP regions must be consistent with MA regions. However, if we determine that access to Part D benefits would be improved by establishing PDP regions that are different than MA regions, we may do so. As discussed in the preamble, we anticipate designating PDP and MA regions before January 1, 2005. The designation of regions will be made after the market study required by the MMA and the opportunity for public discussion and comment on this study.

In designating PDP regions, our primary objective will be to ensure that all beneficiaries have reliable access to PDP plans at the lowest possible cost. The law requires that beneficiaries have a choice of enrolling in at least 2 qualifying plans, at least one of which is a PDP. If it is not possible to achieve that with PDP plans undertaking the standard level of risk, the law makes provision for limited risk PDPs, and in cases where that does not occur a fallback plan that is paid based on cost.

For several reasons, we believe it is beneficial to have several PDP plans operating in a region. Most importantly, more plans means greater beneficiary ability to obtain coverage that meets their needs and greater competitive pressure to provide high quality and low costs. We also believe that PDPs that assume some financial risk, as opposed to a fallback plan that is paid based on cost, are likely to negotiate larger price concessions for beneficiaries. In addition, more competition for enrollees between PDPs, as well as MA–PDs, is likely to generate higher quality service for beneficiaries.

Given the goal of providing beneficiary access to risk-bearing PDP plans in as many areas as possible, an important question is what type of regional configuration, or method of configuring regions, has the greatest likelihood of achieving this. One of the principal questions is whether regions should be comprised of the largest possible number (the 50 States, or a close approximation), or a smaller number of regions covering much larger geographic areas. Designating a smaller number of regions that cover large geographic areas might be desirable in the sense that areas that might be less likely to attract market interest could be grouped with other more sought after areas. Large regions might also offer PDPs a larger potential enrollee market that would provide more leverage in negotiating rebates and discounts with manufacturers. On the other hand, regions of too large a size could deter participation if there are concerns by PDPs about providing uniform benefits and bearing financial risk across large and possibly diverse health care markets. In addition, large regions may make it more difficult for small organizations to participate as PDPs, although there is nothing to preclude small organizations from forming joint ventures to participate.

We recognize that there are a number of other factors that would affect any decision on the designation of regions, including State licensure issues for insurers and size and capital requirements for plans, as well as other potential barriers to initial or subsequent market entry; the number of competitors that are likely to operate in an area; and the goal of initiating and sustaining competition. We seek public comment on the various factors that may influence potential PDP plans' participation decisions and on how we can design regions in such a way to best ensure access to PDP plans. Another issue to be considered in designating PDP regions is whether they should be the same as Medicare Advantage (MA) regions. The statute stipulates that to the extent practicable, PDP and MA regions should be the same. However, because of the nature of health plan markets for physician and provider services, as opposed to the kind of product that PDPs will be offering and the uncertainty related to configuring insurance pools for risk-based drug only products, we believe potentially it may not be feasible to have the same regional configurations for each of these programs. For example, as shown in the regional market entry for the Medicare drug discount card, there are States in which there are no entrants by regional based drug card programs, yet these are markets in which there are MA plans. Also, there were States in which there was market entry by regional card programs but in which no MA plans participate. This might suggest that different regions may be appropriate for PDPs and MA plans. However, as noted previously, it is uncertain the extent to which experience with market entry by Medicare-approved discount card sponsors foreshadows what might occur under the Medicare drug benefit. We welcome comments on issues that should be considered in determining whether or not PDP and MA regions should be the same.

Comment: First Health Services believes that the establishment of PDP regions consistent with MA regions (as described in proposed § 422.55) is of far less importance than establishing PDP regions that are defined by individual State boundaries. It is critical to a number of operational aspects of Part D benefits administration that each State should be a separate PDP region. As the Proposed Rule seemingly acknowledges, existing SPAPs will play a critical role in coordinating benefits with the PDPs for the most vulnerable populations to be

served under the Part D program, as well as in providing "wrap-around" coverage for beneficiaries within these populations. The administrative complexities and burden of effectuating these goals will be enormously – and unnecessarily – increased to the extent that the boundaries of PDP regions are not consonant with the State boundaries defining the relevant SPAP service areas.

For example, it will be difficult for a PDP sponsor to effectively tailor its benefits and formulary so as best to serve individuals transitioning from an SPAP to a PDP, if the PDP must coordinate its program and benefits with multiple SPAPs that have differing formularies and benefit structures in place. Similarly, other aspects of the establishment and operations of PDPs, (e.g., compliance with State licensure requirements under § 423.401(a)(1)) would be rendered substantially more complex if PDP regions were to be established so as to encompass service areas in more than one State.

First Health Services also believes that creating a separate PDP service area for each State will promote beneficial competition between potential PDP sponsors. In fact, the establishment of large, multi-State regions would be anti-competitive because only a small number of potential, corporate PDP sponsors would be of sufficient size to be able to bid for such large, multi-State service areas. However, if separate PDP services areas are designated for smaller States, a greater range of potential PDP sponsors will realistically be able to bid on a service area contract and offer services.

First Health Services therefore urges CMS to amend § 423.112(b)(2) to clarify that the boundaries of MA regions will not be adopted to determine PDP regions except where such MA regions are defined by individual State boundaries. Such an amendment fully complies with the statutory language authorizing the Secretary to establish PDP regions which differ from MA regions if the establishment of such different regions "would improve access to benefits under this part." *See* Section 1860D-11(a)(2) of the Act. Coordinating the efforts of the PDPs and the SPAPs, and increasing competition between PDPs, will ultimately improve beneficiary access to Part D benefits.

4. Administration of Subsidy Program (§ 423.800)

— We would be establishing a process to notify the PDP sponsor or MA organization that an individual is both eligible for the subsidy and the amount of the subsidy. Because CMS has not yet developed such a process, comments are welcome concerning notification to the PDP sponsor or MA organization that an individual is eligible for a subsidy and the amount of the subsidy. Similarly, we request comments on the proposed requirement that the PDP sponsor or MA organization notify CMS that premiums or cost-sharing have been reduced and the amount of the reduction. We are also considering the process for reimbursing the sponsor or organization for the amount of the premium or cost-sharing reductions. Any individually identifiable information must be kept confidential. Finally, we are requesting comments on how to best reimburse subsidy

eligible individuals with respect to out-of-pocket costs relating to excess premiums and cost-sharing incurred before the date the individual was notified of subsidy eligibility but after the effective date the individual became subsidy eligible.

Comment: PDP's must be notified upon enrollment into the Part D program of their eligibility determination for LIS. This notification is critical to ensure proper access to the beneficiary's medications. CMS should provide a daily tape match to the PDP that provides the LIS identifier. This would be similar to the process used in the Medicare drug discount card program for persons eligible for the Transitional Assistance benefit.

CMS-4068-P-1298

Submitter : Ms. Liz Savage **Date & Time:** 10/04/2004 09:10:20

Organization : The Arc of the United States

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter from The Arc of the United States on the Medicare Prescription Drug Benefit

CMS-4068-P-1298-Attach-1.doc

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS – 4068 – P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: Comments to the "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632, CMS File Code CMS-4068-P

To Whom It May Concern:

The Consortium for Citizens with Disabilities (CCD) submits the following comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit." CCD is a Washington-based coalition of national disability organizations that advocates on behalf of the 54 million people with disabilities and chronic conditions in the United States.

We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions to insure that they will have the following: 1) Adequate information and assistance in navigating the enrollment and plan selection process; 2) Access to an affordable benefit that provides the drugs they need; and, 3) Access to an exceptions and appeals system that permits them to easily resolve unfavorable plan decisions in a timely manner.

Many of the CCD organizations worked with the Medicare Consumers Working Group, a broad coalition of advocates for Medicare beneficiaries, who submitted comprehensive comments on the proposed rule. CCD believes that significant revisions in the proposed rule are needed in order to ensure that people with disabilities have access to a quality prescription drug benefit and to ensure that full benefit dual-eligible beneficiaries ("dual eligibles") are not disadvantaged further by inadequate access to needed care. However, rather than duplicating the Medicare Consumers Working Group's extensive effort and detailed comments, CCD is submitting comments on issues we have identified as priorities

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for Medicare beneficiaries with disabilities. We recommend that CMS take the following steps to protect the health of people with disabilities and chronic conditions:

- Delay the implementation of the Part D program for dual-eligibles
- Expand outreach to Medicare beneficiaries with disabilities
- Designate special populations who will receive affordable access to an alternative formulary
- Impose reasonable limits on cost containment tools
- Strengthen and improve the inadequate and unworkable exceptions and appeals processes
- Require plans to dispense a temporary supply of drugs in emergencies

CCD believes that in many ways the Preamble provides much better guidance than the proposed rule itself and that the specificity in the Preamble should be reviewed by CMS and included in any final rule. On the other hand, we are concerned that there are critical gaps in information in the Preamble that also should be expanded upon. This is an extremely complex law with life and death implications for people with disabilities and chronic conditions. Therefore we suggest that CMS support the delay of implementation of the law for dual-eligibles and publish a second NPRM that reflects the input CMS receives on these proposed rules.

SUBPART B—ELIGIBILITY AND ENROLLMENT

A successful implementation of the MMA will require strong regulatory protections to ensure that people with disabilities are adequately informed that they must enroll in the Part D program and select a private prescription drug plan. In addition, for many people with disabilities, Medicaid prescription drug coverage will end—dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) must be clearly informed of the need to take action to prevent interruptions in access to prescription drugs.

The final rule must ensure that the enrollment process takes into account the unique needs of people with disabilities and recognizes the exceptional challenges of appropriately educating, screening, and enrolling people with disabilities.

423.34(d)(1), Temporarily Extend Medicaid FFP for Full Benefit Dual Eligibles

CCD is deeply troubled by the very real possibility that CMS will not be able to implement the MMA under the current timeframe in a way that adequately responds to the needs of people with disabilities and that ensures that access to prescription drugs will not be interrupted for dual eligibles for whom drug coverage will transfer from Medicaid to a private Medicare Part D plan. Therefore, in the strongest possible terms, we request that CMS immediately indicate its support for legislation that would delay the implementation of the MMA for dual eligibles.

Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006.

CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit starting on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the likelihood that not all 6.4 million dual-eligibles will be identified, educated, and enrolled in six weeks (from November 15, 2005, the beginning of the enrollment period to January 1, 2006), we recommend that the transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. The statute requires auto-enrollment on a random basis for all dual eligibles not enrolled on January 1, 2006. CCD has grave concerns regarding how this process might occur for the following reasons:

- It is very likely that many, if not a majority, of dual eligibles will not be able to enroll by January 1, 2006. Existing caseworkers in non-profits, government offices, or SPAPs will not have sufficient time with all 6.4 million dual eligible beneficiaries to educate them on the myriad choices, finding new providers, counseling them on formularies, or shepherding them through a complex enrollment process.

- Assigning dual eligibles on a random basis will—by statute—steer dual eligible beneficiaries into the lowest-cost plan. As a result of being the lowest cost plan, beneficiaries will have significantly restricted access to medications currently being administered to dual eligible beneficiaries.

- Because many dual eligibles will be enrolled in plans not tailored specifically to their unique needs, many beneficiaries will be forced—within a short span of time—to switch critical medications, find a new network pharmacy, and, at worst, go without medications simply because they did not receive enrollment materials in time.

A delay in implementation is critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. The Congress is kidding itself to think that in 6 weeks this complex population will independently enroll in a new plan. Without a doubt, if the current implementation schedule occurs on time, ***some dual eligibles will go to the pharmacy in January 2006 and not come home with needed medication***.

We recognize that this may require a legislative change and hope that ***CMS will actively support such legislation***.

423.36(c)(4), Special Enrollment Periods and Dual Eligibles

The selection of an appropriate prescription drug plan for people with disabilities will be especially challenging given their extensive and complex needs. Moreover, individuals may find that despite their best efforts to evaluate their private plan options, they have selected a plan that does not meet their needs or, their needs may change. For these reasons, we support granting dual eligibles special enrollment periods.

It is critical that dual eligibles receive notice explaining their right to a special enrollment period when they enroll in a plan, and every time their PDP changes its plan in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

423.44(d)(2), Disenrollment for Disruptive or Threatening Behavior

CCD is very concerned that the proposed rules would allow prescription drug plans to disenroll beneficiaries if their behavior is "disruptive, unruly, abusive, uncooperative or threatening." These provisions create great potential for discrimination against individuals with mental illness and cognitive disabilities.

The proposed provisions will be used purposefully to discriminate against persons with mental illness or other disabilities or will result in discrimination as an indirect consequence of plans not making adequate accommodations for individuals with disabilities, e.g., by training plan personnel on the special needs of these individuals and providing simplified processes for them to use to access the medications they need. Therefore, plans must be required to develop mechanisms for accommodating the needs of beneficiaries with these disabilities, and CMS must provide safeguards to ensure that these individuals do not lose access to drug coverage. The provisions to allow involuntary disenrollment for disruptive behavior must not be included in the final rule.

Additionally, CCD particularly urges CMS not to include the proposed expedited disenrollment process in the final rule. This process is offensive and unnecessary - and could lead to abuse by private plans that do not have the cultural competence needed to serve some people with disabilities or who wish to avoid potentially high cost individuals who have significant mental health needs or other types of disabilities.

Alternatively, CMS must provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and must waive the late enrollment penalty for these individuals. Individuals most likely to be disenrolled for disruptive behavior do not have the resources to pay for needed medications out of pocket and would suffer great hardship from losing drug coverage for an extended period.

Section 423.46, Late Enrollment Penalty

CCD urges CMS to delay implementation of a late enrollee penalty for all enrollees for two years. The drug benefit is a new and particularly complex program, especially for many people with disabilities. In our view, many beneficiaries with disabilities will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. During the initial implementation process, people should not be penalized because of the complexity of the program.

After the first two years, CMS should require plans to allow individuals with disabilities a waiver or grace period if they miss an enrollment deadline. These individuals face additional challenges and may need additional time to select a plan and enroll. Furthermore, the rationale for imposing late penalties – i.e., to discourage healthier beneficiaries from waiting to enroll until later – is less likely to apply to people with disabilities who are likely to require on-going treatment for one or more conditions or illnesses.

In addition, after the first two years, implementation of the late enrollment penalty should be delayed for individuals eligible for the low-income subsidy. Again, individuals may not understand that they have to apply separately for the subsidy and a drug plan, and may think application for the subsidy is sufficient. CCD also recommends that the final rule allow enrollees to appeal late enrollment penalties.

Section 423.48, Information about Part D

CCD believes that people with disabilities must have access to information in order to make informed judgments about private plan options. The final rule (rather than guidance) should include binding and enforceable standards defining the information plans must provide to beneficiaries and how they must make this information available. CMS has important obligations to ensure that information is accessible to people with various types of disabilities and the proposed rule is inadequate in this regard.

CMS must require plans to make information available in accessible formats for people who are blind or have low-vision. Materials must also be available in "plain English" for individuals with cognitive disabilities or low-literacy. On request, plans must be required to provide information in Braille, large print, audio-tape or computer disc. In addition, CMS should require that PDPs' Internet web sites are accessible for individuals with vision impairments.

Information should also be provided in languages other than English to reflect the languages spoken in a plan's service area. This should include adequate information about drug plan options and should be provided annually, in writing, and include details about the plan benefit structure, cost-sharing and tiers, formulary, pharmacy network, and the appeals and exception processes.

Need for Targeted Outreach to Beneficiaries with Disabilities

Targeted and hands-on outreach to Medicare beneficiaries with disabilities, especially those with low-incomes, is vitally important in the enrollment process. We strongly urge CMS to develop a specific plan for facilitating enrollment of beneficiaries with disabilities in each region that incorporates collaborative partnerships with state and local agencies and disability advocacy organizations.

The State Health Insurance Assistance Programs (SHIPs) are funded by CMS and are charged with being the local one-stop shop for all Medicare beneficiaries. CCD research on SHIPs finds that while they are well intentioned, they often do not understand the unique needs of individuals with disabilities; may not be physically accessible; and may not have information available in accessible format. We strongly recommend that the SHIPs mandate be clarified to ensure that they address the needs of individuals with disabilities, including non-elderly individuals. This could greatly improve education and outreach to this population.

SUBPART C- BENEFITS AND BENEFICIARY PROTECTIONS

No section of the proposed rule is more important to ensuring that the Part D program provides a prescription drug benefit that will meet the diverse needs of people with disabilities than subpart C. CCD is deeply concerned that the proposed rule fails to meet even minimal standards for ensuring that people with disabilities will be able to access Part D drug coverage that meets their needs.

Definition of "Long-Term Care Facility" to Explicitly Include ICF/MRs and Assisted Living Facilities

For people with disabilities residing in residential facilities, including intermediate care facilities for persons with mental retardation and related conditions (ICF/MRs) and assisted living facilities, it is necessary that Part D prescription drug coverage is compatible with the manner in which residential facilities deliver prescription drugs. The final rule must ensure that persons with disabilities residing in residential living facilities are not subject to additional cost-sharing, or out-of-network cost-sharing if they access prescription drugs through a long-term care (LTC) pharmacy.

For this reason, we recommend that the final rule include a definition of "long-term care facility" that explicitly includes ICF/MRs and assisted living facilities. We believe that many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

423.104(e)(2)(ii), Establishing Limits on Tiered Copayments

CCD strongly opposes the provision in the proposed rule that permits Part D plans to "apply tiered co-payments without limit."

The final rule must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs. Permitting unlimited cost-sharing tiers could allow a Part D plan to effectively bar access to clinically necessary covered Part D drugs because cost-sharing is unaffordable and the exceptions process does not include adequate safeguards or standards to ensure a fair review of an individual's request for an exception to a Part D plan's non-preferred cost-sharing.

Moreover, allowing plans unlimited flexibility in establishing cost-sharing tiers increases their opportunity to discriminate against people who need costly medications or who need multiple medications. We also believe that permitting multiple cost-sharing tiers will greatly complicate the ability of CMS to determine actuarial equivalence and to determine that the design of a plan does not substantially discourage enrollment by certain eligible Part D individuals under the plan.

Section 423.120, Access to Covered Part D Drugs

Balancing Convenient Access with Appropriate Payment for Long-Term Care Pharmacies

CCD believes that CMS must propose a way to ensure that plan enrollees residing in long-term care facilities must have access to the LTC pharmacy in the facility where they reside. We could support one of two approaches for achieving an appropriate balance of convenient access with appropriate payment.

The first option is for the final rule to require PDPs to contract with all LTC pharmacies. Alternatively, the final rule could require PDPs to make available a standard contract to all LTC pharmacies. However, plan enrollees residing in facilities where the LTC pharmacy has elected not to contract with a prescription drug plan must be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy.

Further, we believe that there are overlapping responsibilities for the delivery of services between LTC facilities and prescription drug plans. To the extent that prescription drug plans are responsible for coordination and medication management, the final rule should encourage plans to contract with LTC pharmacies to provide these services to the plan's enrollees in long-term care facilities.

1860D-11(e)(2)(D) Authority to Review Plan Designs to Ensure that They Do Not Substantially Discourage Enrollment by Certain Part D Eligible Individuals

CCD is very concerned that plans will discourage enrollment of people with complex medical needs who will need access to a wide variety of medications. CMS must take advantage of every opportunity to ensure this does not happen.

We urge CMS to use the authority provided under section 1860D-11(e)(2)(D) to review plan designs, as part of the bid negotiation process, to ensure that they are not likely to substantially discourage enrollment by certain Part D eligible individuals.

CMS needs to analyze formularies, cost-sharing tiers and cost-sharing levels, and how cost-sharing (including both tiers and levels) is applied to assure that people with the most costly prescriptions are not required to pay a greater percentage of the cost of those drugs.

CMS also needs to assure that a variety of drugs are included in a formulary at the preferred cost-sharing tier to treat chronic conditions and conditions that require more costly treatments. Furthermore, as recommended previously, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through high cost-sharing for out-of-network access.

423.120(b), Formulary Requirements

CCD has many concerns related to formulary requirements and urges CMS to release a final rule that strengthens the consumer protection requirements and requires special treatment for specific populations.

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must be protected from tiered cost-sharing or burdensome prior authorization procedures that could create insurmountable access barriers.

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing bed rest, unnecessary hospitalizations and even death, on the other. Often, people with disabilities need access to the newest medications, because they have fewer side effects and may represent a better treatment option than older less expensive drugs.

Medicare beneficiaries with disabilities also require access to a broad range of medications. For example, people with spinal cord injuries or diseases of the spinal cord must have access to a broad range of antibiotics. Bacterial infection is a leading cause of hospitalization and death for these individuals. Because bacterial resistance to antibiotics is currently a very serious and growing issue CMS must ensure broad and timely access to a wide variety of

antibiotic medications. Bacterial resistance coupled with the common problem associated with individual beneficiary allergies make broad antibiotic access a matter of life and death for this population and the elderly.

Many individuals have multiple disabilities and health conditions making drug interactions a common problem. Frequently, extended release versions of medications are needed to effectively manage these serious and complex medical conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects, making it more important for the doctor to be able to prescribe the best medication for the individual. Often that process takes time since many people with significant disabilities must try multiple medications and only after much experimentation find the medication that is most effective for their circumstance.

The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury or debilitating side effects, as well as hospitalization or other types of costly medical interventions. It can also impact a person's decisions about work. The Ticket to Work and Work Incentives Improvement Act (TTWWIIA) expanded options for states to cover working people with disabilities under their Medicaid programs. Many of these individuals would already be Title II/Medicare eligible. Because of the state buy-in they have been able to access prescription drugs through Medicaid. If the Medicare formularies are limited for people with disabilities, an important purpose of TTWWIIA would be thwarted.

CCD recommends that the final rule provide for alternative, flexible formularies for special populations that would include coverage for all FDA-approved covered Part D drugs. Further, because of the clinical importance of providing access to the specific drugs prescribed, drugs prescribed to these defined populations must be made available at the preferred level of cost-sharing for each drug. We recommend that this treatment apply to the following overlapping special populations:

- **Dual Eligibles:** In enacting the MMA, Congress and the Administration both promised that dual eligibles (persons eligible both for Medicare and Medicaid) would be better off when coverage for prescription drugs is transitioned from Medicaid to Medicare Part D coverage. Historically, the Medicaid prescription drug benefit has been closely tailored to the poor and generally sicker population it serves, providing beneficiaries with a range of drugs that they need with little or no co-payment. Under federal law, states that elect to provide prescription drugs in their Medicaid programs must cover all FDA-approved drugs from every manufacturer that has entered into an agreement with the Secretary of Health and Human Services to pay rebates to states for the products they purchase.

  Dual eligibles include people with disabilities and other serious conditions who need a wide variety of prescription drugs. Medicare prescription drug plans, as programs serving dual eligibles, must be able to respond to a range of disabilities and conditions, including physical impairments and limitations like blindness and spinal cord injury, debilitating psychiatric conditions, and other serious and disabling conditions such as

cancer, cerebral palsy, cystic fibrosis, Down syndrome, mental retardation, Parkinson's disease, multiple sclerosis, autism, and HIV/AIDS. If dual eligibles are not to be worse off when Part D prescription drug coverage begins, then they must have continued access to an alternative and flexible formulary that permits treating physicians to prescribe the full range of FDA-approved medications.

- **Institutionalized Populations:** Many, but not all, Medicare beneficiaries residing in nursing facilities and other residential facilities are dual eligibles. The same rationale provided for dual eligibles applies to providing institutionalized individuals access to flexible formularies on the basis of their complex and multiple prescription drug needs. Moreover, although we recommend that any alternative formulary include access to all FDA-approved medications, should the final rule permit a more restrictive alternative formulary, it must ensure that all drugs included on the formulary of participating LTC pharmacies are included on the plan's formulary, and drugs that are preferred by the LTC pharmacies' formularies must be treated by the plan as a preferred drug.

  Institutionalized individuals have limited capacity to pay cost-sharing for non-preferred drugs or to purchase drugs for which coverage has been denied. It is imperative that any alternative formulary provides strong protections that prevent individuals from being charged cost-sharing. For dual eligibles residing in institutions, a condition of eligibility requires them to pledge all, but a nominal personal needs allowance, to the cost of their care. For non-dual eligibles, the high cost of nursing home coverage leaves few remaining resources to pay non-preferred cost-sharing or to purchase drugs for which coverage has been denied.

- **Persons with Life-Threatening Conditions**: These are individuals with a diverse range, but limited number of conditions in which the absence of effective treatment would be life-threatening.

These individuals must have unrestricted and affordable access to the full range of available treatments. CCD believes that the MMA intended to ensure that beneficiaries will have access to all needed medications, including newly approved medications. Provisions in the proposed rule are inadequate for persons with life-threatening conditions for whom access to life-saving medications cannot be weighed against the financial interests of for-profit Part D plans. Therefore, these individuals must have immediate access to all FDA-approved medications.

- **Persons with Pharmacologically Complex Conditions:** Medications to treat many complex conditions are not generally interchangeable, including those with the same mechanism of action, and have fundamental differences that render them pharmacologically unique.

  In these circumstances, it is inappropriate to permit private plan formulary and cost-sharing policies to drive utilization to specific preferred drugs within a class. CCD recommends that the final rule require the Secretary to seek input from affected groups

and the general public and publish annually a list of conditions for which pharmaceutical management is complex and which have access to an affordable and flexible alternative formulary. This category should encompass.

- Persons with conditions that are recognized for their pharmacological complexity must include, at a minimum, conditions such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS;

- People who require multiple medications to treat many conditions—where drug-to-drug interactions are a critical challenge and where certain formulations might be needed to support adherence to treatment; and,

- Persons taking drugs with a narrow therapeutic index. These drugs are clinically effective and safe only at a narrow dosage range, and generally require blood level monitoring and highly individualized dosing requirements. To allow automatic substitution without physician approval can be deadly.

423.120(b)(1), Development and Revision by Pharmacy and Therapeutics (P&T) Committee

CCD strongly recommends that the final rule ensures that P&T committee decisions are binding on plans.

P&T committees can provide important checks on the profit-seeking motives of private drug plans by bringing research findings and clinical experiences to bear on decisions that will restrict access to certain medications. P&T committees must be empowered to make policy decisions regarding formulary tiers and any clinical programs to encourage the use of preferred medications, including formulary tiers and any clinical programs to encourage the use of preferred medications including prior authorization, fail first and step therapy.

In order to fulfill these critical functions the P&T committees must be charged with a strong mission to promote and protect the health of the beneficiaries. In all cases, the P&T committee should be responsible for ensuring that adequate access is provided for the most clinically efficacious drugs in the preferred tier for all classes of covered drugs. The final regulations should require a majority of the members to be independent and free of conflicts.

The final rule must require P&T committees to have formalized contractual relationships to advise the P&T committee in decision making with respect to areas where the P&T committee does not have adequate clinical expertise. At a minimum, this must include current clinical expertise and current experience in the following areas of medicine: geriatric medicine, oncology, cardiology, neurology, infectious disease, mental illness, and rare disorders.

The final rule should also require P&T committees to do the following:

- Hold public hearings and receive input from the public prior to the adoption of or revision to plan formularies.
- Specify that meetings of the P&T committee should be open to the public and occur at least quarterly.

In addition, plans should be required to seek input in the P&T committee process from affected enrollee populations, including elderly populations, and a diverse range of organizations representing people with disabilities.

Ensuring the Adequacy of the USP Model Guidelines

We do not support the CMS position that the USP model guidelines should not be required to include classes of drugs if there is no FDA approved drug with an on-label indication for each class, even though there are FDA-approved drugs with commonly accepted off-label uses that would fall within a class.

Further, we do not believe it is appropriate for physicians to be given the new burden to "document and justify off-label use in their Part D enrollees' clinical records."

CCD has written USP urging significant changes to the model guidelines to ensure that individuals have access to the medication they require. We are very concerned that in many cases two drugs per class will not provide a sufficient level of access to ensure a quality prescription drug benefit for individuals with disabilities. CMS must ensure that the model guidelines do not create access barriers to clinically appropriate off-label drugs or to newer, more effective medications within the classes.

We were also significantly concerned that the model guidelines did not have classes for the medications used to treat serious long term conditions like multiple sclerosis and that the classes for psychiatric medications and the anti-convulsants require significant revisions.

Standards for determining PDP/MA Formulary Discrimination

We strongly believe that any review standards developed by CMS must be published as legally enforceable regulations and not as guidelines. We urge CMS to develop criteria and standards that do not allow plans to discourage enrollment by requiring higher levels of cost sharing on drugs that disproportionately affect specific groups of beneficiaries. CMS needs to develop standards that can assess whether the formulary is directing utilization away from efficacious treatments and commonly recognized treatment protocols.

Providing a quality drug benefit to individuals with disabilities will require access to a broad range of medications including many of the newer drugs with fewer side effects. For example, a formulary that only included two anti-convulsants would clearly be discriminatory to people with seizures since epilepsy medications are not interchangeable. Different drugs control different types of seizures and the response to the medication is very

individualized. No one or two products of currently available anticonvulsants will be successful for all people with seizures. Access to the medication an individual requires to control their seizures can be a matter of life and death for people with epilepsy.

CMS must also ensure that the formularies do not exclude whole classes of drugs such as immunomodulating drug therapies used to treat multiple sclerosis. This is one of CCD's significant concerns with the USP model guidelines and must be addressed in order to avoid discrimination toward the people who rely on these medications.

Notification Requirements for Formulary Change

CCD believes that the proposed rule provides inadequate notification provisions regarding formulary changes. They are inadequate both for effectively notifying and protecting beneficiaries.

We recommend that if the final rule limits the notice requirements to persons directly affected by the change, then plans must be required to provide notice in writing, mailed directly to beneficiary, 90 days prior to the change, and the notice must inform the beneficiary of their right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary.

423.128 (d), Access to Call Centers

We believe that it is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center.

The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program. This is a critical requirement that must be included in the final rule.

423.128(e), Required Information in the Explanation of Benefits

We support the inclusion in the final rule of provisions in the proposed rule regarding elements of the explanation of benefits. These elements, however, must be supplemented by the following:

- **Appeals Rights and Processes:** Information about relevant requirements for accessing the exceptions process, the grievance process, and the appeals process.

- **Access for all Beneficiaries to Formulary Information:** Plans should be required to provide information to all Part D eligible individuals, and not just plan enrollees, about the plan formulary. (See our comments in Subpart B, Section 423.48, Information about Part D.)

- **Including Formulary in Explanation of Benefits**: While we are supportive of the provision in the proposed rule that requires plans to make available access to the plan's formulary, in isolation, this is insufficient. Beneficiaries need precise and detailed information about the formulary both to make an informed choice about enrollment and then to minimize their out-of-pocket costs once enrolled in a plan. Simply giving beneficiaries a description of how they can obtain information about the formulary is insufficient to further the goals of the statute. Plan descriptions should include a detailed formulary, listing not only all the drugs but the tier and amount of co-payment upon which each drug is placed, especially if plans will be allowed to require beneficiaries to pay 100% of the cost of certain formulary drugs.

- **Plan terminations:** 423.128(c)(iii) requires plans to tell all Part D eligible individuals that the part D plan has the right to terminate or not renew its contract, but only if the individuals request this information. Information about the potential for contract termination needs to be included in all plan descriptions and in all marketing materials, and not just if requested by an enrollee or Part D eligible individual.

  Based upon experience with the Medicare+Choice market, the drug plan market will experience volatility that results in adverse consequences to many beneficiaries. The Medicare+Choice model summary of benefits requires this information to be in the summary of benefits and in the evidence of coverage; the same rule should apply for Part D.

SUBPART D – COST CONTROL AND QUALITY IMPROVEMENTS REQUIREMENTS FOR PRESCRIPTION DRUG BENEFIT PLANS

Section 423.150, Scope

The need to limit and prohibit unacceptable cost containment strategies—CCD has serious concerns that the proposed rule contains no restrictions on the ability of plans to use cost-containment tools such as dispensing limits, or prior authorization.

Indeed, the preamble to the proposed rule appears to specifically encourage plans to use such cost management tools, without constraint, to limit the scope of the prescription drug benefit. We believe that this is completely inappropriate, and inconsistent with commitments made by CMS to the Congress and the public.

We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration, and scope of coverage for covered Part D drugs. Specifically, the final rule must prohibit plans from limiting access to covered Part D drugs through limits on the number of drugs that can be dispensed within a month, limiting the number of refills an individual can obtain for a specific drug, or by placing dollar limits on the amount of the prescription drug benefit. For example, research in the mental health field has demonstrated that fewer than six mental health medications per month seriously risks patient health.

CCD also strongly recommends that the final rule explicitly prohibit plans from requiring therapeutic substitution. While the MMA authorizes the use of formularies which could lead prescribers' practices to alter their practice in order to comply with standard Part D plan preferences for covered drugs within a class, we believe that the ultimate authority to decide which specific drug a Medicare beneficiary will receive must reside with the treating physician. Therefore, to protect patient safety and health, the final rule must prohibit plans from requiring or encouraging pharmacists to engage in therapeutic substitution without the advance knowledge and written concurrence of the treating physician. We are encouraged that the preamble to the proposed rule indicates that therapeutic substitution will be prohibited without the prescriber's approval, this prohibition must appear in the text of the final rule.

Further, the use of prior authorization has become a common practice in the private sector and Medicaid. For many Medicare beneficiary populations, the manner in which prior authorization and fail first (or step therapy) systems have been implemented in these other contexts has been clearly unworkable both from the perspective of beneficiaries and treating physicians. Prior authorization can delay necessary and appropriate treatment putting at risk the health and safety of individuals who depend on medications for the management of their conditions.

Prior authorization is particularly burdensome to people in group home settings and institutions where often there may not be a well-informed and aggressive advocate or health care professional to ensure that residents with disabilities get the medication they need.

The final rule must establish clear standards and requirements for Part D plans that elect to adopt prior authorization and fail first policies. In particular, the final rule must require plans to ensure that any system of prior authorization is easily accessible to beneficiaries and physicians, and must impose negligible burdens with respect to time needed to complete the prior authorization process, expense, and information documentation.

Most state Medicaid programs exempt certain types of prescription drugs from prior authorization/fail first policies because of the complexity of the underlying condition, the recognized need for physicians to have broad prescribing flexibility, and the grave clinical consequences that could result if necessary access to prescription drugs is denied. Medicaid experience also shows that when certain populations are not exempted from prior authorization, significant problems arise. We propose that the final rule require the Secretary to consult with the public and publish annually a list of conditions which will be exempted from prior authorization/fail first policies, and should include conditions such as mental

illness, epilepsy, HIV/AIDS, multiple sclerosis and cancer, that are widely acknowledged for the difficulty and complexity of pharmaceutical management.

Further, ***we strongly recommend that when prior authorization is imposed, whenever the prior authorization process has not been completed within 24 hours of the time that a prescription was first presented at a pharmacy, plans must be required to dispense a temporary supply of the prescribed drug pending the completion of the prior authorization process***, including any time needed to receive an exception process and appeal decision. The final rule must also provide for exigent circumstances when an emergency temporary supply of a prescription drug must be dispensed immediately, without allowing for a 24 hour prior authorization period.

Requiring beneficiaries who have been stabilized on a particular psychiatric or anti-convulsant medication to switch to another medication can be very dangerous for the beneficiary and is not fiscally prudent. It is very difficult to determine which medication will work best for an individual and most have to try many different kinds of medications. Moreover some of these medications stay in the system for a long time (e.g., up to six weeks) and modifications of drug therapy must be done very carefully to avoid dangerous drug interactions. Each failed trial results in suffering and possible worsening of a person's condition.

We recommend that the final rule require plans when enrolling new enrollees to continue for at least six month any prescription drug regimen for all individuals who have been stabilized on a course of treatment. Moreover, the plan must provide an organization determination within the first month of enrollment for all covered Part D drugs that are part of the treatment regimen and notify, in writing, the beneficiary whether each drug in the regimen is covered and the beneficiary's cost-sharing requirement. Should the plan determine that any drugs in the regimen are not covered, all individuals stabilized on a treatment regimen should be automatically eligible for an exception request, and plans should be prohibited from discontinuing access to all drugs in the regimen pending final resolution of the appeals process.

Cost management tools subject to P&T Committees—In response to a question in the preamble of the proposed rule, we strongly recommend that P&T committees should approve and oversee implementation of utilization management activities of health plans offering the Medicare drug benefit. These committees should be empowered to make policy decisions and be charged with a mission to promote and protect the health of beneficiaries. In overseeing utilization management activities, P&T committees must be empowered to ensure that beneficiaries have access to a variety of drugs that reflect current utilization patterns and current research and that take into account the efficacy and side effects of medications in each therapeutic class and the complex needs of an ethnically diverse, elderly, co-morbid, and medically complex population.

SUBPART M—GRIEVANCES, COVERAGE DETERMINATIONS, AND APPEALS

Many people with disabilities who are dually-eligible for Medicaid and Medicare have cognitive or mental disabilities which make it more difficult for them to navigate a cumbersome and multi-step appeals process. The final rule must ensure that these individuals who currently receive their prescription drugs through Medicaid are not harmed by the enactment of the MMA. Additionally, for many individuals with a variety of physical and mental disabilities, access to appropriate medication is one of the major factors which allow them to live full and more independent lives in their communities. CMS must ensure that the final rule is consistent with the principles and goals of the President's New Freedom Initiative to ensure that all people with disabilities have the opportunity to live in the community where they belong.

The proposed rule fails to meet the requirements of the Due Process Clause of the Fifth Amendment to the Constitution.

CCD believes that the proposed rule fails to meet Constitutional due process requirements and fails to satisfy the requirements of the statute. As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid beneficiaries, whose prescription requests are not being honored, receive a 72-hour supply of medications pending the initial coverage request. They are entitled to notice and face-to-face hearings, pending an appeal if their request is denied and they file their appeal within a specified time frame. Currently, all state Medicaid appeals processes are completed more expeditiously than Medicare appeals. Based on this fact and on the fact that the majority of people with disabilities who are dually-eligible for Medicaid and Medicare, have major health care needs, CCD believes it is completely inappropriate for the proposed rule to expose these individuals to a weakened due process system.

The appeals process as described in Subpart M does not accord dually-eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights; with an adequate opportunity to a face-to-face hearing; with an adequate opportunity to have access to care/prescription drugs pending resolution of the appeal; or with a timely process for resolving disputes. While CCD recognizes that the most efficient means of protecting enrollees – which would be to amend the MMA to provide for an appeals process similar to Medicaid -- is beyond the authority of CMS, CCD does believe that CMS can take steps in the final regulations to improve notice and the opportunity for speedy review.

Sections 1860D-4(f), (g), and (h) require that sponsors of Part D plans establish grievance, coverage determination and reconsideration, and appeals processes in accordance with Section 1852 (f) & (g) of the Social Security Act. In addition, CMS – in the settlement of *Grijalva v. Shalala* and in the Medicare Plus Choice program – already has established the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review. CCD strongly

recommends that CMS incorporate a similar fast-track process for Part D, which would be more in keeping with due process requirements.

Require plans to have an expedited appeals and exceptions process and to dispense a temporary supply of drugs pending the resolution of an exception request or an appeal.

The proposed system does not ensure that beneficiaries' rights are protected and does not guarantee that beneficiaries have access to needed medications. This is a major cause for concern for the CCD. For millions of individuals with disabilities such as epilepsy, mental illness, HIV, Multiple Sclerosis, and spinal cord injuries -- treatment interruptions can lead to serious short-term and long-term problems. For this reason, the CCD strongly recommends that the final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

For people with HIV/AIDS, even temporary interruptions in treatment can spur the development of drug resistant strains of HIV that have broad implications for the public health, and seriously compromise the likelihood that an individual will continue to benefit from their current drug regimen and jeopardize treatment success with any of the available anti-HIV medications. Fifty to seventy percent of people living with AIDS develop drug resistance. Failure to prevent treatment interpretations by supplying a temporary drug supply will contribute to this statistic.

Many people with epilepsy depend on specific medication to control their seizures. A disruption in their medication regimen can cause breakthrough seizures, the consequences of which can be very severe and can include loss of driving privileges, absence from work and hospitalization. Access to a temporary supply of drugs is also critical for people with physical disabilities such as spinal cord injury (SCI). Urinary tract infections, a common secondary condition of SCI, can worsen quickly and result in kidney infections which can lead to autonomic dysreflexia, a life threatening condition.

For many people with mental illness, access to the one specific medication or the critical combination of specific drugs, is what helps them maintain their mental and physical health as well as their independence and the ability to live a full life in the community. Treatment interruptions for these individuals are just as dangerous to them as is a treatment interruption to a person with a physical disability such as epilepsy.

CCD concerns related to treatment interruptions are heightened due to the absence of any adequate protections to ensure that individuals can receive a timely resolution of an appeal. We are also extremely concerned about the lengthy period of time that is allowed to pass before an individual has access to a fair and independent review of their appeal by an independent decision maker at the Administrative Law Judge (ALJ) level. CCD recognizes that the expedited time-frames and the general 72-hour standard are a significant improvement over the standard time-frame of 14 days to make a determination and 30 days for a reconsideration. Nonetheless, from the perspective of individuals with serious and complex health conditions and disabilities, 72 hours is an unacceptable delay.

CCD strongly recommends that the final rule clearly specify that all disputes relating to coverage of Part D drugs for people with disabilities automatically qualify for an expedited decision (for all types of requests including a request for an exception, a grievance, and all level of the appeals). Moreover, we strongly recommend that the final rule clearly require plans to dispense a temporary supply of the drug in dispute pending the final outcome of an appeal.

Strengthen and improve the inadequate and unworkable exceptions and appeals processes by establishing clear standards; expediting decisions; minimizing evidence burdens on physicians; and ensuring that drugs provided through the exceptions process are made available at the "preferred drug" level of cost-sharing.

CCD is also concerned that the appeals processes outlined in the proposed rule are overly complex, drawn-out, and inaccessible to beneficiaries with disabilities. We are specifically concerned about the impact of such a burdensome process on individuals with cognitive and mental disabilities. We strongly recommend that CMS establish a simpler process that places a priority on ensuring ease of access and rapid results for beneficiaries and their doctors. We also strongly recommend that the final rule include a truly expedited exceptions process for individuals with immediate needs. Under the proposed rule, there are too many levels of internal drug plan appeals that a beneficiary must navigate before receiving a truly independent review by an administrative law judge (ALJ) and the timeframes for plan decisions are unreasonably long.

CCD believes that the provisions in the MMA that call for the creation of an exceptions process are a critical consumer protection that -- if properly crafted through enforceable regulations -- could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. However, as structured in the proposed rule, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and appeals process.

CCD is particularly concerned that the proposed rule would require treating physicians to assert that an exceptions request is based on both clinical experience and scientific evidence. This is an inappropriate standard that most doctors could not meet because scientific experience is not always available to support the knowledge which they acquire through clinical experience treating people with a range of disabilities – from HIV to mental illness – to epilepsy – to cerebral palsy – to spinal cord injury – to MS. CCD recommends that this requirement be eliminated from the final rule.

CCD recommends that CMS revamp the exceptions process to:

1. Establish clear standards by which prescription drug plans must evaluate all exceptions requests;
2. Minimize the time and evidence burdens on treating physicians; and

3. Ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

SUBPART P –PREMIUMS AND COST SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

432.772, Definitions

Institutionalized individual: The definition should include those individuals eligible for home and community based services under a Medicaid waiver (see, e.g., definition of "institutionalized spouse" at 42 U.S.C. § 1396r-5(h)(1)(A)), since those individuals must meet the acuity standards for Medicaid coverage in a nursing facility, and should include individuals in ICF/MRs and individuals in any institution in which they are entitled to a personal needs allowance.

423.782(a)(2)(iii), Dual eligible beneficiaries must not be denied medications for failure to pay co-payments.

Dual eligible beneficiaries will be required to pay $1 for generic drugs and $3 for brand-name drugs under Medicare Part D. Currently under Medicaid statute, an individual cannot be denied a medication for failure to pay a co-payment. Many people with disabilities depend on multiple medications including brand name medications. Even minimal co-payments will create a financial burden for individuals who will be left to choose between paying for medications and meeting other needs, like food and housing.

CCD strongly recommends that in the final rule dual eligibles must maintain the protection that they currently have under Medicaid and not be denied a drug for failure to pay cost sharing.

423.782(a)(iv) and §423.782(b)(2), Low-income individuals should not be denied medications for failure to pay co-payments.

Low-income Medicare beneficiaries between 100% and 150% of the FPL face considerable cost-sharing requirements in the proposed regulations that could prevent them from filling necessary prescriptions. Studies have demonstrated that even minimal levels of cost sharing restrict access to necessary medical care for individuals with low incomes. Individuals between 100% and 135% of FPL must pay $2 for generics and $5 for brand-name drugs. Those between 135% and 150% are required to pay a 15% co-insurance for their drugs. For individuals who require expensive treatments or multiple medications, this requirement will

impose an enormous financial burden on thousands of individuals who will be unable to pay out-of-pocket for these medications. Beneficiaries eligible for the full or partial low-income subsidy should not be denied a prescription for failure to pay a co-payment or other co-insurance.

CCD appreciates the opportunity to comment on these critical regulations which will have a profound impact on America's 13 million Medicare beneficiaries with disabilities.

For more information contact the CCD Health Task Force Co-Chairs: Kirsten Beronio (National Mental Health Association) 202-675-8413, Liz Savage (The Arc and United Cerebral Palsy) 202-783-2229, Kathy McGinley (National Association of Protection and Advocacy Systems) 202-408-9514), and Peter Thomas (American Medical Rehabilitation Providers Association) 202-466-6550.

On behalf of:

American Association on Mental Retardation
American Association of People with Disabilities
American Congress of Community Supports and Employment Services
American Congress of Rehabilitation Medicine
American Council of the Blind
American Diabetes Association
American Foundation for the Blind
American Medical Rehabilitation Providers Association
American Network of Community Options and Resources
American Therapeutic Recreation Association
APSE: The Network on Employment
Association of Academic Physiatrists
Association of University Centers on Disabilities
Bazelon Center for Mental Health Law
Center on Disability Issues and the Health Professions
Easter Seals
Epilepsy Foundation
Family Voices
Helen Keller National Center
Learning Disabilities Association of America
Lutheran Services in America
National Association for the Advancement of Orthotics and Prosthetics
National Association of County Behavioral Health Directors
National Association of Protection and Advocacy Systems
National Coalition on Deaf-Blindness
National Mental Health Association
National Multiple Sclerosis Society
National Association for the Advancement of Orthotics and Prosthetics
National Association of Councils on Developmental Disabilities

National Association of Social Workers
National Fragile X Foundation
National Law Center on Homelessness & Poverty
National Organization of Social Security Claimants' Representatives
National Respite Coalition
Paralyzed Veterans of America
Spina Bifida Association of America
TASH
The Arc of the United States
Title II Community AIDS National Network
United Cerebral Palsy
United Spinal Association
Volunteers of America
World Institute on Disability

Submitter : Mr. Thomas Arnold **Date & Time:** 10/04/2004 09:10:57

Organization : Agency for Health Care Administration

Category : State Government

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Definition of Long Term Care Facility

CMS is requesting comments regarding the definition of long-term care facilities. In section 423.100 of the proposed rule, long-term care facility is interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act; or a nursing facility as defined in section 1919(a) of the Act. The definition is limited to these two types because it is CMS? understanding that those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies. The definition does not include other long-term care facilities such as those for the developmentally disabled or mental health centers.

CMS expresses particular interest in whether other facilities such as intermediate care facilities for mentally retarded or related conditions (ICF/MRs), described in section 440.150 of the proposed rule, should be included explicitly in this definition. Many of these individuals are covered by both Medicare and Medicaid and will need continued access to drugs under Part D. We encourage CMS to consider ICF/MRs and other types of facilities that contract with long-term care pharmacies exclusively, in a manner similar to SNFs and other nursing facilities, in its definition of long-term care facilities.

Formularies

We applaud the intent to level the playing field with respect to mail order and community pharmacies by allowing 90-day supplies to be dispensed by both entities.

As provided under section 1860D-4-(b)(3)(c)(ii) of the Act, CMS has requested that the U.S. Pharmacopoeia (USP) develop a model set of guidelines that consist of a list of drug categories and classes that may be used by PDP sponsors and MA organizations to develop formularies for their qualified prescription drug coverage, including their therapeutic categories and classes. CMS expects that the model categories and classes developed by USP will be defined so that each includes at least two drugs approved by the FDA for the indications in the category or class. That is, no category or class would be created for which there is no FDA-approved drug, thus avoiding having to include a drug based on its off-label indication. It is likely, in some cases, that only two drugs will be included in a class. We believe that any established formulary exception criteria must be flexible enough to take into account the actual circumstances of particular recipients. MA-PDs and PDPs should be required to be flexible to accommodate individual recipients.

We would like to note that the AHSP therapeutic classification system is out of date for a number of therapeutic classes and needs to be updated. In addition, the requirement prohibiting any PD or MA PD from changing its therapeutic classification for a drug more than one time per year at the beginning of the plan year does not reflect the rapid changes in the pharmacologic knowledge base and therapeutic uses of many drugs.

Also, the prohibition against changing the cost-sharing tier of co-payment for specific drugs without providing 30-day advance notice to prescribers, pharmacies and enrollees may be counter-productive unless this notice can be made electronically. If mailed notices are required, the costs associated could easily exceed savings to the plan or to enrollees for many products. It is unclear whether the regulations anticipate web-posting as satisfactory notice or whether direct mailing would be required. The regulations may be contradictory in view of the ?at least weekly? update requirement in the following section, 423.128

We agree with the requirement that plans include cost utilization management, medication therapy management programs (MTMP) and fraud and abuse control programs. We feel the regulations should provide more guidance to plans in the structure and reimbursement for MTMPs and we applaud the effort to encourage electronic prescribing by

ELIGIBILITY, ELECTION, AND ENROLLMENT

The Florida Agency for Health Care Administration (AHCA) respectfully submits the following comments about the proposed rule on the Medicare

program and the Medicare prescription drug benefit. AHCA administers Florida's $14 billion Medicaid program and serves more than 2.2 million recipients annually. Nearly 460,000 of the state?s Medicaid recipients are also eligible for Medicare and account for more than $1 billion of the state?s prescription drug budget. This includes spending for approximately 55,000 recipients enrolled in the Silver SaveRx program, Florida?s Pharmacy Plus Program.

Florida?s dual eligibles, like seniors across the country, are expected to take advantage of the opportunity to gain coverage under the new Medicare Part D benefit. We applaud CMS for its efforts in addressing many of the issues that states and recipients will face when the benefit is implemented.

Enrollment

In accordance with Section 1860D-1(b)(1) of the MMA, CMS has proposed rules related to enrollment of Part D eligibles in prescription drug plans. Specifically, the rule proposes an enrollment process by which the state may randomly enroll full dual-eligible individuals who fail to select and enroll in a PDP or a MA-PD plan by a specified date. The process as proposed raises significant concerns and questions.

For full dual eligibles, the time frame allowed for initial enrollment runs from November 2005, through May 2006. This provision can be interpreted to mean that any individual who does not select a plan will be enrolled randomly in May 2006. There are several reasons why a recipient may fail to enroll in a PDP or MA-PD in a timely manner. One possibility is apprehension about relinquishing the familiar benefits available under Medicaid; another is uncertainty about subsidies, program design, and plan availability. Nonetheless, this interpretation, fails to consider the possible lapse in coverage a recipient could face between January 1, 2006, and the date on which he/she actively enrolls in a plan or is automatically enrolled in May. We understand that federal matching funds would no longer be available to state Medicaid agencies for this population after January 1, 2006; however, we are certain it is your intent to ensure that seniors have prescription coverage during this six-month period.

As an alternative we suggest allowing for a delay in enrollment or establishing a phased-in enrollment process for this population, during which time the states could continue to receive federal matching funds for providing prescription drug coverage. This would allow time for adequate outreach and education to ensure that recipients understand the program and the options available to them. Furthermore, it would help ensure that beneficiaries would not lose coverage for any period.

CMS is also seeking input on the appropriate entity to perform automatic and random enrollment functions. These functions include enrollment during initial and special enrollment periods, as well as tracking premium subsidy qualifications. Options include having enrollment conducted by CMS, the state, or a contracted entity. As a condition of state performance, CMS requires proper and efficient administration of the state plan. In the preamble, CMS recognizes that states will need accurate and timely Part D data to perform enrollment functions. We recommend that states have the option of performing automatic and random enrollment functions. CMS should also consider giving the states that choose to perform those functions full federal participation match rather than the administrative match.

Issues 11-20

SPECIAL RULES FOR STATES

Phased Down State Contribution

Under the proposed rule, states are required to contribute to the cost of the Medicare Part D drug benefit. The phased down state contribution is based on expenditures for covered Part D drugs during calendar year 2003 and adjusted by a growth factor in subsequent years. The growth factor will be based on increases in per capita expenditures for Part D drugs for Part D eligible individuals.

We have questions about the methodology with respect to values used in the base year. Specifically, the PDSC calculation includes rebates earned in the base year but collected in subsequent years. We would like clarification as to how CMS intends to account for rebates earned but not collected.

Moreover, we believe that states should be allowed to appeal CMS calculations of the PDSC amount. The preamble and other information suggest that CMS will attempt to arrive at a number that the state and CMS will agree on. This process is not spelled out, and we believe it should include an opportunity for states to dispute calculations that would result in a higher contribution.

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FLORIDA MEDICAID

JEB BUSH, GOVERNOR

ALAN LEVINE, SECRETARY

October 4, 2004

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: CMS Proposed Rule – 4068 – P

Dear Dr. McClellan:

The Florida Agency for Health Care Administration (AHCA) respectfully submits the following comments about the proposed rule on the Medicare program and the Medicare prescription drug benefit. AHCA administers Florida's $14 billion Medicaid program and serves more than 2.2 million recipients annually. Nearly 460,000 of the state's Medicaid recipients are also eligible for Medicare and account for more than $1 billion of the state's prescription drug budget. This includes spending for approximately 55,000 recipients enrolled in the Silver SaveRx program, Florida's Pharmacy Plus Program.

Florida's dual eligibles, like seniors across the country, are expected to take advantage of the opportunity to gain coverage under the new Medicare Part D benefit. We applaud CMS for its efforts in addressing many of the issues that states and recipients will face when the benefit is implemented.

Enrollment

In accordance with Section 1860D-1(b)(1) of the MMA, CMS has proposed rules related to enrollment of Part D eligibles in prescription drug plans. Specifically, the rule proposes an enrollment process by which the state may randomly enroll full dual-eligible individuals who fail to select and enroll in a PDP or a MA-PD plan by a specified date. The process as proposed raises significant concerns and questions.

For full dual eligibles, the time frame allowed for initial enrollment runs from November 2005, through May 2006. This provision can be interpreted to mean that any individual who does not select a plan will be enrolled randomly in May 2006. There are several reasons why a recipient

may fail to enroll in a PDP or MA-PD in a timely manner. One possibility is apprehension about relinquishing the familiar benefits available under Medicaid; another is uncertainty about subsidies, program design, and plan availability. Nonetheless, this interpretation, fails to consider the possible lapse in coverage a recipient could face between January 1, 2006, and the date on which he/she actively enrolls in a plan or is automatically enrolled in May. We understand that federal matching funds would no longer be available to state Medicaid agencies for this population after January 1, 2006; however, we are certain it is your intent to ensure that seniors have prescription coverage during this six-month period.

As an alternative we suggest allowing for a delay in enrollment or establishing a phased-in enrollment process for this population, during which time the states could continue to receive federal matching funds for providing prescription drug coverage. This would allow time for adequate outreach and education to ensure that recipients understand the program and the options available to them. Furthermore, it would help ensure that beneficiaries would not lose coverage for any period.

CMS is also seeking input on the appropriate entity to perform automatic and random enrollment functions. These functions include enrollment during initial and special enrollment periods, as well as tracking premium subsidy qualifications. Options include having enrollment conducted by CMS, the state, or a contracted entity. As a condition of state performance, CMS requires proper and efficient administration of the state plan. In the preamble, CMS recognizes that states will need accurate and timely Part D data to perform enrollment functions. We recommend that states have the option of performing automatic and random enrollment functions. CMS should also consider giving the states that choose to perform those functions full federal participation match rather than the administrative match.

Phased Down State Contribution

Under the proposed rule, states are required to contribute to the cost of the Medicare Part D drug benefit. The phased down state contribution is based on expenditures for covered Part D drugs during calendar year 2003 and adjusted by a growth factor in subsequent years. The growth factor will be based on increases in per capita expenditures for Part D drugs for Part D eligible individuals.

We have questions about the methodology with respect to values used in the base year. Specifically, the PDSC calculation includes rebates earned in the base year but collected in subsequent years. We would like clarification as to how CMS intends to account for rebates earned but not collected.

Moreover, we believe that states should be allowed to appeal CMS calculations of the PDSC amount. The preamble and other information suggest that CMS will attempt to arrive at a number that the state and CMS will agree on. This process is not spelled out, and we believe it should include an opportunity for states to dispute calculations that would result in a higher contribution.

Definition of Long Term Care Facility

CMS is requesting comments regarding the definition of long-term care facilities. In section 423.100 of the proposed rule, long-term care facility is interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act; or a nursing facility as defined in section 1919(a) of the Act. The definition is limited to these two types because it is CMS' understanding that those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies. The definition does not include other long-term care facilities such as those for the developmentally disabled or mental health centers.

CMS expresses particular interest in whether other facilities such as intermediate care facilities for mentally retarded or related conditions (ICF/MRs), described in section 440.150 of the proposed rule, should be included explicitly in this definition. Many of these individuals are covered by both Medicare and Medicaid and will need continued access to drugs under Part D. We encourage CMS to consider ICF/MRs and other types of facilities that contract with long-term care pharmacies exclusively, in a manner similar to SNFs and other nursing facilities, in its definition of long-term care facilities.

Formularies

We applaud the intent to level the playing field with respect to mail order and community pharmacies by allowing 90-day supplies to be dispensed by both entities.

As provided under section 1860D-4-(b)(3)(c)(ii) of the Act, CMS has requested that the U.S. Pharmacopoeia (USP) develop a model set of guidelines that consist of a list of drug categories and classes that may be used by PDP sponsors and MA organizations to develop formularies for their qualified prescription drug coverage, including their therapeutic categories and classes. CMS expects that the model categories and classes developed by USP will be defined so that each includes at least two drugs approved by the FDA for the indications in the category or class. That is, no category or class would be created for which there is no FDA-approved drug, thus avoiding having to include a drug based on its off-label indication. It is likely, in some cases, that only two drugs will be included in a class. We believe that any established formulary exception criteria must be flexible enough to take into account the actual circumstances of particular recipients. MA-PDs and PDPs should be required to be flexible to accommodate individual recipients.

We would like to note that the AHSP therapeutic classification system is out of date for a number of therapeutic classes and needs to be updated. In addition, the requirement prohibiting any PD or MA PD from changing its therapeutic classification for a drug more than one time per year at the beginning of the plan year does not reflect the rapid changes in the pharmacologic knowledge base and therapeutic uses of many drugs.

Also, the prohibition against changing the cost-sharing tier of co-payment for specific drugs without providing 30-day advance notice to prescribers, pharmacies and enrollees may be counter-productive unless this notice can be made electronically. If mailed notices are required,

the costs associated could easily exceed savings to the plan or to enrollees for many products. It is unclear whether the regulations anticipate web-posting as satisfactory notice or whether direct mailing would be required. The regulations may be contradictory in view of the "at least weekly" update requirement in the following section, 423.128

We agree with the requirement that plans include cost utilization management, medication therapy management programs (MTMP) and fraud and abuse control programs. We feel the regulations should provide more guidance to plans in the structure and reimbursement for MTMPs and we applaud the effort to encourage electronic prescribing by allowing plans to include differential payments to prescribers using e-prescribing standards.

Section 423.279 addresses potential geographic adjustments to the national average monthly bid amount. This section requires that any adjustment CMS applies be budget-neutral to CMS; in addition, any increase for one region will affect one or more other regions. As a result, we would expect this issue to be highly controversial. We suggest deleting this provision from the final rule.

In section 423.336, Risk Sharing Arrangements, the description of risk corridors and first and second threshold lower and upper limits is difficult for all but trained actuaries. Examples of these calculations similar to that used to calculate the states' phased-down contribution will help to eliminate confusion on this issue.

Section 423.782 describes cost sharing subsidies and cost sharing responsibilities. Because beneficiaries are increasingly involved in choice of therapies as a result of direct-to-consumer advertising by drug manufacturers, the regulations should require that plans provide clear tabular explanations of cost sharing responsibilities by product included on their formularies and the alternative products available in that therapeutic class.

We appreciate the opportunity to submit comment on this proposed rule and look forward to working with CMS to implement this important benefit. Should you have any questions, please contact me directly at 850-413-9660.

Sincerely,

Thomas W. Arnold
Deputy Secretary for Medicaid

Submitter : Mrs. Mary Thompson **Date & Time:** 10/04/2004 09:10:24

Organization : YKHC

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-4068-P-1300-Attach-1.doc

YUKON-KUSKOKWIM HEALTH CORPORATION

Mary I. Thompson, Dir. of Revenue Mgmt.
P.O. Box 3427 • Bethel, Alaska 99559
(907) 543-6216 • fax: (907) 543-6926

Financial Services Division
Patient Financial Services

October 3, 2004

CMS

RE: Comments on the Treatment of American Indians and Alaska Natives and Reimbursement to Tribal, Indian Health Service and Urban Indian Programs Under August 3, 2004 Proposed Rules for 42 CFR Parts 417 and 422, The Medicare Advantage Program

File Code CMS-4069-P

Dear Administrator:

The **Yukon-Kuskokwim Health Corporation (YKHC)** is concerned about the impact of the proposed regulations for Medicare Part C. The proposed regulations for the Medicare Advantage (MA) program published on August 3, 2004, do not mention American Indians, Alaska Natives, tribes, tribal organizations, tribal health services or the Indian Health Service.

The preamble to the regulations provides an analysis of the effects on small entities under the Regulatory Flexibility Act (RFA). The RFA analysis states: "We welcome comments on this approach and on whether we have missed some important category of effect or impact." We would like to state emphatically that you have missed an important category of effect and impact by omitting consideration of Tribal governments and Indian health care facilities.

The National Indian Health Board (NIHB) has submitted comments on the Part C regulations and YKHC endorses those comments.

Furthermore, we urge you to consult with Tribes to identify issues and workable solutions when new programs are being designed by the Centers for Medicare and Medicaid Services.

Sincerely yours,

Mary I. Thompson

Director of Revenue Management

FOR YOUR REVIEW, THESE ARE THE COMMENTS NIHB WILL SUBMIT TO CMS.

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Comments on the Treatment of American Indians and Alaska Natives and Reimbursement to Tribal, Indian Health Service and Urban Indian Programs Under August 3, 2004 Proposed Rules for 42 CFR Parts 417 and 422, The Medicare Advantage Program

File Code CMS-4069-P

Dear Administrator:

The National Indian Health Board (NIHB) is deeply concerned about the impact of August 3, 2004, proposed Medicare Modernization Act (MMA) rules regarding the **Medicare Advantage** program on American Indians and Alaska Natives (AI/AN) as well as the Indian Health Service, Tribal and urban (I/T/U) health programs that serve them. These comments and recommendations are submitted to the Centers for Medicare and Medicaid Services (CMS) with the very serious concerns of Tribes across the nation.

INTRODUCTORY STATEMENT REGARDING INDIAN HEALTH SYSTEM

These comments address the implications of the proposed rules on the Indian health care delivery system and the changes that must be made to prevent Part C implementation from destabilizing the system responsible for providing health care to the approximately 1.3 million American Indians and Alaska Natives (AI/AN) served by the IHS system. In the form proposed by CMS, the rules will put in jeopardy significant revenues the Indian health system now collects from Medicaid for "dual eligibles". Since the loss of revenue to Indian health was **not** Congress's objective in enacting the Part C benefit, the rules must be revised in several respects to protect the Indian health system from what could be substantial harm. Furthermore, to enable voluntary enrollment by AI/AN in Part C requires substantial modifications to the proposed rules.

We ask that all CMS staff charged with reviewing comments and revising the proposed regulations be supplied with a copy of this introductory statement regarding the Indian health care system. Compliance with the dictates of notice and comment rulemaking requires that all relevant information supplied by commenters must be taken into account. Full consideration of the comments we offer on individual regulations can only be accomplished by a thorough understanding of the unique nature of the Indian health care system, and the responsibility of our steward, the Secretary of Health and Human Services, to assure that inauguration of Medicare Part C does not result in inadvertent and unintended harm to that system.

The regulations governing the Part C must be revised to achieve the following goals:

- Encourage MA enrollment by AI/AN by removing financial barriers and allowing AI/AN to voluntarily participate in Medicare Advantage plans, without financial penalty because of location of residence, selection of a plan that includes I/T/U, or use of I/T/U.

- Ensure that I/T/U, under all conditions, are held harmless financially and are fully reimbursed for covered services provided to AI/AN who enroll in a Medicare Advantage plan.

- Allow I/T/U the flexibility to sponsor AI/AN in Medicare Advantage plans, under a special group payer arrangement.

- Allow, in the future, the development of an AI/AN special Medicare Advantage plan that includes the active participation of Tribes in its design and implementation.

- Explicitly exempt AI/AN dual eligibles from mandatory participation in a State Title XIX MA or MA-PD Plan.

In order to fully comprehend the potential adverse impact Part C implementation will have on the Indian health care system -- particularly with regard to the dual eligibles it serves -- one must have an understanding of the way health care services are delivered to AI/ANs and the current state of Indian health. These considerations must be kept in mind as CMS reviews these comments in order to promulgate regulations that assure the inauguration of the Part C or Medicare Advantage (MA) program does not have negative consequences on the Indian health system by reducing the level of reimbursements from Medicaid or Medicare on which the system has come to rely.

Indian Health Care System and Indian Health Disparities

Overview. The Indian health care system does not operate simply as an extension of the mainstream health system in the United States. To the contrary, the Federal government has built a system that is designed specifically to serve American Indian and Alaska Native people in the context in which they live -- remote, sparsely-populated and, in many cases, poverty-stricken areas where the Indian health system is the only source of health care. Integral to that system are considerations of tribal cultures and traditions, and the need for culturally competent and sensitive care.

U.S. Trust Responsibility for Indian Health. The United States has a trust responsibility to provide health care to AI/ANs pursuant to federal laws and treaties with Indian Tribes.[1] Pursuant to statutory directive,[2] this responsibility is carried out by the Secretary of Health and Human Services, primarily through the Indian Health Service (IHS) with annual appropriations supplied by Congress. The IHS-funded health system follows the public health model in that it addresses the need for both medical care and preventive care. In order to perform this broad mission, the IHS funds a wide variety of efforts including: direct medical care (through hospitals, clinics, and Alaska Native Village health stations); pharmacy operations; an extensive (but underfunded) Contract Health Services program through which specialty care IHS cannot supply directly is purchased from public and private providers; health education and disease prevention programs; dental, mental health, community health and substance abuse prevention and treatment; operation and maintenance of hospital and clinic facilities in more than 30 states; and construction and maintenance of sanitation facilities in Indian communities.

Health Disparities. AI/ANs have a higher rate of disease and illness than the general population and consequently require more medications and incur higher prescription drug costs than most Americans. A recent in-depth study of Indian health status performed by the staff of the U.S. Commission on Civil Rights[3] reveals a number of alarming statistics such as:

- AI/ANs have the highest prevalence of Type II diabetes *in the world*, are 2.6 times more likely to be diagnosed with the disease than non-Hispanic whites, and are 420% more likely to die from the disease.
- The cardiovascular disease rate among AI/ANs is two times greater than the general population.
- AI/ANs are 770% more likely to die from alcoholism.
- Tuberculosis deaths are 650% higher among AI/ANs than the general population.
- AI/AN life expectancy is 71 years, five years less than the general U.S. population.

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[1] *See, e.g.,* 25 U.S.C. § 1601.
[2] 42 U.S.C. § 2001.
[3] U.S. Commission on Civil Rights, *Broken Promises: Evaluating the Native American Health Care System*, July 2, 2004 (staff draft).

- The ratio of cancer deaths to new cancer cases is higher for Native Americans than the ratios for all other races, even though incidence rates are lower.
- The Indian suicide rate is 190 percent of the rate of the general population.

Composition of the Indian Health Care System. Operationally, health services to AI/ANs are delivered through the following entities:

- The Indian Health Service directly operates hospitals and clinics throughout Indian Country that are staffed by federal employees.
- Indian Tribes and tribal organizations may elect to assume management and control over IHS programs at the local tribal level through authority of the Indian Self-Determination and Education Assistance Act. At present, over one-half of the IHS budget is distributed to ISDEAA tribal programs.
- In 34 cities, urban Indian organizations operate limited health programs (largely referral services) for Indian people living in urban areas through grants authorized by the Indian Health Care Improvement Act.

Funding Sources. Indian health programs are supported primarily from annual federal appropriations to the Indian Health Service. Regardless of the operational form, all Indian health programs are severely underfunded. In a 2003 report[4], the U.S. Commission on Civil Rights found that the per-capita amount spent by the Indian Health Service for medical care was nearly 50% lower than spending for federal prisoner medical care and only slightly more than one-third of the average spending for the U.S. population as a whole. The Veterans Administration spends nearly three times as much for its medical programs as the Indian Health Service.

In an effort to improve the level of funding for Indian health programs, Congress, in 1976, made IHS/tribal hospitals eligible for Medicare Part A reimbursements, and enabled hospitals and clinics to collect Medicaid reimbursements, either as IHS facilities or as FQHCs. It was not until the 2000 BIPA that IHS facilities were authorized to collect for some Medicare Part B services. With enactment of the MMA, Congress authorized these facilities to collect for remaining Part B services for a five-year period.

Pursuant to Federal law, the cost of Medicaid-covered services, including pharmacy services, provided by I/T/Us to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. If coverage for dual eligibles changes from Medicaid to Medicare, the Federal government must assure that the reimbursement of services for Indian dual eligibles continues without interruption and without reduction to I/T/U.

Indian health programs have become critically reliant on the third-party revenues, especially those supplied by Medicare and Medicaid. According to the IHS, Medicare, Medicaid and other third party collections can represent up to 50% of operating budgets at some facilities.

Scope of Services. The compliment of health services provided at a single site or by a Tribe varies from a single health station, common in Alaska, to comprehensive in and outpatient hospital services. Other health services provided directly by or through Indian health programs can include medical, dental, mental health, chemical dependency treatment, ambulance, pharmacy, home health, hospice, dialysis, public health and traditional healing.

The diversity of services provided through Indian health programs, and the generally limited size of the population they serve makes comprehensive contracting with private plans an expensive and challenging task.

Pharmacy Services for Dual Eligibles and Impact of Part D

[4] U.S. Commission on Civil Rights, *A Quiet Crisis: Federal Funding and Unmet Needs in Indian Country*, July 2003.

Because most Indian health facilities are located in remote areas far distant from the mainstream health system, they must also operate pharmacies so their patients can access needed medications. IHS, Tribes, and urban Indian organizations operate 235 pharmacies throughout Indian Country. IHS and Tribes dispense pharmaceuticals to their Indian beneficiaries without charge, as is the case for all health services they offer.

A sizeable portion of the patient base for I/T/U pharmacies consists of dual eligibles. IHS estimates that there are between 25,963[5] and 30,544[6] individuals in the IHS patient database who are receiving both Medicare and Medicaid. Since this database does not include information from some tribally-operated facilities (those who do not use the IHS computerized data system) nor information about Indians served by urban Indian clinics, the number of dual eligibles system-wide is even greater than the IHS database reveals.

While there is no comprehensive data on the per-capita drug costs for dual eligibles in the Indian health system, we have been able to make some rough estimates by examining average state per-capita spending for this population. In 2002, the average per-capita spending for dual eligibles was $918.[7] We believe this is a very conservative figure for Indian Country, in view of the higher rates of illness that have expensive drugs associated with their treatment, including diabetes and mental illness. Furthermore, the IHS calculates that the cost of pharmaceuticals has increased by 17.6 percent per year between FY 2000 and FY 2003. This includes the cost of new drugs, increases in drug costs and population growth. Thus, if we trend the average out to the year 2006, the expected average per capita spending on drugs for dual eligibles would be $1,756.

Using these population and per-capita spending data, we estimate that the Medicaid recovery for dual eligible drug costs in the Indian health system ranges between **$23.8 million**[8] **and $53.6 million**.[9] It is vital that these revenues, so critical to the Indian health system, not be interrupted or reduced when dual eligibles are removed from the Medicaid for pharmacy services and placed into either an MA-PD or a Part D plan.

Part A and B Services for Dual Eligibles and the potential Impact of Medicare Advantage

As with Part D, the most serious concerns and most immediate reduction in Indian health program revenues are related to AI/AN who are dually eligible for Medicaid and Medicaid. If States are allowed to mandate enrollment of these individuals in special MA or MA-PD plans, the result will be disastrous for effected Tribes. Although a financial analysis has not been conducted, potential revenue loss to I/T/U on a per patient basis would far exceed losses estimated for Part D alone.

The Secretary of Health and Human Services, as the principal steward of Indian health, has a responsibility to assure that the MMA, which was intended to benefit *all* Medicare beneficiaries, does not produce the opposite result for *Indian* Medicare beneficiaries who use the Indian health care system. He can guard against such an outcome by exercising the broad authority granted to the Secretary to assure access to Part C for AI/AN. We believe that Congress recognized that access for Indian beneficiaries means the ability to utilize Part C benefits through I/T/U and that AI/AN should be able to enjoy voluntary participation in Medicare Advantage plans on a equal basis with all other Medicare beneficiaries.

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[5] This number represents 85 percent of the three-year total of active users.
[6] This is the number of active users, defined as at least one visit in the past three years.
[7] From Table 2, "Full" Dual Eligible Enrollment and Prescription Drug Spending, by State, 2002, in "The 'Clawback:' State Financing of Medicare Drug Coverage" by Andy Schneider, published by the Kaiser Commission on Medicaid and the Uninsured, June 2004.
[8] This low number was calculated using the 25,963 figure for dual eligibles in 2003 and the $918 per capita spending in 2002. It is probably unrealistically low for 2006 given the increase in aging population in Indian Country and the increase in drug prices.
[9] This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.

BACKGROUND FOR PART C ISSUES

There is a fundamental mismatch between the Indian health care system and the proposed rules to implement the MMA. The result of this flaw in the proposed regulations could result in a critical loss of revenue for the Indian health programs across the nation and will further contribute to an even greater disparity in health care between the AI/AN and the general population than already exists. In fact, the proposed rules for Part C make no mention of AI/AN or I/T/U at all. As written, it is unlikely that many AI/AN who receive health care through an I/T/U will be able to benefit from these important Medicare changes. If they do chose to participate in a Part C plan, it is unlikely that Indian health facilities will be able to obtain compensation for the services provided to those Medicare beneficiaries. Furthermore, to the extent that States require dual eligibles to enroll in Title XIX Medicare Advantage (MA) plans, I/T/U will experience significant reductions in revenue associated with these patients.

As sovereign nations and recognized governments, Tribes insist that HHS and CMS acknowledge the impact and financial burden MMA regulations have on Tribal governments and Indian people.

Appropriately including AI/AN and I/T/U in MMA proposed regulations for Medicare Advantage first requires the recognition of key elements of this fragile health system.

- AI/AN are a unique political group guaranteed health care through treaties.
- The federal government has failed to meet this obligation and currently funds Indian health programs at only about 50% of need.
- The Department of Health and Human Services has and continues to develop Tribal consultation policies which have not been used in the process of drafting or assessing the impact of the proposed MMA rules.
- AI/AN, especially those living on or near reservations, suffer from the highest levels of poverty and disease burden in the United States.
- I/T/U, as culturally appropriate providers, have achieved great success in promoting preventive services and improving the health of AI/AN but still face daunting challenges.
- The IHS and Tribally-operated facilities do not charge AI/AN individuals for the health services provided to them, but they do rely upon third party payments, including Medicare and Medicaid.
- Unlike other populations, AI/AN are often reluctant to enroll in Medicaid and Medicare because they understand health care to be a right, thus premiums, and other cost sharing significantly discourages their participation and acts as an insurmountable barrier to program enrollment.
- Unlike other health care providers, I/T/U cannot charge AI/AN patients and therefore beneficiary "cost sharing" merely results in significant and inappropriate reimbursement reductions.
- Many I/T/U facilities provide services in remote areas where the size of the population is insufficient to support a private health care delivery system and where the market forces key to the implementation of this legislation do not exist.
- Private health and prescription drug plans often do not want to contract with I/T/U for many reasons including the health status and small size of the AI/AN population, the special contracting requirements, and the high administrative costs associated with developing and maintaining new contractual relationships with numerous small clinics.
- Resources spent by I/T/U to implement MMA by providing staff time for training, outreach, education, enrollment assistance, contract negotiation, and redesigning IT and administrative systems to accommodate new contracts with Medicare Advantage plans, further reduce funding for the health care of AI/AN.
- The number of AI/AN in the United States who are enrolled in Medicare and who use I/T/U is estimated to be 103,000. Approximately half of this group are thought to be dually eligible for Medicaid. Even if 20% of the remaining AI/AN Medicare population enrolls in a MA or MA-PD plan, the number of Indian enrollees in any MA plan will likely be very small and will have minimal impact

on plans. However, because of the small and widely dispersed population, the per enrollee cost to plans (and I/T/U) to develop, negotiate, execute and implement contracts will be high.

- Although the impact of AI/AN enrollment in MA and MA-PD plans may seem insignificant to plans and CMS, the relative impact on individual Tribes could represent significant losses.

We hope CMS agrees that these regulations should minimize unintended consequences of MMA on I/T/U as well as promoting access to new Medicare options for AI/AN. There are two basic approaches to address Indian issues: 1) simple blanket policies requiring MA and MA-PD plans to pay I/T/U for covered services and limited exemptions for AI/AN; or, 2) numerous, extremely complex policies and exceptions to the proposed rules. **We challenge CMS to closely consider the issues presented here and assist in crafting language for the final rules that will "first do no harm" to Indian health programs and, second, step forward to actually improve access to Medicare for AI/AN and reimbursement for services provided to them by I/T/U**.

Options for AI/AN MMA Policy

Five policy decisions to alleviate well-documented problems I/T/U have experienced contracting with private plans would address a majority of concerns raised by the proposed rules:

1. Encourage MA enrollment by AI/AN by removing financial barriers and allowing AI/AN to voluntarily participate in Medicare Advantage plans, without financial penalty because of location of residence, selection of a plan that includes I/T/U, or use of I/T/U.
    - Waive AI/AN cost sharing for all plans.
    - If AI/AN dual eligibles are required to enroll in an MA or MA-PD plan, establish the default enrollment for AI/AN to an MA or MA-PD plan for which the network includes local I/T/U facilities, or pays fully for out of network services.
    - Allow unlimited plan switching to facilitate enrollment in plans with culturally sensitive I/T/U providers. Exempt AI/AN from "lock-in" or "lock-outs".
    - Exempt AI/AN from cost differentials associated with selection of a plan that includes culturally appropriate I/T/U provider or more robust networks

2. Ensure that I/T/U, under all conditions, are held harmless financially and are fully reimbursed for covered services provided to AI/AN who enroll in a Medicare Advantage plan. We see three basic options to implement this policy:
    a. Require all MA (and MA-PD) plans to recognize I/T/U as in-network providers and reimburse at IHS Medicaid rates (as paid under the original or traditional Medicare), even without contracts. We believe this would be the desired option of plans and CMS because the minimal administrative burden and simplicity of regulations would reduce the cost of implementation.[10]
    b. Require MA (and MA-PD) plans to recognize I/T/U as in-network providers, even without contracts, and reimburse at Plan's standard Medicare rates. CMS provides "wrap-around" reimbursement to hold I/T/U harmless for difference between plan reimbursement and IHS Medicaid rate.
    c. Require all MA (and MA-PD) plans to contract with all willing I/T/U under similar special contract provisions terms as those used for the special endorsed Prescription Drug Discount Card contracts and using IHS Medicare rates. Also exempt I/T/U from plan credentialing, risk

[10] Washington State Administrative Code provides a precedent and contains sample language for this provision. **WAC 284-43-200 Network adequacy.** (7) To provide adequate choice to covered persons who are American Indians, each health carrier shall maintain arrangements that ensure that American Indians who are covered persons have access to Indian health care services and facilities that are part of the Indian health system. Carriers shall ensure that such covered persons may obtain covered services from the Indian health system at no greater cost to the covered person than if the service were obtained from network providers and facilities. Carriers are not responsible for credentialing providers and facilities that are part of the Indian health system. Nothing in this subsection prohibits a carrier from limiting coverage to those health services that meet carrier standards for medical necessity, care management, and claims administration or from limiting payment to that amount payable if the health service were obtained from a network provider or facility.

sharing, and other contracting requirements that are conducted or prohibited by federal or tribal statute, rule or policy. These contract provisions are outlined under 422.112 and are similar to those recommended for Part D.

3. Allow I/T/U the flexibility to sponsor AI/AN in Medicare Advantage plans, under a special group payer arrangement.
    - Permit sponsorship of AI/AN with flexibility and adequate timelines to add and drop individuals
    - Require plans and CMS to send sponsors information normally sent to enrollees so sponsors can respond quickly
    - Add special plan disenrollment rule for sponsored AI/AN and require communication and problem resolution process between plan and sponsor prior to plan disenrollment of AI/AN

4. Allow, in the future, the development of an AI/AN special Medicare Advantage plan that includes the active participation of Tribes in its design and implementation.

5. Explicitly exempt AI/AN dual eligibles from mandatory participation in a State Title XIX MA or MA-PD Plan.
    - MMA should not reduce the funding currently going to support Indian health programs; however, the effect of mandatory AI/AN dual eligible enrollment would result in significant losses for effected I/T/U
    - Sec. 1932 [42 U.S.C. 1396u-2] exempts AI/AN from mandatory Medicaid managed care plan enrollment, in recognition of the many difficulties facing I/T/U in interfacing with private plans. For these same reasons, we believe AI/AN dual eligibles should not be required to enroll in MA or MA-PD plans.
    - Allow same options, or exemptions, for AI/AN as currently exists under state Medicaid plans.

Additional AI/AN policy issues that require changes in the proposed rules:

- Remedy potential reimbursement and Contract Health Services funding problems for I/T/U created by MSA without restricting as an option for AI/AN.

- Require consistency with Part D rules relative to AI/AN policy.

Recommended Revisions to August 3, 2004 Proposed Rules

Proposing specific section-by-section language changes to the proposed rules to accomplish the AI/AN policy objectives stated above would require time and resources beyond our current means. **We challenge CMS to come forward with comprehensive changes to the proposed rules that will appropriately allow access to MA for AI/AN and I/T/U as special populations and providers.** Listed here is a limited set of suggested revisions.

Subpart A – General Provisions

To enable an AI/AN specific MA or MA-PD plan in the future:

422.2 *Definitions*

Basic benefits add, “including covered services received through an Indian health service program.”

Special needs individuals add “American Indians and Alaska Natives (AI/AN) are exempt from mandatory enrollment in Title XIX plans but would qualify for optional enrollment in an AI/AN specialized MA plan.”

In establishing contracts with a national, statewide or regional MA or MAPD plans preference should be given to state licensed managed care organizations that are controlled by Indian Health Service funded Tribal and /or Urban Indian Health Programs which are funded to provide services in clients. This approach is the best means of assuring access to culturally competent and geographically proximal services to individual Indians.

To address the cost of implementation at the I/T/U level:

422.6 *Cost Sharing in Enrollment Related Costs*

We have commented to CMS on several occasions about the high cost to I/T/U for MMA implementation costs related to outreach, education and enrollment of AI/AN. We strongly encourage CMS to identify in this or another section the need for funding to support these activities be specifically directed to local I/T/U where the work is done and bearing the costs is most difficult. Unlike other Medicare populations, AI/AN are unlikely to enroll in MA plans without specific information from their I/T/U.

Subpart B – Eligibility, Election and Enrollment

To address potential intended loss of revenue to I/T/U:

422.52 *Eligibility to elect MA plan for special needs individual*

(b)(2) add, “except mandatory enrollment for AI/AN is prohibited.”

To discuss and address unique issues related to AI/AN Medicare MSA:

422.56 *Enrollment in an MA MSA plan*

(c) The enrollment of AI/AN in MSAs presents unique challenges. Tribes would like an opportunity to discuss this issue with CMS to ensure it is implemented in a way that will improve access to services.

To accommodate I/T/U group payer arrangements:

422.60 *Election process*

Require MA and MA-PD plans to accept AI/AN enrollment, even if CMS has allowed the plan to close due to capacity limits. Rationale: AI/AN could enroll in MA plans under a variety of circumstances, including a group sponsorship. Because the number of AI/AN is small and the number of culturally appropriate plans available will be very limited, CMS should require plans to enroll AI/AN at anytime.

422.62 *Election coverage under an MA plan*

We request that CMS add the following provisions in an appropriate place:

- AI/AN may switch MA or MA-PD plan at any time if local I/T/U is not reimbursed by plan as in-network provider at original (or traditional) Medicare rate
- AI/AN who are in a sponsorship program may, with the consent of the sponsor, switch plans at any time
- Sponsors may add AI/AN enrollees to an MA plan at anytime under the following conditions: relocation to sponsor service area; loss of alternative health insurance coverage; change in sponsorship policies.
- AI/AN sponsored in a group payer arrangement are exempted from “lock-ins” and “lock-outs”.

422.66 *Coordination of enrollment and disenrollment through MA organizations*

We request that CMS add the following provisions in an appropriate place:

- Establish a default enrollment process for AI/AN that uses a plan that reimburses local I/T/U at in-network rates
- Provide flexibility for switching plans under conditions AI/AN are likely to encounter

- Communicate directly with local I/T/U about patient enrollment/disenrollment

422.74 *Disenrollment by the MA organizations*

Add "Process for disenrolling an AI/AN under a sponsorship or group program must include direct communication with sponsor with adequate documentation of problem and steps taken to resolve as well as adequate timelines."

422.80 *Approval of marketing materials and election forms*

This language lists as prohibited marketing activities for MA Plans to *"Engage in any discriminatory activity, including targeted marketing to Medicare beneficiaries. . .and (iii) solicit Medicare beneficiaries door-to-door."* While the intent of this language is to prohibit aggressive enrollment practices that favor healthier individuals, the unintended consequence may be to limit the development of needed materials targeted to AI/AN. While MA Plan representative should be prohibited from soliciting business by going door-to-door, the outreach workers employed by tribal and IHS facilities should be encouraged to provide information about Medicare alternatives in the homes of AI/AN elderly. We ask that CMS clarify this issue.

Subpart C – Benefits and Beneficiary Protections

To address potential intended loss of revenue to I/T/U:

422.100 *General Requirements*

If not clearly addressed in another section, MA and MA-PD plans should be required to reimburse I/T/U at the original Medicare rate under all circumstances when the I/T/U provides a covered benefit.

To remove financial barriers for AI/AN enrollment:

422.101 (d) *Requirements relating to basic benefits special cost sharing rules*

Add (5) “Special rules for AI/AN. Covered services provided to AI/AN through I/T/U, including both direct care, contract health care and other payments, will be credited toward all AI/AN cost sharing including deductibles, copayments, coinsurance and catastrophic limits.”

To facilitate a special AI/AN MA or MA-PD plan and accommodate I/T/U group payer arrangements:

422.106 *Coordination of benefits with employer group health plans and Medicaid*

The discussion in the Federal Register states: *“Section 222(j)(2) of the MMA allows us to waive or modify requirements that hinder the design of, the offering of, or the enrollment in an MA plan offered by an employer, a labor organization. . .”* This type of waiver authority should also be used to create the flexibility to develop a national plan for AI/AN beneficiaries. We also ask CMS if this section could explicitly allow I/T/U or other entities to sponsor groups of AI/AN under a group plan. We assume this option to be exercised locally but could also envision a national AI/AN plan that would allow optional local sponsorship. We believe that few AI/AN who receive services through I/T/U will enroll in a MA plan on their own, therefore we ask CMS to develop an enabling option for I/T/U, or Tribes to enroll and pay for groups of AI/AN as sponsors.

As stressed above, we ask that dual eligible AI/AN be explicitly exempt from mandatory enrollment in MA or MA-PD plans.

To remove financial barriers for AI/AN enrollment:

422.111 *Disclosure requirements*

(e) *Changes to provider network* add “Changes to provider networks which affect AI/AN will provide cause for a AI/AN to switch to another plan at anytime without penalty.”

422.122 *Access to Services*

Access to services for AI/AN requires the inclusion of I/T/U. All MA and MA-PD plans, including private fee-for-service plans referenced under 422.114 (c), should be required to include Indian health facilities as in-network providers to achieve network adequacy (without requiring the I/T/U to serve individuals who are not IHS beneficiaries), and AI/AN beneficiaries should be exempted from higher cost sharing if they use I/T/U. There are several reasons for this recommendation including: 1) AI/AN should be able to seek care at I/T/U as culturally appropriate services; 2) AI/AN could not be charged any cost sharing by I/T/U thus differences in premium or copayments

would only serve to further reduce revenue to tribal and Indian health facilities; 3) many I/T/U may be unable to contract with desirable MA or MA-PD plans for reasons already documented by CMS.

To enable I/T/U contracting with Part C plans:

Add "(a)(1)() *Access to IHS, tribal and urban Indian programs.* In order to meet access standards a Medicare Advantage plan or MA-PD plan must agree to contract with any I/T/U in its plan service areas.

(i) Such contracts shall incorporate, within the text of the agreement or as an addendum, provisions:

A. Acknowledging the authority under which the I/T/U is providing services, the extent of available services and the limitation on charging co-pays or deductibles.
B. Stating that the terms of the contract may not change, reduce, expand, or alter the eligibility requirements for services at the I/T/U as determined by the MMA; Sec. 813 of the Indian Health Care Improvement Act, 25 U.S.C. §1680c; Part 136 of Title 42 of the Code of Federal Regulations; and the terms of the contract, compact or grant issued to Provider by the IHS for operation of a health program, including one or more pharmacies or dispensaries.
C. Referencing federal law and federal regulations applicable to Tribes and tribal organization, for example, the Indian Self-Determination and Education Assistance Act, 25 U.S.C. §450 *et seq*. and the Federal Tort Claims Act, 28 U.S.C. §2671-2680.
D. Recognizing that I/T/Us are non-taxable entities.
E. Clarifying that Tribes and tribal organizations are not required to carry private malpractice insurance in light of the Federal Tort Claims Act coverage afforded them.
F. Confirming that a MA plan may not impose state licensure requirements on IHS and tribal health programs that are not subject to such requirements.
G. Including confidentiality, dispute resolution, conflict of law, billing, and payment rate provisions.
H. Recognizing that an I/T/U formulary cannot be restricted to that of the MA-PD plan.
I. Declaring that the Agreement may not restrict access the I/T/U otherwise has to Federal Supply Schedule or 340b drugs.
J. Stating that the I/T/U shall not be required to impose co-payments or deductibles on its Indian beneficiaries.
K. Authorizing I/T/U to establish their own hours of service.
L. Eliminating risk sharing or other provisions that conflict with federal, IHS or tribal laws, rules or policies."

We support the provision for payments to *"essential hospitals"* and request that I/T hospitals be explicitly identified by adding to (c)(6) All hospitals operated by Tribes or the Indian Health Service will be considered essential under this provision."

Subpart F – Submission of Bids, Premiums, and Related Information and Plan Approval

To remove financial barriers for AI/AN enrollment and accommodate I/T/U group payer arrangements:

422.262 *Beneficiary Premiums*

AI/AN served by an I/T/U will most likely not elect to pay Part D premiums because these patients can access health care through the Indian Health Service (IHS) based on the Federal Government's obligation to Federally recognized Tribes. It is our interpretation that the payment options cited to implement 422.262, Beneficiary Premiums, includes the IHS and Tribes. (Preamble, page 46651, "the IHS may wish to pay for premiums to eliminate any barriers to Part D benefits"). We specifically ask CMS to remove barriers Tribes have encountered in paying Part B premiums for AI/AN under current CMS group payer rules (size of group and switching an individual from automatic deduction to group pay). Without these changes it is unlikely that AI/AN, who are entitled to health care without cost sharing, will enroll in MA plans.

Subpart G – Payments to Medicare Advantage Organizations

To discuss and address unique issues related to AI/AN Medicare MSA:

422.314 *Special rules for beneficiaries enrolled in MA MSA plans*

The enrollment of AI/AN in MSAs presents unique challenges. Tribes would like an opportunity to discuss this issue with CMS to ensure it is implemented in a way that will improve access to services.

To address potential intended loss of revenue to I/T/U:

422.316 *Special rules for payments to federally qualified health centers*

Add "Tribal FQHCs are not required to contract with MA or MA-PD plans as a condition for reimbursement. CMS will pay tribal FQHC at the same rate they would receive under original Medicare."

Conclusion

We understand that some of the MMA proposed rules related to point of service options and coverage of areas without adequate networks are intended to encourage the availability of MA and MA-PD plans in rural areas. However, because I/T/U operate in a diverse range of environments, the patient populations tend to be small and the array of possible local options is unknown, proposing complex policies to shoehorn in AI/AN seems ill advised. Our assessment of the negative impact on AI/AN and their access to MA plans is based on years of experience under implementation of State Medicaid managed care waivers. While the experience of Tribes and AI/AN under these private health plans was frequently

disastrous, a number of Indian policy models have emerged which can be adopted for MMA implementation. In fact, to acknowledge these problems, a July 17, 2001 “Dear State Medicaid Director” letter, was issued by CMS directing states to notify and communicate with Tribes during a waiver or renewal and inform Tribes of “the anticipated impact on Tribal members.” We encourage CMS to consult with Tribes in a similar manner, and although it has, by default, fallen on Tribes themselves to assess the impact of MMA proposed regulations, we expect CMS to seriously consider remedies for all of the issues raised in this letter.

Again we urge CMS to consider eliminating unnecessary administrative cost burdens to all involved (AI/AN, I/T/U, CMS, Tribes, Indian Health Service and MA plans) and adopt simple blanket policies for AI/AN and I/T/U that will promote access to these new benefits as well as guarantee Medicare reimbursements from the MA and MA-PD plans.

CMS-4068-P-1301

Submitter : Ms. Kathleen Means **Date & Time:** 10/04/2004 09:10:01

Organization : Patton Boggs LLP

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

see attached letter

CMS-4068-P-1301-Attach-1.doc

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October 4, 2004

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4068-P, Comments on the "Medicare Program; Medicare Prescription Drug Benefit; 69 Fed. Reg. 46631 (Proposed Rule, August 3, 2004)."

Patton Boggs LLP respectfully submits these comments on behalf of QMed, Inc. in response to the proposed rule on the Medicare Prescription Drug Benefit as issued by the Centers for Medicare and Medicaid Services ("CMS") in the Federal Register on August 3, 2004. Patton Boggs LLP, with offices in the United States and abroad, is a major law firm with a leading public policy and health care practice. The foregoing comments are relevant to the "General Provisions" section of the proposed regulations.

QMed provides coordinated disease management services to chronically ill individuals (including diabetes and cardiovascular diseases), enrolled in commercial health insurance plans, Medicare+Choice, and Medicare demonstrations. The company's physician and patient engagement model is designed to ensure high rates of participation, to optimize medical therapies, and to reduce unexplainable variations in medical practice. QMed's information management systems provide quality assessment data for clinical and policy purposes at the individual. physician, plan and/or market level. QMed's comments focus on the area of specialty health plans.

QMed believes that Specialized MA Plans (SMAPs) must coordinate physicians, patients, pharmacy, formulary, clinical laboratory data, Disease Management nurses and educators into a seamless clinical information loop. When this coordination is present, evidence-based best practice medicine (EBM) becomes a reality, not just a goal. Relying on mere administrative claims data will allow neither satisfactory risk assessment nor optimized medical therapies. QMed accomplishes this for individuals suffering from heart failure, stroke, coronary artery disease, complex diabetes, hypertension.

QMed believes that such SMAPs will have to incorporate disease management (DM). Such DM services must be fully coordinated since standard non-coordinated DM services cannot ensure that special needs patients will have received optimized medical therapies from physicians. In consequence, educating and motivating SMAP patients will not ensure that health and financial outcomes will be optimized.

Clinical programs targeted to individuals must incorporate clinical information, which is found most fully in patient charts at physician offices. Clinical programs can then be devised that respond directly to clinical evidence. The programs ought to have processes that assure that clinical lab data is current. The clinical data obviously form a more fine-grained diagnosis than administrative data. Patient self-reported data is also only supplementary to this clinical data but is not a substitute. Clinical programs for SMAPs ought to meet this criterion.

Clearly, coordinating clinical data to optimized and efficient pharmacy use require full integration of physicians into the information loop. QMed accomplishes this through generating recommendations specific to each individual patient. Recommendations are based on charted clinical data, claims and continuously updated clinical lab values.

Chronic sufferers of heart failure, stroke, coronary artery disease, complex diabetes, or hypertension form an ideal set for SMAPs because the disease progression and medical therapy treatments are well supported by scientific literature. In addition, this group is clearly the most expensive in Medicare. The opportunity to improve quality and reduce variation of medical practice is enormous. QMed has numerous implementations with health plans demonstrating outcomes, and is engaged in several CMS demonstrations.

Oversight in QMed's system includes identifying quality at the physician level through their adherence to evidence-based medicine. The program comports well with CMS' stated desire to measure quality.

Thank you for the opportunity to provide comments on behalf of QMed. We respectfully request that any inquiries be directed to the firm's representative, Mr. Robert Mosby on (732) 544-5544.

Sincerely,

Kathleen E. Means